UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

MARLYN RILEY and DEBRA RILEY, Plaintiffs, v. CORDIS CORPORATION and JOHNSON & JOHNSON, Defendants.	Case No. 08-CV-5031 (PJS/RLE) MEMORANDUM OPINION AND ORDER

Ronald S. Goldser and Stacy K. Hauer, ZIMMERMAN REED, P.L.L.P., for plaintiffs.

Tracy J. Van Steenburgh and Dana M. Lenahan, HALLELAND LEWIS NILAN & JOHNSON, P.A., and John D. Winter, PATTERSON BELKNAP WEBB & TYLER, LLP, for defendants.

Plaintiff Marlyn Riley was implanted with a stent manufactured by defendant Cordis Corporation, a subsidiary of defendant Johnson & Johnson (collectively "Cordis"). Riley later suffered a heart attack because of a blood clot that had formed at the site of his stent. Riley and his wife, Debra Riley, bring state-law claims of negligence, strict liability, breach of express and implied warranties, negligent misrepresentation, fraud, and loss of consortium against Cordis. This matter is before the Court on Cordis's motion for judgment on the pleadings. For the reasons set forth below, the Court dismisses all of plaintiffs' claims — some with prejudice because they are expressly or impliedly preempted by federal law, and others without prejudice because they are not pleaded sufficiently under the Federal Rules of Civil Procedure. The Court will give plaintiffs leave to replead the latter claims.

I. BACKGROUND

Cordis manufactures a drug-eluting stent sold under the brand name "Cypher." The Cypher stent is a tiny metal mesh tube that is implanted in a coronary artery for the purpose of opening the artery and improving blood flow through the heart. The Cypher stent is coated with the drug Sirolimus under a license from Wyeth Corporation. After implantation, the Cypher stent slowly releases Sirolimus to prevent the artery from being narrowed through restenosis (the build-up of new tissue). But the release of Sirolimus also slows the normal healing process; specifically, it slows the beneficial growth of a thin, slippery layer of endothelial cells over the stent and arterial wall. Before this healing process is complete, there is an increased risk of blood-clot formation. In order to prevent clotting, patients with drug-eluting stents are normally placed on antiplatelet drug therapy for a period of time after implantation.

The Cypher stent is a Class III medical device regulated by the Food and Drug Administration ("FDA") pursuant to the 1976 Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c et seq., to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 et seq. Class III devices are those devices that are "for a use in supporting or sustaining human life," that are "for a use which is of substantial importance in preventing impairment of human health," or that "present[] a potential unreasonable risk of illness or injury . . . ." 21 U.S.C. § 360c(a)(1)(C). Class III devices receive more extensive federal oversight than any other class of medical devices and are subject to a comprehensive and rigorous process known as "premarket approval" ("PMA"). *See* 21 U.S.C. § 360e; *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1004-05 (2008) (describing the PMA process). During the PMA process, manufacturers must provide the FDA with, among other things,

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a "full statement" of the device's "components, ingredients, and properties and of the principle or principles of operation"; "a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device"; samples or device components required by the FDA; and a specimen of the proposed labeling. § 360e(c)(1). Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, 21 CFR § 814.44(a) (2007), and may request additional data from the manufacturer, § 360e(c)(1)(G).

Riegel, 128 S. Ct. at 1004. The FDA grants PMA only if the agency 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. 21 U.S.C. § 360e(d)(2).

The Cypher stent received PMA on April 24, 2003. Goldser Aff. Ex. 4 at 1-1, Oct. 20, 2008 (hereinafter "PMA ___").[1] The PMA states that the Cypher stent "is indicated for improving coronary luminal diameter in patients with symptomatic ischemic disease due to discrete *de novo* lesions of length ≤30 mm in native coronary arteries with a reference vessel diameter of ≥ 2.5 to ≤ 3.5 mm." PMA 1-1. The PMA sets forth certain restrictions on the marketing and use of the Cypher stent. In particular, the PMA states that "[a]dvertising and other printed materials prepared by your firm or its distributors should not include indications or claims not included in the FDA-approved labeling for the device, e.g., use in diabetic patients, small vessels (<2.5 mm in diameter), in-stent restenosis, bifurcation lesions, or patients with acute myocardial infarction." PMA 1-2. In addition, plaintiffs allege that the Cypher stent is not

[1]Exhibit 4 to the October 20, 2008 affidavit of Ronald Goldser consists of two documents: an approval letter from the FDA and a document entitled "Conditions of Approval." Because these documents are separately paginated, the Court cites the pages as "1-*n*" or "2-*n*" to distinguish between them.

approved for implantation by "direct stenting," which occurs when the stent is implanted in an artery that has not first been predilated with a balloon catheter. Compl. ¶ 17.

Riley was implanted with a Cypher stent in late April 2003, about a week after the Cypher was approved by the FDA. The stent was placed in Riley's mid-left-anterior descending coronary artery using direct stenting at a site containing a bifurcation lesion (a lesion located at the intersection of two arteries). Following his doctor's instructions, Riley took Plavix, an antiplatelet drug, for twelve weeks after the surgery. Nearly two years later, in March 2005, Riley suffered a heart attack as a result of a thrombotic occlusion (blood clot) that had formed at the site of the stent. Riley now seeks to recover damages to compensate him for the injuries that he suffered as a result of the heart attack.

II. ANALYSIS

A. Standard of Review

In reviewing a motion for judgment on the pleadings under Fed. R. Civ. P. 12(c), a court applies the same standard used to address a motion to dismiss for failure to state a claim under Fed. R. Civ. P. 12(b)(6). *Ashley County v. Pfizer, Inc.*, 552 F.3d 659, 665 (8th Cir. 2009). Under this standard, the court must accept as true all of the factual allegations in the complaint and draw all reasonable inferences in the plaintiff's favor. *Id.* Although the factual allegations in the complaint need not be detailed, they must be sufficient to "raise a right to relief above the speculative level . . . ." *Bell Atlantic Corp. v. Twombly*, 127 S. Ct. 1955, 1964-65 (2007).

Ordinarily, if the parties present, and the court considers, matters outside of the pleadings, the motion must be treated as a motion for summary judgment. Fed. R. Civ. P. 12(d). But the court may consider materials that are necessarily embraced by the complaint, as well as any

exhibits attached to the complaint, without converting the motion into one for summary judgment. *Mattes v. ABC Plastics, Inc.*, 323 F.3d 695, 697 n.4 (8th Cir. 2003). Here, the parties have submitted materials outside the pleadings, but the Court has not considered them. The Court therefore applies the standard of review applicable to Rule 12(c) motions.

B. Preemption

1. Express and Implied Preemption under the FDCA

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.

21 U.S.C. § 360k(a).

The Supreme Court addressed the meaning of § 360k(a) in *Riegel v. Medtronic, Inc.*, a recent case that, like this one, involved a Class III medical device that had received PMA. 128 S. Ct. 999 (2008). The Court first concluded that the PMA process imposes "requirement[s] applicable under this chapter to the device" for purposes of § 360k(a)(1). *Riegel*, 128 S. Ct. at 1007. As the Court noted, PMA is specific to individual medical devices. *Id.* 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." *Id.* The Court further held that state common-law duties impose "requirement[s]" that, notwithstanding their general nature, are "with respect to" medical devices. *Id.* at 1007-10. As a result, to the extent that a state common-law duty imposes requirements "different from, or in addition to" the requirements imposed by the FDCA, those state common-law duties are expressly preempted by § 360k(a). *Id.*

To escape preemption by § 360k(a), then, a state-law claim must be premised on the breach of a state-law duty that is the same as a duty imposed under the FDCA (or one of its implementing regulations). *Riegel*, 128 S. Ct. at 1011 ("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.").[2] Put differently, the conduct that is alleged to give the plaintiff a right to recover under state law must be conduct that is forbidden by the FDCA. Thus, to determine whether Riley's claims are preempted, it is first necessary to identify precisely what conduct by Cordis is alleged to give rise to a claim under state law. If that conduct is not prohibited by the FDCA, then Riley's claim, if successful, would have the effect of imposing on Cordis a requirement that is different from or in addition to the requirements imposed by the FDCA — and, for that reason, Riley's claim would be expressly preempted by § 360k(a).[3]

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[2]Cordis consistently ignores this aspect of *Riegel* in arguing that all of Riley's claims are preempted. Cordis also argues, without any supporting authority, that parallel claims must be based on state statutes rather than state common law. The Court rejects this contention, which finds no support in either logic or law. *See O'Shea v. Cordis Corp.*, No. 50 2006 CA 013019 AA, slip. op. at 3 (Fla. Cir. Ct. Oct. 21, 2008) ("The Court is not aware of any case which holds that parallel claims must be statutory.").

[3]Section 360k(a) also requires that the state-law requirement at issue "relate[] to the safety or effectiveness of the device or to any other matter included in a requirement applicable

If the conduct *is* prohibited by the FDCA, then a state-law claim premised on that conduct is not expressly preempted by § 360k(a). 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 under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman*, the Supreme Court held that, because enforcing the FDCA is exclusively the province of the federal government, there is no private right of action under the FDCA. *Id.* at 349 n.4 ("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.' 21 U.S.C. § 337(a)."). Thus, a private litigant cannot sue a defendant for violating the FDCA. Similarly, a private litigant cannot bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA — that is, when the state claim would not exist if the FDCA did not exist. *Id.* at 352-53. So, for example, a state-law claim that the defendant made misrepresentations to the FDA is preempted because such a claim would not exist absent the federal regulatory scheme established by the FDCA. *Id.*

This does not mean (as Cordis argues) that a plaintiff can never bring a state-law claim based on conduct that violates the FDCA. Indeed, as explained above, the conduct on which the plaintiff's claim is premised *must* violate the FDCA if the claim is to escape express preemption by § 360k(a). Instead, to avoid being impliedly preempted under *Buckman*, a claim must "rely[]

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to the device under this chapter." 21 U.S.C. § 360k(a)(2). Riley does not dispute that the state-law requirements on which his claims are based meet this requirement. As in *Riegel*, "[s]afety and effectiveness are the very subjects of [Riley's] common-law claims . . . ." *Riegel*, 128 S. Ct. at 1007.

on traditional state tort law which had predated the federal enactments in question[]." *Buckman Co.*, 531 U.S. at 353. In other words, the conduct on which the claim is premised must be the type of conduct that would traditionally give rise to liability under state law — and that would give rise to liability under state law even if the FDCA had never been enacted. If the defendant's conduct is not of this type, then the plaintiff is 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*. *Id.* at 349 n.4.

In sum, *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*). For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.

2. Riley's Broad-Based Arguments Against Preemption

Riley makes a number of general arguments for why § 360k(a) should not preempt any of his claims against Cordis. To begin with, Riley argues that § 360k(a) only applies when the medical device is used in a manner that was reviewed and approved by the FDA. In other words, Riley contends that § 360k(a) does not preempt any claim that arises out of the "off-label" use of a device. Riley asserts that the use of his stent was "off-label" because his stent was implanted without predilation and at the site of a bifurcation lesion. Because the FDA did not review or approve the Cypher stent for use in this particular manner, Riley contends, § 360k(a) is entirely

inapplicable. According to Riley, the point of preemption is to replace a patchwork system of state tort law with a comprehensive regime of federal regulatory review. But when a device is used off-label, Riley contends, preemption of state-law claims is unwarranted.

Riley admits that this argument is inconsistent with the result in *Riegel*, in which the plaintiff's claims were found to be preempted by § 360k(a) even though the device at issue (a balloon catheter) had been used off-label. *Riegel*, 128 S. Ct. at 1005 (catheter was used in a diffusely diseased and heavily calcified artery, despite warnings that such use was contraindicated, and was inflated beyond its rated burst pressure). But Riley seeks to avoid *Riegel* on the ground that the plaintiffs in *Riegel* did not actually argue that the off-label use of the device rendered § 360k(a) inapplicable. As the Supreme Court recognized in *Buckman*, though, off-label usage is not illegal or even disfavored under federal law. Rather, it is an accepted and indeed valuable part of the practice of medicine:

> "[O]ff-label" usage of medical devices (use of a device for some other purpose than that for which it has been approved by the FDA) is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine. See, *e.g.*, Beck & Azari, FDA, Off-Label Use, and Informed Consent: Debunking Myths and Misconceptions, 53 Food & Drug L.J. 71, 76-77 (1998) (noting that courts, several States, and the "FDA itself recogniz[e] the value and propriety of off-label use"). Indeed, a recent amendment to the FDCA expressly states in part that "[n]othing in this chapter shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship." 21 U.S.C. § 396 (1994 ed., Supp. V). Thus, the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals.

> State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants — burdens not contemplated by Congress in enacting the FDCA and the MDA. Would-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable civil liability. In effect, then, fraud-on-the-FDA claims could cause the Administration's reporting requirements to deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine, see 21 U.S.C. § 396 (1994 ed., Supp. V), and even though off-label use is generally accepted.

Buckman Co., 531 U.S. at 350-51. Thus, in *Buckman*, the Supreme Court found that fraud-on-the-FDA claims are preempted in part because the Court did not want to deter off-label use of medical devices.

Under Riley's theory, though, a manufacturer of a medical device could scrupulously adhere to the FDA's every command — and meet every requirement imposed on the design, manufacture, labeling, and marketing of the device — and nevertheless be sued under the tort law of any of the fifty states because a health-care provider, without the manufacturer's consent or even knowledge, decided to put the device to an off-label use. Given what the Supreme Court said in *Buckman* about the off-label use of medical devices, it seems highly unlikely that the Court intended to create such a loophole in *Riegel*.

Even assuming that *Riegel* does not foreclose the argument that off-label use renders § 360k(a) inapplicable, that argument must fail because it is inconsistent with the text of the statute. According to Riley, the FDA has not established any requirements with respect to the

off-label use of the Cypher stent, and thus there are no federal requirements with which his state-law claims will conflict. But under § 360k(a)(1), the question is not whether there are federal requirements applicable to a particular *use* of a device; the question is whether there are federal requirements applicable "to the *device*." If there are — and, as *Riegel* makes clear, the PMA process unquestionably imposes such requirements — then any state requirements that are different from, or in addition to, those federal requirements are preempted. Nothing in the statute suggests that the preemption analysis somehow depends on how the device is used.

Riley also argues that his claims are not preempted because Cordis did not give the FDA all relevant information that it had about the Cypher stent. According to Riley, express preemption only applies when the FDA has regulated a device with full knowledge of that device's safety and efficacy. Because Cordis's fraud deprives the FDA of such knowledge, Riley argues, his claims are not preempted by § 360k(a).

In *Brooks v. Howmedica, Inc.*, the Eighth Circuit rested its holding that the plaintiff's failure-to-warn claim was preempted partly on the fact that the FDA was aware of the risk at issue when it approved the language on the label. 273 F.3d 785, 797-98 (8th Cir. 2001) (en banc). Judges of this Court have read *Brooks* to imply that, if the FDA was *not* aware of a particular risk at the time it approved a device, then a failure-to-warn claim premised on that risk may not be preempted. *In re Medtronic, Inc., Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886, 896 (D. Minn. 2006); *In re St. Jude Med., Inc. Silzone Heart Valves Prods. Liab. Litig.*, No. MDL 01-1396, 2004 WL 45503, at *11 (D. Minn. Jan. 5, 2004). These decisions predate *Riegel*, however, and nothing in *Riegel* even hints that whether a state-law claim is expressly

preempted by § 360k(a) turns on the nature or extent of the information made available to the FDA at the time it approved a device.

Moreover, *Buckman* impliedly preempts any claim that, but for the defendant's fraudulent statements to the FDA, the Cypher stent would not have been approved and Riley would not have been injured. 531 U.S. at 343. Riley's argument that his claims are not preempted because the FDA was fraudulently deprived of the knowledge it needed to make an informed decision about the Cypher stent is just a thinly veiled way of claiming that the FDA would not have approved the Cypher in the absence of fraud — a claim that is squarely foreclosed by *Buckman*. *See Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1095 (D. Minn. 2008) (rejecting the argument that the defendant fraudulently concealed problems with its device from the FDA both because the record did not support his claim and because such a claim would be barred under *Buckman*).

Riley also argues that, because the Cypher stent is coated with a drug, the preemption analysis of § 360k(a) is inapplicable, and the Court must instead undertake the implied-preemption analysis that applies to claims relating to federally regulated drugs. *Cf. Wyeth v. Levine*, 129 S. Ct. 1187, 1204 (2009) (holding that a failure-to-warn claim against a pharmaceutical company was not impliedly preempted). But the Cypher stent is not merely a drug or merely a drug-delivery system; it is instead a compound of mechanical and chemical parts that work together as a single medical device. In approving the Cypher stent, the FDA exercised its authority to regulate medical devices, not its authority to regulate drugs.[4] And Riley's claims are manifestly claims against the device as a whole. Riley has not sued Wyeth,

[4]Although the parties do not say, it is safe to assume that the drug was the subject of a separate review by the FDA.

the manufacturer of Sirolimus, nor has he argued that the drug itself was adulterated or suffered from some manufacturing defect. Rather, according to Riley, it is the combination of the drug and the stent (in other words, it is the medical device as a whole) that is unreasonably dangerous and defective. It makes no sense — indeed, it would probably be impossible — to pick apart the components of a medical device and apply different preemption analyses to different components. Because the FDA regulated the Cypher stent as a medical device, the Court applies the express preemption analysis of § 360k(a) to the entire device.

Finally, Riley argues that the FDA is a poorly run agency that is not able to ensure the safety of the medical devices it reviews. For that reason, Riley argues, the Court should permit him to proceed with his claims, so that judges and juries can, in the course of litigating state-law tort claims, provide the oversight that the FDA is unable to provide. As a matter of policy, Riley's argument may or may not have merit. But this Court is not called on to weigh policy considerations in this case. Rather, this Court must apply an express-preemption clause that was enacted by Congress and construed in *Riegel*. If Riley believes that § 360k(a) represents a poor policy choice, his argument is better addressed to Congress.

C. Plaintiffs' Claims[5]

Having addressed Riley's preliminary arguments, the Court now turns to Riley's specific claims. As explained, to determine whether a claim is preempted, the Court must (1) identify the conduct that allegedly gives Riley a right to recover damages under state law; (2) determine whether that conduct is prohibited by the FDCA (because, if it is not, the claim is expressly preempted by § 360k(a)); and (3) determine whether the conduct would give rise to liability under state law even if the FDCA had never been enacted (because, if it would not, the claim is impliedly preempted under *Buckman*).

1. Failure to Warn or Disclose

Riley brings a number of claims alleging that, in one way or another, Cordis is liable for various pre- and post-sale failures to warn about or disclose the allegedly defective nature of the Cypher stent. Riley's primary claim seems to be that Cordis should have disclosed the need for long-term use of antiplatelet therapy. But Riley also alleges, more generally, that Cordis failed to

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[5]Riley has filed the quintessential "kitchen-sink" complaint, in which he has thrown just about every conceivable legal theory up against the wall — sometimes over and over again — in the hope that something will stick. Riley pleads separate counts of negligence and negligence per se, strict liability (defective product), strict liability (defective marketing and inadequate warnings), breach of implied warranties, breach of express warranty, negligent misrepresentation, and fraud. Most of these counts are pleaded rather abstractly, with little in the way of specifics to back them. And most of these counts contain overlapping allegations of defects in the design, research, development, manufacture, inspection, labeling, and marketing of the Cypher stent. Riley's complaint manages to be both prolix and uninformative.

It would be very difficult to discuss Riley's overlapping claims on a count-by-count basis. For that reason, the Court groups the claims according to their common underlying factual allegations (such as misrepresentation, design defect, and failure to warn). *Cf. Worden v. Gangelhoff*, 241 N.W.2d 650, 651 (Minn. 1976) (whether the plaintiff's cause of action rests on negligence, warranty, or strict liability, a plaintiff must establish that the product was defective, that he was injured by the defect, and that the defect existed when it left the hands of the defendant).

warn of risks and adverse side affects associated with the Cypher stent, failed to warn of the need for comprehensive medical screening of potential recipients of the Cypher stent, and failed to warn that Cordis itself had not conducted adequate testing of the stent. In nearly all of these claims, Riley is seeking to impose liability on Cordis for failing to do more than the FDA required. If such claims were successful, Riley would be imposing requirements under state law that would be in addition to those imposed by federal law (with one possible exception, which the Court discusses below). Under § 360k(a), such state-law requirements are preempted.

Riley argues that all of his failure-to-warn claims parallel federal law because the implantation of the Cypher stent in him was off-label, and Cordis was required, under 21 C.F.R. § 801.4, to warn of dangers associated with certain off-label uses. FDA regulations require that a device's label include adequate directions for the device's intended uses, *see, e.g.*, 21 C.F.R § 801.5, and § 801.4 defines the meaning of "intended uses" for the purpose of those regulations. Among the "intended uses" of a device described by § 801.4 are off-label uses of which a manufacturer knows or has reason to know:

> [I]f 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.

21 C.F.R. § 801.4.

Riley is correct that, 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. But § 801.4 must be read in conjunction with other statutes and regulations governing both

a manufacturer's right to disseminate information about off-label uses and a manufacturer's ability to alter a label that has been approved by the FDA.

During the time period relevant to this action, the FDCA permitted a manufacturer of a medical device to disseminate certain types of information about off-label uses of that device. Roughly speaking, the manufacturer could provide unabridged copies of peer-reviewed scientific articles or reference publications to health-care practitioners, insurers, or governmental agencies. 21 U.S.C. §§ 360aaa, 360aaa-1.[6] As long as the manufacturer complied with these limitations, its dissemination of information about off-label uses of its device would "not be construed by the Secretary as evidence of a new intended use of the drug or device that is different from the intended use of the drug or device set forth in the official labeling of the drug or device." 21 U.S.C. § 360aaa-6(b).

Under this safe harbor, then, the manufacturer could disseminate information about an off-label use of a device without triggering the duty to provide instructions or warnings about that off-label use. Again, manufacturers were obligated to warn only about intended uses, and, under the safe harbor, evidence of the dissemination of information about an off-label use was deemed not to be evidence of an intended use that was different from the use on the label. The

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[6]Sections 360aaa through 360aaa-6 were enacted as part of the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296. That Act contains a sunset provision providing that §§ 360aaa through 360aaa-6 would no longer be effective as of September 30, 2006, or seven years after the date on which regulations were promulgated under the Act, whichever was later. 21 U.S.C. § 360aaa note; Pub. L. No. 105-115 § 401(e), 111 Stat. 2296, 2364. Accordingly, §§ 360aaa through 360aaa-6 expired on September 30, 2006 and are no longer effective. *See* FDA, 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), *available at* http://www.fda.gov/oc/op/goodreprint.html (last visited June 4, 2009) [hereinafter "Guidance for Industry"].

statute made clear that this safe harbor applied "[n]otwithstanding subsection (a), (f), or (o) of section 352 of this title, or any other provision of law . . . ." 21 U.S.C. § 360aaa-6(b).

Clearly, then, federal law at the time relevant to this action explicitly permitted manufacturers to promote off-label uses of their devices by disseminating certain types of information about those off-label uses — and to do so without having to provide instructions or warnings about those off-label uses. It seems highly unlikely that, at the same time, § 801.4 was forcing manufacturers who knew of off-label uses of their devices but did not promote those off-label uses to provide instructions or warnings. It would make no sense to impose on manufacturers who were *not* promoting off-label uses of their devices a duty to instruct or warn, but to impose no such duty on manufacturers who *were* promoting off-label uses. The existence of this statutory scheme at the time relevant to this action strongly suggests that § 801.4 did not impose additional labeling requirements on manufacturers of Class III devices when those manufacturers become aware of off-label uses of their products.[7]

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[7]Although §§ 360aaa through 360aaa-6 are no longer in effect, the FDA currently takes a position consistent with those provisions regarding the distribution of information about off-label uses:

> FDA recognizes that the public health can be served when health care professionals receive truthful and non-misleading scientific and medical information on unapproved uses of approved or cleared medical products. Accordingly, if a manufacturer follows the recommendations described in Section IV of this guidance, FDA does not intend to consider the distribution of such medical and scientific information in accordance with the recommendations in this guidance as establishing intent that the product be used for an unapproved new use.

Guidance for Industry, *supra* note 6.

Another reason why § 801.4 should not be read to impose additional labeling requirements on manufacturers of Class III devices is that such manufacturers are severely limited in the changes that they can make to their labels. A Class III device may not be labeled in a manner that is inconsistent with any conditions specified in its PMA, 21 C.F.R. § 814.80, 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, 21 U.S.C. § 360e(d)(6)(A)(i); 21 C.F.R. § 814.39(a); *Riegel*, 128 S. Ct. at 1005 ("Once a device has received premarket approval, the MDA 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. § 360e(d)(6)(A)(i). "). Before approving a change to a label, of course, the FDA would need to give the proposed change careful study. It seems unlikely that § 801.4 was intended to establish an open-ended requirement that the manufacturer of a Class III device go to the FDA to seek permission to alter its label every time the manufacturer becomes aware of a new off-label use of the device.

It is true, as Riley notes, that there is an exception to the general prohibition on making labeling changes without FDA approval. Under that exception, a manufacturer may temporarily change a label to enhance safety pending FDA approval of the change. 21 C.F.R. § 814.39(d); *see also Brooks*, 273 F.3d at 796 (stating that such changes "are valid only after the manufacturer has submitted a Supplemental PMA and only during the pendency of that application"). Riley points out that in *Levine*, the Supreme Court relied on a similar regulation to find that a failure-to-warn claim against a pharmaceutical manufacturer was not preempted. *Levine*, 129 S. Ct. at 1196-99. But *Levine* addressed implied preemption, which involves weighing policy

considerations; the "pros" and "cons" of preemption are weighed by the court. This case, by contrast, addresses express preemption, which involves interpreting the words of a statute; the "pros" and "cons" have already been weighed by Congress.

In *Levine*, the manufacturer argued that the plaintiff's claim was impliedly preempted because it would be impossible to comply with both state and federal law. *Levine*, 129 S. Ct. at 1196. Here, the issue is not whether it would be impossible for Cordis to comply with both state and federal law; the issue is whether Riley is seeking to add a requirement under state-law "which is different from, or in addition to, any requirement applicable under [the FDCA] to the device . . . ." § 360k(a)(1). As other courts have explained, a failure-to-warn claim cannot parallel § 814.39(d) because § 814.39(d) merely *permits* a device manufacturer to make a temporary change to a label whereas a successful failure-to-warn claim would *require* such a change. *See McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005) ("Where a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted."). Section 814.39(d) thus does not help Riley.

The Court therefore concludes that Riley's failure-to-warn claims are preempted, with one possible exception. Riley alleges throughout his complaint that Cordis actually promoted off-label uses of the Cypher stent in violation of the FDCA. Most of Riley's off-label allegations relate to his argument that any off-label use of the stent renders § 360k(a) inapplicable — an argument that the Court has already rejected. Moreover, as this Court has held, it was not unlawful, under the FDCA, for Cordis to become aware of off-label uses of the Cypher stent and not seek to change its label to warn of those uses; thus, any claim based on this omission is

preempted by § 360k(a). Finally, Riley cannot sue Cordis for merely *promoting* the off-label use of the Cypher stent. If Cordis promoted the off-label use of the stent in a manner that was not authorized by the FDCA, then Cordis's conduct would violate federal law, and thus § 360k(a) would not expressly preempt a state-law claim based on this conduct. But such a claim would be impliedly preempted under *Buckman*, because promoting the off-label use of an FDA-approved medical device is not unlawful under "traditional state tort law which had predated the federal enactments in question[]." *Buckman Co.*, 531 U.S. at 353.

It seems possible, though, that Riley could plead a narrow failure-to-warn claim that would escape preemption. Specifically, if Riley pleaded that (1) Cordis affirmatively promoted the off-label use of the Cypher stent in a manner that violated federal law, and (2) that, while promoting the device in violation of federal law, Cordis failed to include adequate warnings and directions about the off-label use that it was promoting, then Riley's claim might survive. Arguably, the first allegation would protect the claim from being expressly preempted by § 360k(a), because Cordis's conduct in promoting the off-label use of the stent violated federal law.[8] And arguably the second allegation would protect the claim from being impliedly preempted under *Buckman*, because traditional state tort law imposes a duty to warn on a

[8]As noted above, during the time period relevant to this action, the FDCA permitted manufacturers to disseminate limited information about off-label uses of a medical device. Riley alleges that Cordis violated these limitations and unlawfully marketed the Cypher stent for off-label use, thus rendering the device "adulterated" and "misbranded" under federal law. *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)."). 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. 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)).

supplier of a product if it is reasonably foreseeable that an injury could result from the use of the product — and this duty includes the duty to give adequate instructions for the safe use of the product. *Gray v. Badger Mining Corp.*, 676 N.W.2d 268, 274 (Minn. 2004). Insofar as Riley sufficiently alleges that, in the course of unlawfully promoting the Cypher stent for off-label use, Cordis failed to adequately warn of foreseeable dangers of that use, Riley may succeed in asserting a claim that is neither expressly nor impliedly preempted.

The problem is that Riley has not adequately pleaded such a claim. In his complaint, Riley generally alleges that Cordis marketed the Cypher stent for off-label or unapproved uses. But there are many such potential uses, and thus Riley's allegations are too vague to make his claim more than speculative.

Riley's complaint alleges that the implantation of the Cypher stent in his artery was off-label because his doctor failed to predilate the artery before implantation. Riley's brief adds the allegation that implantation of Riley's stent was off-label because the stent was implanted at the site of a bifurcation lesion. For Riley's complaint to survive a Rule 12(c) motion, then, Riley must specifically allege — if he can do so consistently with Rule 11 — that Cordis affirmatively promoted the use of the Cypher stent in arteries that had not been predilated and at the sites of bifurcation lesions. And, while Riley need not plead these allegations with the specificity required by Rule 9(b), he must nevertheless include sufficient "[f]actual allegations . . . to raise a right to relief above the speculative level . . . ." *Bell Atlantic*, 550 U.S. at 555. Riley might, for example, identify a particular oral or written communication in which Cordis promoted the use of the Cypher stent in arteries that had not been predilated or at the sites of bifurcation lesions.

In addition to sufficiently alleging that Cordis unlawfully promoted the Cypher stent for the particular off-label uses relevant to this action, Riley must also specifically allege that Cordis 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. Again, under *Bell Atlantic*, Riley must allege this in more than a conclusory way.

Finally, Riley must sufficiently allege causation — both that implanting the Cypher stent in a particular off-label way caused his heart attack, and that, had Cordis adequately warned or instructed about this particular off-label use, Riley's physician would not have implanted a Cypher stent (or would have implanted it in a different way). The Court is frankly skeptical that Riley can allege causation with the specificity required by *Bell Atlantic* and consistently with Riley's obligations under Rule 11. As noted above, Riley's stent was implanted *one week* after the Cypher received PMA. It is difficult to believe that the decision of Riley's physician to implant the stent one week after the stent received FDA approval was related to unlawful efforts by Cordis to promote the off-label use of the stent. The fact that all of the examples of off-label marketing cited by Riley took place years after his stent was implanted (or are irrelevant to Riley's failure-to-warn claim[9]) deepens the Court's skepticism.

Nonetheless, the Court will give Riley leave to file an amended complaint so that, if he can do so with the detail required by Rule 8 (as interpreted by *Bell Atlantic*) and consistently with Rule 11, Riley can plead that Cordis affirmatively and unlawfully promoted the off-label use of

[9]Riley alleges that Cordis's off-label marketing misled physicians into believing that off-label uses were safe and that long-term use of Plavix was unnecessary. But this is not a failure-to-warn claim; it is more in the nature of a fraud claim. As discussed below, Riley has failed to allege fraud with particularity because he has not alleged to whom the representations were made nor how he relied on them.

the Cypher stent in arteries that had not been predilated and at the sites of bifurcation lesions; that, in the course of that unlawful promotion of the Cypher stent, Cordis failed to adequately warn or instruct about those particular off-label uses; and that Riley's heart attack was caused by Cordis's failure to warn. If Riley successfully pleads such a claim, the Court will then decide whether that claim is expressly or impliedly preempted.

2. Fraudulent and Negligent Misrepresentation

a. Preemption

The Cypher stent is a "restricted device" within the meaning of 21 U.S.C. § 360j(e). PMA 1-1. Under the FDCA, a restricted device is deemed misbranded, and its introduction into interstate commerce is prohibited, if its advertising is false or misleading in any particular. 21 U.S.C. § 352(q)(1); *see also* 21 U.S.C. § 331(a). Riley alleges that Cordis made three affirmative misrepresentations: (1) that the interior coronary-artery wall heals within thirty days of implantation; (2) that the polymer used to coat the Cypher stent does not increase the inflammatory response in coronary arteries; and (3) that a three-month post-implantation course of treatment with Plavix, an antiplatelet drug, is safe, effective, and acceptable medical care.

Cordis does not dispute that the first two alleged statements were not approved by the FDA and are not a part of any FDA-approved label. Thus, if Cordis made such representations, it did so in violation of the FDCA. Imposing liability on Cordis under state law for making such representations would not impose any requirements on Cordis that differ from, or add to, the requirements imposed under the FDCA. And there can be no doubt that false or misleading advertising can give rise to liability under state law even in the absence of the applicable federal law. The Court therefore concludes that Riley's misrepresentation claims may not be preempted

insofar as they are based on Cordis's alleged misrepresentations about the length of the healing process and the lack of an inflammatory response associated with the polymer coating.

But the Court cannot make a final determination about the preemption of these claims because, as discussed below, Riley has failed to allege them with the specificity required by Fed. R. Civ. P. 9(b). In particular, Riley has not alleged to whom most of the representations were supposedly made. There is no doubt, though, that Riley is basing his claims at least in part on representations that Cordis made to the FDA during the PMA process. *See* Compl. ¶ 62. To the extent that is true, Riley's claims are impliedly preempted under *Buckman* and are therefore dismissed with prejudice. *Buckman Co.*, 531 U.S. at 343.

With respect to Riley's allegation that Cordis misrepresented that a three-month course of treatment with Plavix is safe, effective, and acceptable medical care: Riley does not seem to dispute that the label approved by the FDA recommends three months of antiplatelet therapy after implantation of the Cypher stent.[10] Compl. ¶ 32. Yet Riley would impose liability on Cordis for failing to make a recommendation that conflicts with the recommendation found on the FDA-approved label — the label that Cordis is *required* by law to use. Riley's claims, if successful, would plainly impose on Cordis a requirement different from the requirements that the FDA has imposed. Therefore, Riley's fraud and misrepresentation claims are expressly

[10]The parties are a little vague as to whether the Cypher stent's FDA-approved labeling specifically recommends the use of Plavix or other antiplatelet drugs for three months. Cordis submitted the label as an exhibit to its answer, but the label consists of over seventy pages of extremely technical information in tiny type, and neither Riley nor Cordis pointed out where in the label the Court could find information about antiplatelet drugs. *See* Answer Exs. A, B. Nevertheless, based on Riley's allegation in ¶ 32 of his complaint, there does not appear to be any dispute that the FDA-approved labeling recommends the three-month use of Plavix. If the Court is mistaken, the parties can bring that mistake to the Court's attention.

preempted to the extent that they are based on Cordis's recommendation that patients use an antiplatelet drug for three months after implantation.

b. Rule 9(b)

Although the Court has concluded that some aspects of Riley's misrepresentation claims may not be preempted, those claims must nevertheless be dismissed because Riley has failed to plead them with the particularity required by Fed. R. Civ. P. 9(b). Rule 9(b) requires parties to allege "with particularity the circumstances constituting fraud or mistake." Under Minnesota 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. *Juster Steel v. Carlson Cos.*, 366 N.W.2d 616, 618 (Minn. Ct. App. 1985). The strictures of Rule 9(b) therefore apply to all of Riley's misrepresentation claims. *See Roberts v. Francis*, 128 F.3d 647, 650-51 (8th Cir. 1997) (Rule 9(b) applies to state-law claims in diversity cases).

Under Rule 9(b), a party must allege "'the who, what, when, where, and how: the first paragraph of any newspaper story.'" *Great Plains Trust Co. v. Union Pac. R.R.*, 492 F.3d 986, 995 (8th Cir. 2007) (quoting *DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990)). Riley's complaint describes the contents, as well as the time and place, of some of the allegedly false representations, but he has not alleged, with specificity, who made the representations, when the representations were made, to whom the representations were made, or how he (or his physician) relied on the representations.[11] *See In re NationsMart Corp. Sec. Litig.*, 130 F.3d 309,

[11]In the complaint, Riley cites a number of documents to support his misrepresentation claims. It is possible that the information necessary to meet the standards of Rule 9(b) is contained in those documents. But Riley did not attach those documents to the complaint or

321-22 (8th Cir. 1997) (affirming dismissal of fraud claims under Rule 9(b) for failure to plead reliance with particularity). For that reason, the Court will dismiss these claims without prejudice.

3. Breach of Express Warranty

a. Preemption

Riley also brings an express-warranty claim that appears to be premised, at least in part, on the same alleged assertions that underlie his misrepresentation claims. In other words, Riley seems to allege that Cordis expressly warranted (1) that the interior coronary-artery wall heals within thirty days of implantation; (2) that the polymer used to coat the Cypher stent does not increase the inflammatory response in coronary arteries; and (3) that a three-month post-implantation course of treatment with Plavix, an antiplatelet drug, is safe, effective, and acceptable medical care.

As noted, Riley's complaint manages to be both prolix and uninformative, and thus it is difficult to know when or how Cordis is alleged to have made these (or other) express warranties. But to the extent that Riley's breach-of-warranty claim is based on the contents of the Cypher stent's *label*, the Court finds that his claim is preempted by § 360k(a). Courts are divided over the question whether plaintiffs may maintain express-warranty claims based on representations made in an FDA-approved label. *See Huber v. Howmedica Osteonics Corp.*, No. 07-2400, 2008 WL 5451072, at *3 (D.N.J. Dec. 31, 2008) (collecting cases). Courts holding that such claims

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provide an index to them, and, assuming that those documents form part of the record, the Court is not able to decipher Riley's citations. If Riley should decide to replead his misrepresentation claims, he must include the allegations necessary to meet the standards of Rule 9(b) in the body of the complaint.

are not preempted reason that permitting plaintiffs to sue for breach of warranties on an FDA-approved label does not impose on manufacturers requirements that are different from, or in addition to, the requirements imposed by the PMA process. *Id.*

This Court disagrees. Suppose, for example, that the only assertion that Cordis made about the three-month course of treatment with Plavix was the statement made in the Cypher label. If an express-warranty claim cannot be brought against Cordis based on that representation, then Cordis needs to do nothing to avoid legal liability. It can sell its FDA-approved product, with the FDA-approved label, and not worry about being held liable for breach of warranty. But if an express-warranty claim can be brought against Cordis, then the conduct that does *not* get it into trouble under federal law — selling the Cypher stent with the FDA-approved label — *does* get it into trouble under state law. Thus, to avoid state-law liability, Cordis would be required to do something "which is different from, or in addition to" what federal law requires. For that reason, express-warranty claims that are based solely on the contents of an FDA-approved label are expressly preempted by § 360k(a). *See Martello v. Ciba Vision Corp.*, 42 F.3d 1167, 1168-69 (8th Cir. 1994) (finding all of the plaintiff's claims, including an express-warranty claim, to be preempted because they "would add requirements in areas reviewed in the premarket approval process").[12]

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[12]*Martello* pre-dated *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Supreme Court's first foray into the issue of preemption under the MDA. After *Lohr*, the Eighth Circuit held that *Martello* "requires some modification because common law claims are only preempted to the extent that they threaten to interfere with specific federal requirements." *Brooks*, 273 F.3d at 795. Despite the limiting language in *Brooks*, though, the analysis of *Martello* seems entirely consistent with *Riegel*. To the extent that Riley's express-warranty claim is based on FDA-approved labeling, then, it is barred by *Martello*.

To the extent that an express-warranty claim is *not* based solely on the contents of an FDA-approved label — or on statements that were otherwise approved or mandated by the FDA — the claim is not preempted. Federal law permits, but does not require, manufacturers like Cordis to make warranties, as long as those warranties are truthful and accurate. For example, the PMA requires that any warranties Cordis chooses to make "be truthful, accurate, and not misleading, and . . . consistent with applicable Federal and State laws," PMA 1-3, and federal regulations require that the Cypher stent be distributed and advertised consistently with these terms of the PMA, 21 C.F.R. § 814.80. Therefore, to the extent that Riley seeks to impose liability on Cordis for voluntarily making warranties, Riley is not imposing any different or additional requirements on Cordis. Federal law already requires Cordis to ensure that any warranty statements it voluntarily makes are truthful, accurate, not misleading, and consistent with applicable federal and state law.

In sum, a claim for breach of an express warranty that is based on statements that a manufacturer is *required* to make — such as statements in an FDA-approved label — is preempted by § 360k(a) because, in order to avoid state-law liability, the manufacturer would have to do something "which is different from, or in addition to" what federal law requires. But a breach-of-express-warranty claim based on *voluntary* statements is not preempted by § 360k(a) because, in order to avoid state-law liability, the manufacturer need do nothing more than refrain from making voluntary warranties. Any other result would turn FDA approval of some statements into a free pass to deceive consumers by making other statements.

b. Sufficiency of Allegations

For the reasons described above, to the extent that Riley bases his breach-of-warranty claim not on statements in the label, but on statements voluntarily made by Cordis, Riley's claim is not preempted. But Riley has not sufficiently pleaded such a breach-of-warranty claim under *Bell Atlantic*.

An express warranty is created when a seller makes "[a]ny affirmation of fact or promise . . . to the buyer which relates to the goods and becomes part of the basis of the bargain . . . ." Minn. Stat. § 336.2-313(1)(a). Riley has not alleged any facts that could lead a jury to conclude that the representations at issue were "part of the basis of the bargain." As it stands, the only representations Riley has identified were not made either to him or his doctor and were made long *after* his stent was implanted. It is a mystery how such statements could be part of the basis of the bargain and thus could give rise to liability for breach of express warranty.[13]

The Court will therefore dismiss Riley's express-warranty claim entirely, but without prejudice to Riley's ability to replead his claim in a manner consistent with this order.

4. Manufacturing Defect

Under 21 C.F.R. part 820, Cordis is required to follow "good manufacturing practices." Riley alleges that Cordis failed to comply with these requirements. Because these requirements are imposed by federal law, Riley argues, his manufacturing-defect claim is not preempted.

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[13]Riley argues that such statements could influence his post-implantation treatment. That may be true — and that may permit a recovery on some other theory — but an express-warranty claim is a contract claim, and Riley does not explain how representations made to other people long after he purchased his stent could be part of his purchase contract.

Riley may well be right. But Riley's manufacturing-defect claim is so poorly pleaded that it must be dismissed even if it is not preempted.

Riley does not allege any specific manufacturing failure. Instead, he relies entirely on the findings of FDA inspections that occurred well after his stent was implanted. According to the FDA, at the time of its inspections, Cordis was failing to establish and maintain certain quality-control procedures. As recounted in the complaint, however, the FDA's findings are quite general and merely track the regulatory language. For example, under 21 C.F.R. § 820.90(a), Cordis was required to "establish and maintain procedures to control product that does not conform to specified requirements." According to Riley's complaint, the FDA found that Cordis failed to do so.

This allegation is itself quite vague, but what is worse is that Riley does not clearly allege that any of Cordis's violations actually resulted in the manufacture of a single defective stent, much less that the particular stent that was implanted in Riley was defective. Obviously, Riley cannot sue Cordis for negligently manufacturing stents that were implanted in other people. Riley has not come close to alleging facts sufficient to "raise a right to relief above the speculative level . . . ." *Bell Atlantic Corp.*, 127 S. Ct. at 1964-65. Riley's manufacturing-defect claim is therefore dismissed without prejudice.

5. Remaining Allegations

Riley raises a host of additional claims that are obviously preempted, either expressly or impliedly. For example, Riley alleges that Cordis should have used a different polymer coating on the Cypher stent, that the Cypher is defective because bare-metal stents are safer, that Cordis failed to disclose certain information to the FDA, and that Cordis did not conduct adequate

premarket testing. If a jury were to agree with Riley, Cordis would clearly be subject to state-law requirements that conflict with the conditions imposed by the FDA; indeed, under some of Riley's theories, Cordis would be altogether precluded from selling a drug-eluting stent.

Riley also brings a claim for breach of implied warranties. Riley's only argument with respect to this claim is that FDA regulations indicate that implied-warranty claims are not preempted. *See* 21 C.F.R. § 808.1(d)(1) (stating that the MDA does not preempt state requirements of general applicability such as the Uniform Commercial Code warranty of fitness). *Riegel* explicitly rejected this argument, explaining that § 808.1(d)(1) "add[s] nothing to our analysis but confusion." *Riegel*, 128 S. Ct. at 1011.

Finally, Riley alleges that Cordis failed to comply with its PMA because it neither conducted adequate post-marketing surveillance nor made timely reports to the FDA of clinical outcomes and adverse events. As Cordis notes, though, Riley's stent was implanted only a week after Cordis received PMA, and hence no reports were due. More importantly, Riley does not identify any state-law cause of action under which he would have the right to recover for these failures if the FDCA and its implementing regulations did not exist; it is nonsensical to speak of a state-law claim for "failure to follow the conditions of the PMA" in the absence of the federal regulatory structure that provides for that PMA. Thus, under the logic of *Buckman*, any such state-law claim would be preempted. *See Buckman Co.*, 531 U.S. at 353 (a violation of the FDCA cannot support a state-law cause of action where "the existence of [the] federal enactments is a critical element in their case"). The Court therefore dismisses these claims with prejudice.

6. Loss of Consortium

Plaintiff Debra Riley brings a claim of loss of consortium that is derivative of Riley's claims. Because the Court is dismissing Riley's claims, the Court will also dismiss Debra Riley's consortium claim, but without prejudice to replead it should Riley decide to file an amended complaint.

ORDER

Based on the foregoing, and on all of the files, records, and proceedings herein, IT IS HEREBY ORDERED that:

1. Defendants' motion for judgment on the pleadings [Docket No. 4] is GRANTED.
2. The following claims are DISMISSED WITHOUT PREJUDICE as described more fully in the text of the Court's opinion: Plaintiffs' claims of failure to warn, fraud, express warranty, manufacturing defect, and loss of consortium, insofar as such claims are premised on conduct (1) that violates the FDCA or its implementing regulations, and (2) that would give rise to a recovery under state law even in the absence of the FDCA or its implementing regulations.
3. Plaintiffs may, within thirty days of the date of this order, file an amended complaint asserting the claims that have been dismissed without prejudice in ¶ 2 of this order.
4. On the filing of an amended complaint, the stay [Docket No. 38] will be lifted.
5. All remaining claims are DISMISSED WITH PREJUDICE AND ON THE MERITS.

6. If plaintiffs fail to file an amended complaint as permitted in ¶¶ 2-3 within thirty days of this order, the Court will enter a final judgment disposing of this case.

Dated: June 5, 2009

s/Patrick J. Schiltz
Patrick J. Schiltz
United States District Judge