UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

MARLENE PRUDHEL, RANDALL S. PRUDHEL, BRADLEY K. PRUDHEL, RYAN K. PRUDHEL, and SHAYNE R. PRUDHEL,

Plaintiffs,

v.

ENDOLOGIX, INC., and DOES 1 through 50, inclusive,

Defendants.

_____/

NO. CIV. S-09-0661 LKK/KJM

O R D E R

Plaintiffs bring various state-law claims arguing that a medical device designed and manufactured by defendant caused the death of Edwin Prudhel. Defendants move to dismiss on the ground that plaintiffs' claims are expressly preempted by federal law.

I. BACKGROUND

Decedent underwent an aortic stent graft repair. First Amended Complaint ("FAC") ¶¶ 19, 20. During this procedure, the treating physician attempted to use a Powerlink stent. FAC ¶ 21.

The operation was unsuccessful, and decedent suffered fatal injuries, which plaintiffs attribute to malfunction of the stent. FAC ¶¶ 9, 24-25. The Powerlink stent is designed, manufactured, and sold by defendant Endologix. FAC ¶¶ 7, 12-13, 26. Defendant's argument for dismissal turns on the Food and Drug Administration's ("FDA") regulation of medical devices. The court reviews this regulatory framework before returning to plaintiffs' particular claims.

A. Federal Regulation of Medical Devices

The Food, Drug, and Cosmetic Act, 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq., requires FDA approval prior to the introduction of new drugs into the market. See Riegel v. Medtronic, Inc., ___ U.S. ___, 128 S.Ct. 999, 1002 (2008). In 1976, Congress passed the Medical Device Amendments to this Act, 21 U.S.C. § 360c et seq. ("MDA"). The MDA broadened the Act to include medical devices. These devices are divided into three levels of regulation, Class III of which is relevant here. 21 U.S.C. § 360c(a)(1).[1]

Class III devices are subject to a premarket approval process which the Supreme Court has described as "rigorous." Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). "[T]he manufacturer must provide the FDA with a 'reasonable assurance' that the device is both safe and effective." Id. (quoting 21 U.S.C. § 360e(d)(2)). An applicant must submit, inter alia,

[1] Unqualified § 360 et seq. numbers hereinafter refer to sections of 21 U.S.C.

> 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.

Riegel, 128 S.Ct. at 1004 (quoting 21 U.S.C. § 360e(c)(1)). In determining whether this evidence demonstrates that approval is warranted, the FDA "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." § 360c(a)(2)(C). Thus, a device that presents great risks may be approved if it also provides great benefits. Riegel, 128 S.Ct. at 1004. After completing review, the FDA may grant or deny approval outright, or it may grant an approval conditioned on adherence to various requirements. See 21 U.S.C. §§ 360e(d), 360j(e)(1). The FDA may also deny approval but send a letter to the applicant indicating what changes or conditions could render the device approvable. 21 C.F.R. §§ 814.44(e), (f).

The MDA imposes further requirements after devices have been approved. After 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." Riegel, 128 S. Ct. at 1005 (citing § 360e(d)(6)(A)(i)). Approved devices are also subject to

ongoing reporting requirements related to the device's health and safety. § 360i.

B. Factual Background and Plaintiffs' Claims

Defendant received premarket approval for the Powerlink stent in October 2004. A Powerlink stent was used in an operation on decedent on April 3, 2008. FAC ¶¶ 19-20. During the procedure, the tip and/or cap of the stent's delivery device (a component included in the premarket approval) allegedly "disengaged," a malfunction. FAC ¶ 24. This malfunction allegedly caused decedent's injuries. FAC ¶ 25.

Plaintiffs attribute this malfunction to manufacturing and/or design defects. As to manufacturing, the stent's manufacture allegedly violated the FDA's manufacturing requirements imposed by the premarket approval and 21 C.F.R. § 820, resulting in "an impurity, imperfection, and/or other product defect" in the stent and components. FAC ¶¶ 50, 52, 55. As to design, plaintiffs allege that the stent suffered design defects rendering it "unreasonably dangerous," FAC ¶ 65, and that it was neither as safe nor as adequately tested as defendant represented to the FDA. FAC ¶ 67. Plaintiffs generally allege that defendant violated numerous federal regulations, including medical device reporting procedures, 21 C.F.R. § 803k, failure analysis and quality assurance procedures, § 820, recall and notification procedures, § 806, and provision of instructions for use, § 814. FAC ¶¶ 45-47, 49.

Plaintiffs' general allegations also claim that defendant had previously recalled several batches of Powerlink stents. FAC ¶¶

27-30. Some batches were recalled because "the tip may separate from the catheter sheath inner core during insertion of the graft," causing the delivery catheters to be recalled. FAC ¶ 27. Other batches were recalled because of separation problems with the delivery catheter which prevented deployment of the graft. FAC ¶ 29.[2] Plaintiffs contend that defendant should have expanded the scope of the recalls, FAC ¶ 30, although plaintiffs do not allege that the particular stent used on decedent was subject to the above recalls, nor do plaintiffs specifically allege that the stent used should have been recalled. Although plaintiffs do not specifically connect these recall allegations to any claim for relief, these allegations provide some indication of the type of defects alleged to exist. Under the court's obligation to give the pleader the benefit of all reasonable inferences (see §II, infra), it is not unreasonable to infer that plaintiffs' claims are based on these alleged faults.

Based on the above, plaintiffs enumerate four causes of action: a strict liability claim for a manufacturing defect, a strict liability claim for a design defect, negligence, and breach of both express and implied warranty. Defendant moves to dismiss all claims as explicitly preempted by the MDA.

II. STANDARD FOR A FED. R. CIV. P. 12(B)(6) MOTION TO DISMISS

In order to survive a motion to dismiss for failure to state

[2] Specifically, plaintiffs allege that "The stated reason for [the second] recalls was that the front sheath of the delivery catheter separation, [sic] preventing deployment of the stent graft." FAC ¶ 29.

a claim, plaintiffs must allege "enough facts to state a claim to relief that is plausible on its face." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 569 (2007). While a complaint need not plead "detailed factual allegations," the factual allegations it does include "must be enough to raise a right to relief above the speculative level." Id. at 555.

The Supreme Court recently held that Federal Rule of Civil Procedure 8(a)(2) requires a "showing" that the plaintiff is entitled to relief, "rather than a blanket assertion" of entitlement to relief. Id. at 555 n.3. Though such assertions may provide a defendant with the requisite "fair notice" of the nature of a plaintiff's claim, the Court opined that only factual allegations can clarify the "grounds" on which that claim rests. Id. "The pleading must contain something more. . . than . . . a statement of facts that merely creates a suspicion [of] a legally cognizable right of action." Id. at 555, quoting 5 C. Wright & A. Miller, Federal Practice and Procedure, § 1216, pp. 235-36 (3d ed. 2004).[3]

On a motion to dismiss, the allegations of the complaint must be accepted as true. See Cruz v. Beto, 405 U.S. 319, 322 (1972). The court is bound to give the plaintiff the benefit of every reasonable inference to be drawn from the "well-pleaded"

[3] The holding in Twombly explicitly abrogates the well established holding in Conley v. Gibson that, "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." 355 U.S. 41, 45-46 (1957); Twombly, 550 U.S. at 560.

allegations of the complaint. See Retail Clerks Int'l Ass'n v. Schermerhorn, 373 U.S. 746, 753 n.6 (1963). In general, the complaint is construed favorably to the pleader. See Scheuer v. Rhodes, 416 U.S. 232, 236 (1974), overruled on other grounds by Harlow v. Fitzgerald, 457 U.S. 800 (1982). Nevertheless, the court does not accept as true unreasonable inferences or conclusory legal allegations cast in the form of factual allegations. W. Mining Council v. Watt, 643 F.2d 618, 624 (9th Cir. 1981).

III. ANALYSIS

A. The MDA's Preemption of State Law

Defendant moves to dismiss all of plaintiffs' claims on the ground that these claims are preempted by the MDA. The MDA explicitly preempts any state requirement "'which is different from, or in addition to, any requirement applicable . . . to the device' under federal law." Riegel, 128 S.Ct. at 1006 (quoting 21 U.S.C. § 360k(a)(1)). Thus, for state law to be preempted, federal law must impose requirements on a device, and state law must impose additional requirements. The first step of this analysis is not disputed here. Although federal requirements only trigger preemption when there is a requirement specific to a particular device, premarket approval of the Powerlink under the MDA is such a specific requirement. Id. (citing Lohr, 518 U.S. at 495), id. at 1007. State law is therefore preempted insofar as it imposes requirements on the Powerlink that exceed those imposed by the FDA. Id. at 1007.

In Riegel and Lohr, the Supreme Court concluded that state

common law duties impose "requirements" within the meaning of the MDA's preemption clause. Riegel, 128 S.Ct. at 1008; Lohr, 518 U.S. at 512 (opinion of O'Connor, J., joined by Rehnquist, C.J., and Scalia and Thomas, JJ.), 503-05 (opinion of Breyer, J.).[4] "State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." Riegel, 128 S.Ct. at 1008. In particular, the court noted that juries applying state common law may focus on the risks demonstrated by a single case rather than the benefits realized by the device's other users. Id.

However, state common law duties are not preempted entirely. Instead, "§ 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." Id. at 1011. Other than to hold generally that parallel claims were permitted, Riegel did not discuss parallel claims.

The present case raises at least three questions regarding Riegel and the MDA's preemption provision. These are whether the MDA's preemption provision applies to all claims, what types of claims are parallel, and what a plaintiff must allege to successfully plead a parallel claim.

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[4] Lohr was, prior to Riegel, the primary Supreme Court opinion interpreting the MDA's preemption provision. Lohr produced a divided opinion, in which Justice Breyer's concurring opinion is controlling.

No decision of the Ninth Circuit directly speaks to any of these three questions. Nor has any other Circuit addressed these issues since Riegel was decided. Accordingly, this court must independently analyze the issues, but in doing so, can draw on the decisions of other district courts.[5]

B. Scope of the MDA's Preemption Provision, 21 U.S.C. § 360k

Plaintiffs first argue that under Riegel, the MDA's preemption clause, § 360k, does not apply to claims for breach of express warranty--i.e., that a claim for breach of express warranty may proceed regardless of whether it parallels federal requirements.[6] The FAC alleges that defendant "provided express warranties that the Powerlink was safe for intended and foreseeable use," and that defendant made "representations . . . on the product label, in other promotional and sales materials and otherwise." FAC ¶¶ 87, 68. Plaintiffs have not otherwise alleged the content or details of these representations. Defendant has not responded to, or even acknowledged, plaintiffs' argument that the express warranty claim is not subject to preemption under the MDA. Although defendants' silence may constitute an admission, the court nonetheless examines

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[5] Curiously, as far as this court can determine, no district court within this Circuit has directly addressed the problem.

[6] Plaintiffs also argue that Riegel does not apply to claims for manufacturing defects. Plaintiffs misinterpret the authorities upon which they rely. The cases have held, as Riegel obviously requires, that manufacturing defects claims are preempted to the extent that they impose additional state law requirements, but that such claims may be the type that permissibly enforces parallel duties. The question of whether plaintiffs' manufacturing defect claim is parallel is discussed in the following section.

the issue.

The MDA preempts requirements imposed by states that exceed federal requirements. 21 U.S.C. § 360k. The Supreme Court has observed that in general, state law claims for breach of express warranty sound in contract, rather than tort. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 526 (1992) (Stevens, J., for the plurality). While tort duties are imposed by the state, contractual obligations are voluntarily assumed by the parties, and such obligations may therefore fall outside preemption clauses. For example, the Supreme Court has held that a breach of express warranty claim is not preempted by the Federal Insecticide, Fungicide, and Rodenticide Act's preemption of state imposition of different or additional labeling packaging requirements. Bates v. Dow Agrosciences L.L.C., 544 U.S. 431, 444-45 (2005) (discussing 7 U.S.C. § 136v(b)). The court explained that

> a cause of action on an express warranty asks only that a manufacturer make good on the contractual commitment that it voluntarily undertook by placing that warranty on its product. Because this common-law rule does not require the manufacturer to make an express warranty, or in the event that the manufacturer elects to do so, to say anything in particular in that warranty, the rule does not impose a requirement for labeling or packaging.

Id. (internal quotation omitted); see also Cipollone, 505 U.S. at 525-26 (express warranty claim similarly not preempted by the Public Health Cigarette Smoking Act). California's breach of express warranty law follows this general pattern, in that a California claim for breach of express warranty is based on a

violation of a voluntary representation made by defendant. See Krieger v. Nick Alexander Imports, Inc., 234 Cal. App. 3d 205, 212 (1991) (citing Cal. Uniform Comm. Code § 2313 and Cal. Civ. Code § 1791.2).

Following Cipollone, several courts have held that a claim for breach of express warranty lies outside the scope of the MDA's preemption clause. The case most often cited for this proposition is Mitchell v. Collagen Corp., 126 F.3d 902, 915 (7th Cir. 1997). In Mitchell, the Seventh Circuit held that because a claim for breach of express warranty is contractual, it "does not necessarily interfere with the operation of the [pre-market approval], and therefore we cannot say that such a cause of action is preempted." Id. at 915.[7]

Other courts have held that the MDA preemption analysis turns on whether the language purportedly giving rise to an express warranty was compelled by the FDA, approved by the FDA, or extraneous to FDA approval. The FDA may require product labels to contain certain information. Other representations on product labels must by approved by the FDA. In approving labels, the FDA determines that the labels are neither false nor misleading. § 360e(d)(1)(A). The parties have not identified any FDA involvement

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[7] In the initial district court opinion in Riegel, the district court followed Mitchell to conclude that an express warranty claim was not preempted by the MDA. Riegel v. Medtronic, Inc., 2002 WL 34234093, *9 (N.D.N.Y. 2002). This claim was otherwise resolved before the case was heard by the Supreme Court, and neither the Second Circuit nor the Supreme Court addressed this claim on appeal.

in other (i.e., non-label) communications regarding medical devices.

Mitchell did not address this point, instead granting summary judgment to defendant on the ground that plaintiff had not identified any evidence that an express warranty had been communicated. Id. Among courts looking at particular communications, the Fifth Circuit has taken the most restrictive approach, concluding that express warranty claims are preempted whenever they are based on language approved by the FDA. Gomez v. St. Jude Med. Daig Div., Inc., 442 F.3d 919, 932 (5th Cir. 2006); accord Parker v. Stryker Corp., 584 F. Supp. 2d 1298, 1303 (D. Colo. 2008), Horowitz v. Stryker Corp., 2009 WL 436406 (E.D.N.Y. 2009); see also Carter, 582 F. Supp. 2d at 1286 (interpreting a similar preemption provision relating to drugs, rather than devices, in this way). Gomez explained that to succeed on a breach of express warranty claim under Louisiana law, the expressed warranty must be "untrue." Gomez, 442 F.3d at 932 (quoting La. Rev. Stat. Ann. § 9:2800.58). In approving language, the FDA determines that it is neither false nor misleading. § 360e(d)(1)(A). In Gomez, the court held that a breach of express warranty claim would therefore impose a requirement that was "potentially inconsistent with" the federal requirements. Id.

Preemption was interpreted more narrowly by the First Circuit, which held that "manufacturers will not be held liable [in breach of express warranty claims] for packaging and labeling *imposed* by the FDA." King v. Collagen Corp., 983 F.2d 1130, 1135 (1st Cir.

1993) (emphasis added).

Most permissively, the Third Circuit has held that no express warranty claims are preempted. Michael v. Shiley, Inc., 46 F.3d 1316, 1328 (3d Cir. 1995) overruled on other grounds as stated in In re Orthopedic Bone Screw Products Liability Litigation, 159 F.3d 817, 825 (3rd Cir. 1998); accord Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 839 (S.D. Ind. 2009). This court is not aware of any decision addressing whether a breach of express warranty claim based on language not approved by the FDA was preempted.

Although the above cases provide a useful background for medical device express warranty claims, this court need not decide among them, because plaintiffs' claim suffers a separate problem. Plaintiffs allege that defendant "provided express warranties that the Powerlink was safe for intended and foreseeable use." To succeed on this particular breach of express warranty claim, plaintiffs will need to show that the product was unsafe. As noted by the Supreme Court in Riegel, "safe" has different meanings under the MDA and state law. Plaintiffs do not tie their express warranty claim to an allegation that the product was unsafe within the meaning of the MDA. Nor do plaintiffs allege that defendant somehow voluntarily sought to implicate the definition of "safe" used by California law. To the extent that defendant represented that the product was safe within the meaning of the MDA, but that plaintiffs seek to impose liability on the ground that the product is unsafe within the meaning of California law, plaintiffs' claim

is preempted, for the reasons discussed in the following section. To the extent that plaintiffs intended to allege a different basis for their claim, plaintiffs have failed to put defendant or this court on notice of that basis. Heisner ex rel. Heisner v. Genzyme Corp., 2008 WL 2940811, *6 (N.D. Ill. 2008) (dismissing a claim that was either preempted or, if construed alternatively, insufficiently pled under Twombly).

C. What Constitutes a Parallel Claim

District courts have divided on what constitutes a "parallel claim" under Riegel.

The first question is what the state requirements must be parallel to. Courts have generally held that state law claims are not preempted if they parallel either specific or general FDA regulations, notwithstanding the fact that only a specific requirement will trigger the MDA's preemption clause. See, e.g., Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 835 (S.D. Ind. 2009), In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp. 2d 1147, 1157-58 (D. Minn. 2009). The court follows this approach here.

The second question is what it means to parallel a federal requirement. The most restrictive approach was taken by the Northern District of Illinois in Bausch v. Stryker Corp, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008). In essence, the court held that a claim is "parallel" to a federal requirement only when it provides a cause of action for violation of the federal requirement. A strict liability claim was preempted because under

Illinois law, such a claim "would, by necessity, require a trier of fact to assess whether a product is unreasonably dangerous," and the court held that a violation of federal regulations would be collateral to, and not the predicate of, a finding of strict liability. Id. *4. The court also held that negligence claims were preempted. "The preemption clause in the MDA bars all claims 'different from, or in addition to' federal regulations." Id. at *5 (quoting § 360k). "[A]lthough [plaintiff] has alleged that Defendants violated the FDA, [plaintiff]'s negligence claim is not based on a duty that is 'substantially identical' to the duty that is imposed on the [device] by FDA regulations." Id. at *6 (quoting Lohr, 518 U.S. at 496-97). Thus, negligence claims were preempted even though "plaintiff alleges that the same conduct that violated the FDA also" constituted the negligence. Id. at *5. Bausch would therefore apparently hold that the state law claims at issue in this case are preempted, because each requires proof of elements other than mere violations of the federal requirements.

This court declines to follow Bausch, because notwithstanding the Supreme Court's use of the phrase "substantially identical" in Lohr, Bausch cannot be squared with Lohr. In Lohr, the majority of the court held that a state law strict liability claim was not preempted despite the fact that to recover on the claim, the plaintiff would need to show more than merely a violation of federal requirements. Lohr, 518 U.S. at 495 (plurality opinion of JJ. Stevens, Kennedy, Souter and Ginsburg) (quoting § 360k), id. at 508 (concurring opinion of J. Breyer, joining this portion of

the majority opinion). Even though the state law of strict liability might impose a "narrower requirement . . . 'different from' the federal rules in a literal sense," a rule that contracted, rather than expanded, liability did not conflict with the federal rules. Id. at 495.

Most courts interpreting Riegel have continued to adopt this view of Lohr. For example, the Southern District of Indiana held that the MDA only preempts "claims that the device at issue 'violated state tort law notwithstanding compliance with the relevant federal requirements.'" Hofts v. Howmedica Osteonics Corp., 597 F. Supp. 2d 830, 835 (S.D. Ind. 2009) (quoting Riegel, 128 S.Ct. at 1011). Hofts held that "'claims [are] premised on a violation of FDA regulations,'" and therefore permissible under Riegel, whenever they are based on a violation of federal regulations regardless of whether the claim incorporates additional elements. Id. at 835 (quoting Riegel, 128 S.Ct. at 1011). The court therefore found no preemption of a strict liability claim alleging that "deviation from the FDA's manufacturing requirements was unreasonably dangerous" or of a negligence claim alleging that defendant "breached the duty of care . . . by failing to adhere to the FDA's manufacturing requirements." Id. at 836-37. See also In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp. 2d 1147, 1157-58 (D. Minn. 2009) (holding that the MDA did not preempt various manufacturing defect tort claims premised on violations of federal requirements, but that plaintiffs' allegations failed to satisfy Twombly), Parker v.

Stryker Corp., 584 F. Supp. 2d 1298, 1302 (D. Colo. 2008) (same); Horowitz v. Stryker Corp., 2009 WL 436406, *6 (E.D.N.Y., Feb. 20, 2009), Purcel v. Advanced Bionics Corp., 2008 WL 3874713 *3 (N.D. Tex. Aug 3, 2008).

This court concludes that Hofts articulates the better view. 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.

Applying this standard to this case, plaintiffs have adequately alleged a parallel claim in their first claim, but not in their second, third, and fourth claims. Plaintiffs' first claim is for strict liability arising out of a manufacturing defect. The manufacturing defect claim alleges that the manufacturing was not in compliance with the requirements imposed by 21 C.F.R. § 820, resulting in a defect. FAC ¶ 55. This alleged defect concerned separation of the components of the delivery device. Plaintiffs allege that the tip or cap of the stent's delivery device became disengaged during insertion into decedent. ¶ 24. Plaintiffs

further allege that prior manufacturing lots of the stents had been recalled because "the tip may separate from the catheter sheath inner core during insertion of the graft." ¶ 27. These allegations undoubtedly suffice to state a parallel claim under Riegel.

Plaintiffs' second claim, for strict liability for a design defect claim, is also apparently based on the separation and associated malfunction of the delivery device. Fed. R. Civ. P. 8. However, the only alleged connection between this claim and a federal violation is that the stent "was not safe for its intended use as [defendant] represented to the FDA it would be" and "was inadequately tested as [defendant] represented to the FDA it would be tested." FAC ¶ 67. These allegations do not establish a federal violation. It is unclear whether plaintiffs allege that defendant misrepresented this information to the FDA, or whether defendant's representations to the FDA instead merely later proved to be untrue. While the former might be a federal violation, it would implicate the FRCP 9 pleading requirements, which clearly are not met here. The latter, however, does not appear to amount to a federal violation. Accordingly, plaintiffs have not alleged how this claim is predicated on a federal violation, and this claim is therefore dismissed.

Plaintiffs' third claim, for negligence, and fourth claim, for breach of warranty, contain no allegations that in any way demonstrate that these claims are predicated upon violations of federal requirements. Although plaintiffs' generally allege that

many violations of federal requirements occur, to state a parallel claim, a federal violation must be a predicate to the theory of liability. Accordingly, these claims are dismissed: either they are not parallel, in which case they are preempted by the MDA, or they are inadequately pled, in that they fail to put the defendant on notice of the violation of federal requirements that serves as the basis for the claim.

D. Pleading Requirements for Parallel Claims

Courts are further divided as to what Twombly requires of a plaintiff seeking to plead a parallel claim. The most liberal view was taken by the Southern District of Indiana in Hofts, 597 F. Supp. 2d 830. The plaintiff in Hofts brought negligence and strict liability claims for manufacturing defects. Id. at 836. The plaintiff predicated these claims on violations of the premarket authorization and FDA manufacturing regulations. Id. However, the plaintiff did not allege precisely what conduct violated these federal requirements, or what the manufacturing defect was. Nonetheless, the court held to require such specific allegations would impose a heightened pleading requirement and exceed the requirements of Twombly. Id. at 838.

Most courts have instead held that a plaintiff must allege the particular federal requirement that was violated, and how. In In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp. 2d 1147, 1158 (D. Minn. 2009), the court held that while an allegation that a product "was defective because the manufacturing processes for the device . . . did not satisfy

the Food and Drug Administration's Pre-Market Approval standards . . . . appears to constitute [a permissible] parallel claim . . . nowhere does plaintiff's complaint provide any factual detail to substantiate that crucial allegation." See also Parker v. Stryker Corp., 584 F. Supp. 2d 1298, 1302 (D. Colo. 2008) (allegation that defendant violated the PMA manufacturing process insufficient; plaintiff must allege facts identifying the alleged violation), Heisner ex rel. Heisner v. Genzyme Corp., 2008 WL 2940811, 5 (N.D. Ill. 2008) (dismissing complaint that did not allege whether "defect" was or was not in violation of federal requirements).

The court need not decide between these approaches for purposes of this motion. As explained above, plaintiffs' second, third, and fourth claims fail under either approach. Plaintiffs' first claim, on the other hand, meets the stricter of these two requirements.

IV. CONCLUSION

For the reasons stated above, defendant's motion to dismiss, Doc. No. 15, is GRANTED IN PART. Defendant's motion is DENIED as to plaintiffs' first claim. Plaintiffs' second, third, and fourth claims are DISMISSED WITHOUT PREJUDICE.

IT IS SO ORDERED.

DATED: July 8, 2009.

LAWRENCE K. KARLTON
SENIOR JUDGE
UNITED STATES DISTRICT COURT