UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

In re Medtronic, Inc. Sprint Fidelis
Leads Products Liability Litigation,

This document relates to:
ALL CASES

Multidistrict Litigation
No. 08-1905 (RHK/JSM)
MEMORANDUM OPINION AND ORDER

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INTRODUCTION

The federal courts are frequently confronted with sympathetic plaintiffs who are, nevertheless, without remedy by operation of law. Doctrines such as qualified immunity often shield defendants from liability even when plaintiffs have been injured by the defendants' conduct. As one court has stated, "[l]itigants must believe that judges spend an inordinate amount of time wringing their hands while informing persons who have been [injured] that the court will do nothing. This is not because judges like to make

litigants feel bad – or themselves feel good by expressing sympathy – but because it is important to point out that the absence of a particular remedy . . . does not imply . . . the lack of a legal wrong." Pacelli v. deVito, 972 F.2d 871, 879 (7th Cir. 1992).

Like qualified immunity, the doctrine of federal preemption also leaves some plaintiffs without judicial recourse to pursue claims for damages. In one recent example, hundreds of people injured by the release of noxious gas following a 2002 train derailment in Minot, North Dakota were left without any remedy because their claims were preempted by the Federal Railroad Safety Act. See Lundeen v. Canadian Pac. Ry. Co., 532 F.3d 682, 687 (8th Cir. 2008).[1] Medtronic, the Defendant in this multidistrict litigation,[2] asserts the same doctrine here, arguing that Plaintiffs' claims – sounding in negligence and strict products liability – are preempted by the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq*. Having carefully considered the parties' voluminous submissions, the Court agrees.

[1] Congress later amended the Federal Railroad Safety Act to clarify that preemption was not intended, enabling the plaintiffs' claims to proceed. Lundeen, 532 F.3d at 688.

[2] Named as defendants in this action are Medtronic, Inc. and two of its wholly owned subsidiaries, Medtronic International Technology, Inc. and Medtronic Puerto Rico Operations Co. Because the parties do not differentiate between these three entities, the Court refers to them collectively as "Medtronic."

BACKGROUND

I. The statutory and regulatory framework and the pre-market approval process

Every medical device intended for human use is placed into one of three categories by the Food and Drug Administration ("FDA"), based on the risks of injury or illness the device presents; each category is subjected to a different level of FDA scrutiny. See 21 U.S.C. § 360c(a)(1); Riegel v. Medtronic, Inc., __ U.S. __, 128 S. Ct. 999, 1003 (2008). Devices that either "support[] or sustain[] human life" or "present[] a potential unreasonable risk of illness or injury" are categorized as "Class III" devices. 21 U.S.C. § 360c(a)(1)(c)(ii). Class III devices are subject to the greatest level of FDA scrutiny and "must complete a thorough review process with the FDA before they may be marketed." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 344 (2001). Through this process, known as pre-market approval ("PMA"), a device maker must provide the FDA with "reasonable assurance" that its device is both safe and effective. 21 U.S.C. § 360e(d)(2).

The PMA process is "a rigorous one." Medtronic, Inc. v. Lohr, 518 U.S. 470, 477 (1996). "Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission." Id. When analyzing that information, the FDA must weigh the "probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). Accordingly, the FDA

sometimes grants PMA to potentially life-threatening devices, if they "offer great benefits in light of available alternatives." Riegel, 128 S. Ct. at 1004; accord Heisner *ex rel.* Heisner v. Genzyme Corp., No. 08-C-593, 2008 WL 2940811, at *5 (N.D. Ill. July 25, 2008) ("Out of practical necessity and the cold calculus of nationwide regulation, the FDA may be aware of a certain failure rate associated with a medical product and yet approve it."). The PMA process also requires the FDA to review a device's proposed labeling to ensure that it is neither false nor misleading. See 21 U.S.C. § 360c(a)(2)(B).

If a device receives PMA, the manufacturer may not change its design specifications, manufacturing processes, labeling, or any other attribute that would affect the device's safety or efficacy without FDA approval. 21 U.S.C. § 360e(d)(6)(A)(i). Should a manufacturer wish to make such changes, it must submit to the FDA an application for supplemental PMA, which is evaluated "under largely the same criteria as an initial application." Riegel, 128 S. Ct. at 1005; accord 21 C.F.R. § 814.39(c) ("All procedures and actions that apply to an application [for PMA] also apply to PMA supplements."). In addition, once a device receives PMA, a manufacturer must inform the FDA when it becomes aware of adverse events in patients using the device. See 21 C.F.R. §§ 803.50, 803.53.

II. The FDCA's express preemption clause

In response to a bevy of state laws regulating medical devices largely enacted due to the failure of the Dalkon Shield contraceptive in the 1970s, Congress passed the Medical Device Amendments to the FDCA in 1976. See Riegel, 128 S. Ct. at 1003. The

Medical Device Amendments include an express preemption clause that "swept back some state obligations and imposed a regime of detailed federal oversight." Id. The preemption clause states:

> Except as provided in subsection (b) of this section, no 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).[3]

The scope of Section 360k(a) has been the subject of repeated litigation and the results are, charitably speaking, utterly conflicted. The Supreme Court got into the act in 1996 in Lohr, but did little to clear up the confusion. That "wondrously complex" decision, In re Medtronic, Inc. Implantable Defibrillators Litig., 465 F. Supp. 2d 886, 892 (D. Minn. 2006) (Rosenbaum, J.) – which has been described by one court of appeals as "fractured in an all but irreconcilable manner," Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1371 (11th Cir. 1999) – concluded that the plaintiff's claims for negligence and strict products liability arising out of the use of a Medtronic pacemaker were not

[3] The exception in subsection (b) referred to in Section 360k(a) is irrelevant for present purposes.

preempted by Section 360k(a).[4] While Justice Breyer agreed with the Lohr plurality that the plaintiff's claims were not preempted, he also agreed with the four dissenters that the Medical Device Amendments "ordinarily . . . pre-empt . . . state-law tort action[s]." 518 U.S. at 504-05 (Breyer, J., concurring in part and concurring in the judgment).

Given the uncertainty left in Lohr's wake, in the years that followed courts were divided over how broadly Section 360k(a) reached in medical-device cases. Compare Goodlin, 167 F.3d at 1382 (concluding that state tort-law claims regarding alleged defects in Medtronic pacemaker lead were not preempted) with Kemp v. Medtronic, Inc., 231 F.3d 216, 237 (6th Cir. 2004) (concluding that state tort-law claims regarding the *same* types of defects in the *same* Medtronic pacemaker lead *were* preempted). Nevertheless, over time the scales began to tip decidedly in favor of preemption, with more and more courts ruling that state-law claims concerning FDA-approved medical devices were indeed preempted. See In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig., 455 F. Supp. 2d 709, 716 (N.D. Ohio 2006) (canvassing case law and concluding that majority

[4] Justice Stevens authored the plurality opinion in Lohr, joined by Justices Kennedy, Souter, and Ginsburg. Justice O'Connor concurred in part and dissented in part, and dissented from the judgment; she was joined by then-Chief Justice Rehnquist and Justices Scalia and Thomas. Justice Breyer authored an opinion concurring in part and concurring in the judgment. Because no single opinion received the approval of five Justices, the Court's holding is somewhat unclear. Justice Breyer's concurrence, however, is of the greatest importance. See Marks v. United States, 430 U.S. 188, 193 (1977) ("When a fragmented Court decides a case and no single rationale explaining the result enjoys the assent of five Justices, the holding of the Court may be viewed as that position taken by those Members who concurred in the judgments on the narrowest grounds.") (internal quotation marks and citation omitted).

view is that "virtually all state law claims seeking to hold a defendant liable for injuries caused by an FDA-approved medical device are preempted").

Early last year, the Supreme Court confirmed that the prevailing view is the correct one. In Riegel, the Court held that the plaintiffs' state-law claims for strict products liability, breach of implied warranty, and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of an FDA-approved medical device were preempted under the FDCA. 128 S. Ct. at 1007-10. In reaching that conclusion, the Court undertook a two-step analysis. First, tracking the language of Section 360k(a), the Court opined that pre-market approval of a medical device by the FDA imposes "requirements" under the FDCA, because the device must be "made with almost no deviations from the specifications in [the PMA] application." Id. at 1007. Second, the Court opined that permitting the plaintiffs' claims to proceed would impose requirements "different from, or in addition to" the requirements imposed via the PMA process. Id. In so holding, the Court noted that

> [s]tate tort law that requires a manufacturer's [device] 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. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation.

Id. at 1008. Because both prongs of Section 360k(a) had been met, the Court concluded that the plaintiffs' claims were preempted.[5]

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[5] The FDA, which appeared as *amicus curiae* in Riegel, agreed with the Supreme Court's decision. See 128 S. Ct. at 1009; see also Should FDA Drug & Medical Device Regulation Bar

In the ten months following Riegel, courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, see, e.g., Bausch v. Stryker Corp., No. 08 C 4248, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008); Despain v. Bradburn, __ S.W.3d __, 2008 WL 1067202 (Ark. Apr. 10, 2008), to breach of warranty, see Link v. Zimmer Holdings, Inc., __ F. Supp. 2d __, 2008 WL 5047677 (N.D. Ill. Nov. 26, 2008); Blanco v. Baxter Healthcare Corp., 70 Cal. Rptr. 3rd 566 (Cal. Ct. App. 2008), to failure to warn and manufacturing- and design-defect, see Parker v. Stryker Corp., __ F. Supp. 2d __, 2008 WL 4716879 (D. Colo. Oct. 22, 2008), to negligence *per se*, see Heisner, 2008 WL 2940811.

Yet Riegel left open a back door for plaintiffs: claims alleging that a manufacturer failed to adhere to the specifications imposed by a device's PMA are not preempted. Id. at 1011; accord Stevens v. Pacesetter, Inc., No. 3:07-cv-3812, 2008 WL 2637417, at *1 (D.S.C. Apr. 1, 2008) (noting that a "narrow category" of claims survive Riegel – those "alleging a failure to comply with the federal standards which were established through the PMA process"). Such claims are not preempted because they merely "parallel"

State Liability Claims?: Hearing Before H. Comm. on Oversight & Gov't Reform, available at http://www.hhs.gov/asl/testify/2008/05/t20080514b.html (May 14, 2008) (statement by Randall W. Lutter, FDA Deputy Commissioner for Policy). However, the FDA's position on preemption has changed over time. See FDA *Amicus Curiae* Letter Brief, Horn v. Thoratec Corp., 2004 WL 1143720, at *3 (3rd Cir. May 11, 2004) (noting FDA's position in 1997 that state-law tort claims concerning FDA-approved devices were not preempted); Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52,602, 52,603 (Oct. 7, 1996) (same). Currently, the FDA takes the position that "PMA approval by the FDA triggers preemption of a wide array of requirements imposed under state tort law." Horn v. Thoratec Corp., 376 F.3d 163, 171 n.13 (3rd Cir. 2004).

federal requirements – that is, they do not *add to* or *differ from* federal requirements, which is the cornerstone of FDCA preemption. Riegel, 128 S. Ct. at 1011 (citing 21 U.S.C. § 360k(a)(1)).

III. Medtronic and the medical devices at issue here

The following allegations, which the Court must accept as true for purposes of the instant Motion, e.g., Stodghill v. Wellston Sch. Dist., 512 F.3d 472, 476 (8th Cir. 2008), are set forth in Plaintiffs' Master Consolidated Complaint for Individuals.[6]

Medtronic is a Minnesota corporation with its principal place of business in Minneapolis. (Compl. ¶ 7.) It is one of the world's largest manufacturers of medical devices, including implantable cardiac defibrillators ("ICDs"). (Id. ¶ 2.) ICDs are small devices implanted in patients' chests to monitor heart rates and correct heart-rhythm abnormalities. (Id.) They do so through small wires called "leads" that on one end are attached to the ICD and on the other end are attached directly to the patient's heart muscle through a coronary vein. (Id.) If electrodes on the leads detect that the patient's heart is out of rhythm, the ICD sends an electric shock to the heart muscle through the leads in order to correct the problem. (Id.) ICDs and the leads attached to them are categorized as "Class III" devices under the FDCA.

Medtronic has manufactured ICD leads since at least 1992, when it submitted an application (later approved) for PMA of its Transvene Leads System. (Id. ¶ 18.) Since

[6] All references hereafter to the "Complaint" and citations to "Compl." mean the Master Consolidated Complaint for Individuals (Doc. No. 129).

that time, Medtronic has manufactured several different types of ICD leads, which have grown progressively smaller in subsequent iterations. (Id. ¶¶ 17-18.)[7] For example, Medtronic's Sprint Quattro leads, approved by the FDA in 2001 as part of a PMA supplement to the Transvene Lead System, measured 2.8 inches wide. (Id. ¶¶ 17, 20, 27.) Later, in November 2003, Medtronic submitted a PMA supplement for its Sprint Fidelis leads,[8] which measured 2.1 inches wide. (Id. ¶ 21.) The FDA granted Medtronic's applications for supplemental PMA of the Sprint Fidelis leads in June 2004. (Id.)

According to Plaintiffs, the Sprint Fidelis leads substantially differ from the Sprint Quattro leads and were not adequately tested by Medtronic prior to seeking FDA approval. (Id. ¶¶ 22, 24.) Plaintiffs further claim that the method of manufacturing the Sprint Fidelis leads, which involves "direct resistance spot welding of two different metals," is prone to damaging them, and that Medtronic knew (but failed to disclose to the FDA) that such a welding technique was likely to result in the leads failing. (Id. ¶¶ 32, 34.) Finally, Plaintiffs claim that Medtronic failed to take adequate steps to ensure that the Sprint Fidelis leads were not damaged during production, including failing to perform adequate testing on the leads' components and failing to take corrective action to prevent lead failures. (Id. ¶ 38.)

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[7] Although no party has explained why Medtronic's leads have grown smaller over time, the Court surmises that it is because a smaller lead takes up less space in a coronary vein, and therefore restricts less blood flow to the heart.

[8] Specifically, models 6930, 6931, 6948, and 6949. (Compl. ¶ 21.)

In 2006, patients with ICDs using Sprint Fidelis leads began to suffer unnecessary and painful shocks. (Id. ¶ 43.) An investigation by a physician at the Minneapolis Heart Institute concluded that the shocks were caused by fractures in the leads and that the leads were failing at a significantly higher rate than the Sprint Quattro leads, a sentiment echoed by another physician at Cornell University Medical Center in New York. (Id. ¶¶ 43, 45, 49-52.) Plaintiffs claim that upon being confronted with this information, Medtronic undertook a campaign to defend the Sprint Fidelis leads, even though it knew that they were unsafe. (Id. ¶¶ 44-61.) As part of that campaign, Medtronic purportedly delayed filing "adverse event reports" with the FDA concerning failures of the leads. (Id. ¶ 62.)

In May 2007, Medtronic filed a supplemental PMA application containing design and manufacturing changes to the Sprint Fidelis leads. (Id. ¶ 58.) According to Plaintiffs, Medtronic filed this supplement in order to correct defects endemic to the leads. (Id.) Yet, Medtronic did not advise the FDA that it was filing the PMA supplement because of the lead failures and the resulting "public health crisis," instead merely informing it that the proposed changes were intended to make the leads more "robust." (Id.) The FDA approved Medtronic's PMA supplement in July 2007, but previously manufactured (and allegedly defective) Sprint Fidelis leads continued to be shipped to hospitals and implanted into patients. (Id.)

On September 10, 2007, Medtronic "finally" filed more than 120 adverse event reports concerning Sprint Fidelis leads. (Id. ¶ 62.) On October 7, 2007, Medtronic

suspended sales of the leads but did not inform the FDA, doctors, or the public of its decision, and they continued to be implanted into patients. (Id. ¶ 63.) On October 15, 2007, Medtronic recalled the Sprint Fidelis leads, and the FDA issued a "Class I" recall shortly thereafter. (Id. ¶¶ 64-65.) A Class I recall is "the most serious type of medical device recall" and occurs only when "there is a reasonable probability that the use of the produc[t] will cause serious injury or death." (Id.) At the time of the recall, approximately 257,000 Sprint Fidelis leads remained implanted in patients. (Id. ¶ 69.)

Following the recall, plaintiffs across the country began to file actions against Medtronic alleging (among other things) claims for negligence, strict products liability, fraud, and breach of express and implied warranties regarding the Sprint Fidelis leads. On February 21, 2008, the Judicial Panel on Multidistrict Litigation consolidated 27 of those actions before the undersigned for coordinated and consolidated pretrial proceedings, pursuant to 28 U.S.C. § 1407. Scores of other cases were later transferred here as "tag along" actions. The Court has appointed lead counsel for Plaintiffs and a steering committee to direct the course of the litigation on their behalf.

Pursuant to the Court's Order dated June 4, 2008 (Doc. No. 115), Plaintiffs' steering committee has now filed a Master Consolidated Complaint against Medtronic containing 21 claims, each of which is deemed incorporated into the Complaints in the individual actions pending before the Court in this Multidistrict Litigation. (See id.

¶ 17.A.)[9] Medtronic now moves to dismiss each of the claims as preempted by the FDCA.

STANDARD OF REVIEW

The recent Supreme Court case of Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 127 S. Ct. 1955 (2007), sets forth the standard to be applied when evaluating a motion to dismiss under Rule 12(b)(6). To avoid dismissal, a complaint must include "enough facts to state a claim to relief that is plausible on its face." Id. at 1974. Stated differently, a plaintiff must plead sufficient facts "to provide the 'grounds' of his 'entitle[ment] to relief,' [which] requires more than labels and conclusions, and [for which] a formulaic recitation of the elements of a cause of action will not do." Id. at 1964-65 (citation omitted). Thus, a complaint cannot simply "le[ave] open the possibility that a plaintiff might later establish some 'set of undisclosed facts' to support recovery." Id. at 1968 (citation omitted). Rather, the facts set forth in the complaint must be sufficient to "nudge[] the[] claims across the line from conceivable to plausible." Id. at 1974.

When reviewing a motion to dismiss, the complaint must be liberally construed, assuming the facts alleged therein as true and drawing all reasonable inferences from

[9] The 21 claims are: (1) strict liability – failure to warn; (2) strict liability – manufacturing defect; (3) negligence; (4) negligence per se; (5) breach of implied warranty; (6) breach of express warranty; (7) negligent misrepresentation; (8) intentional misrepresentation; (9) fraud; (10) constructive fraud; (11) violation of the Minnesota False Statements in Advertising Act; (12) violation of the Minnesota Deceptive Trade Practice Act; (13) violation of the Minnesota Prevention of Consumer Fraud Act; (14) violation of the Minnesota Senior Citizen and Handicapped Person Consumer Fraud Act; (15) negligent infliction of emotional distress; (16) loss of consortium; (17) wrongful death; (18) survival action; (19) medical monitoring; (20) unjust enrichment; and (21) Medicare Secondary Payer Act.

those facts in the plaintiff's favor. Id. at 1964-65. A complaint should not be dismissed simply because a court is doubtful that the plaintiff will be able to prove all of the factual allegations contained therein. Id. Accordingly, a well-pleaded complaint will survive a motion to dismiss "'even if it appears that a recovery is very remote and unlikely.'" Id. at 1965 (citation omitted).

ANALYSIS

Medtronic argues that, following Riegel, each claim in the Complaint is preempted under Section 360k(a) because it requires a determination that "the leads should have been designed, manufactured, tested, marketed, or labeled differently from the manner approved by the FDA via the PMA process." (Def. Mem. at 11.) Plaintiffs respond that Medtronic lost its preemption argument when the Sprint Fidelis leads were recalled and, in any event, that their claims fall within the narrow window left open by Riegel for "parallel" claims. (Mem. in Opp'n at 16-32.)

I. The recall does not deprive Medtronic of its preemption argument

Plaintiffs first argue that Medtronic "has lost its federal preemption defense altogether" because the recall "invalidated" the leads' PMA. (Mem. in Opp'n at 16-18.) Building on that assertion, Plaintiffs contend that the federal interest preemption is intended to protect – the PMA process – no longer exists because the PMA is no longer valid. (Id. at 17.) This argument is flawed for several reasons.

First, the argument is predicated on the faulty assumption that the recall invalidated the leads' PMA. Plaintiffs have cited no authority for that proposition, and

Medtronic correctly notes that the PMA process is governed by a completely separate statutory and regulatory regime than that governing withdrawal of a PMA – a process to which the Sprint Fidelis leads have never been subjected. Several courts have recognized this distinction. See, e.g., Theofanis *ex rel.* Theofanis v. Boston Scientific Corp., No. IP 01-752-C-Y/K, 2003 WL 24049229, at *2 (S.D. Ind. June 24, 2003) (noting that notwithstanding manufacturer's recall of device, "the PMA for the [device] has never been revoked by the FDA"); Blanco, 70 Cal. Rptr. 3rd at 580 ("The fact the FDA has implemented a Class I recall does not necessarily mean the FDA has completely removed the device from the marketplace."). The FDA, too, recognizes the distinction between the recall of a device and the revocation of a device's PMA – it has noted that "[w]hen a company recalls a medical device, it . . . takes action to prevent the problem *from happening again*." http://www.fda.gov/cdrh/recalls/learn.html#1 (emphasis added) (last visited January 2, 2009). There cannot be an "again" for a recalled device if the recall invalidated the device's PMA.[10]

[10] A simple hypothetical also demonstrates why Plaintiffs' assumption is faulty. Imagine that a medical device received PMA and the manufacturer began to market and distribute it. Two months later, the manufacturer discovered that an error occurred on the device's assembly line and all of the devices that had been manufactured and distributed were missing a critical component. A recall of the already manufactured devices would be appropriate, in order to "remov[e] [the] violative, distributed products" from the marketplace. 21 C.F.R. § 7.40(a). Yet, there would be no reason to invalidate the device's PMA – if the assembly error were corrected, then the device could (and would) be manufactured according to the FDA-approved PMA specifications. In other words, the company could "take[] action to prevent the problem from happening again." http://www.fda.gov/cdrh/recalls/learn.html#1 (last visited January 2, 2009).

Second, Plaintiffs' argument ignores that PMA for the Sprint Fidelis leads was in place *at the time the leads were implanted*. This is what matters, because liability under Plaintiffs' various legal theories hinges upon whether the leads were defective *at that time*. See Baker v. St. Jude Med., S.C., Inc., 178 S.W.3d 127, 134 n.5 (Tex. App. 2005) (rejecting contention that preemption "evaporates if the FDA later determines that the PMA approval was wrongly granted"; "Whether St. Jude was in compliance with federal requirements setting the standard of care *at the time the alleged tort was committed* is the appropriate issue.") (emphasis added); see also Moore v. Sulzer Orthopedics, Inc., 337 F. Supp. 2d 1002, 1009-12 (N.D. Ohio 2004) (finding preemption despite device recall); Theofanis, 2003 WL 24049229, at *5-6 (same); Blanco, 70 Cal. Rptr. 3d at 579 (same).

Third, Plaintiffs' argument would fail even if the recall somehow invalidated the PMA. Plaintiffs correctly note that the federal interest preemption is designed to protect is the PMA process. (Mem. in Opp'n at 17.) But the assertion that this interest would "no longer exist" if a PMA were invalidated is wrong – preemption necessarily looks *backward* (to the time of PMA) rather than *forward*. Riegel illustrates this point. There, the PMA process had concluded long before the plaintiffs commenced their lawsuit. Nevertheless, the Supreme Court recognized that the plaintiffs' claims threatened to interfere with the PMA process because allowing them to proceed would, in essence, result in *retroactive* second-guessing of the FDA's decision-making. This logic would apply with equal force if a PMA were invalidated or withdrawn – because, as in Riegel, a jury confronting such a situation would be required to retroactively question the FDA's

initial decision to approve the medical device at issue. Doing so would interfere with the PMA process *ipso facto*.

II. Plaintiffs' claims are all preempted

Plaintiffs next argue that they avoid preemption because they have asserted "parallel" claims – that is, claims that are not "different from, or in addition to" federal requirements. The Court cannot agree.[11]

As noted above, there are 21 claims asserted in the Complaint. Plaintiffs have not addressed these claims individually but have instead loosely grouped them into categories, and Medtronic appears to agree that those categories include all of Plaintiffs' claims. Accordingly, the Court will address each category in turn.

[11] There is no dispute that the PMA imposed federal requirements on the Sprint Fidelis leads. See Riegel, 128 S. Ct. at 1007 ("Premarket approval . . . imposes 'requirements' under the MDA as we interpreted it in Lohr."). The only issue, therefore, is whether Plaintiffs' claims would impose requirements on Medtronic that are "different from, or in addition to" those imposed by the PMA (or other federal law). Id.; 21 U.S.C. § 360k(a). If so, the claims are preempted. Id.

A. Manufacturing-defect claims

Plaintiffs' manufacturing-defect claims are based on a simple assertion: "Medtronic's defective welds caused the Sprint Fidelis leads to fracture." (Mem. in Opp'n at 21.) The welds purportedly were "defective" because "Medtronic used inadequate welding techniques" that did not comply with the FDA's Current Good Manufacturing Practices ("CGMPs") and Quality System Regulation ("QSR"). (Id. at 21-23 (citing, *inter alia*, Compl. ¶¶ 32-33, 91).) Plaintiffs further allege that Medtronic's testing and quality-assurance protocols were inadequate and failed to comply with the CGMPs and QSR. (Id. at 22.) Hence, Plaintiffs claim that they are seeking only to enforce FDA requirements (the CGMPs/QSR) and, as a result, their manufacturing-defect claims are merely "parallel."

Plaintiffs' reliance on the CGMPs and QSR, however, does not save these claims from preemption. It is true that the CGMPs and QSR govern "the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labeling, storage, installation, and servicing of all finished devices intended for human use." 21 C.F.R. § 820.1(a)(1). But they are simply too generic, standing alone, to serve as the basis for Plaintiffs' manufacturing-defect claims. The CGMPs and QSR require manufacturers to develop *their own* quality-system controls to ensure that medical devices are safe and effective for their intended use, and they are inherently flexible. See FDA Device Advice, Good Manufacturing Practices (CGMP)/Quality System (QS) Regulation, available at http://www.fda.gov/cdrh/devadvice/32.html#flexibility (last visited January 2,

2009) ("FDA has identified in the QS regulation the essential elements that a quality system shall embody for design, production and distribution, *without prescribing specific ways to establish these elements. Because the QS regulation covers a broad spectrum of devices and production processes, it allows some leeway in the details of quality system elements.*") (emphasis added). The FDA recognizes that the CGMPs and QSR simply cannot cover, in detail, all of the design, production, and marketing elements for every medical device in existence. Id. ("It is not practical for a regulation to specify details of quality system elements for such a wide range of products."). Rather, they are intended to serve only as "an umbrella quality system," providing "general objectives" medical-device manufacturers must seek to achieve. Id. In fact, the CGMPs/QSR provide specific methods to be used for only a small number of medical devices. "In most cases, *it is left to the manufacturer to determine the best methods to obtain quality objectives.*" Id. (emphasis added).[12] As the FDA stated when it promulgated the CGMP/QSR final rule:

> Because this regulation must apply to so many different types of devices, the regulation does not prescribe in detail how a manufacturer must produce a specific device. Rather, the regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device. FDA has made changes to the proposed regulation . . . to provide

[12] Even where particular methods are called for by the CGMPs and QSR, a manufacturer may "vary from the method specified if the intent of the CGMP requirement can be met by another method." FDA Device Advice, Good Manufacturing Practices (CGMP)/Quality System (QS) Regulation, available at http://www.fda.gov/cdrh/devadvice/32.html#flexibility (last visited January 2, 2009).

> manufacturers with ever greater flexibility in achieving the quality requirements.

Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52,602, 52,603 (Oct. 7, 1996).

The flexibility inherent in the CGMPs and QSR demonstrates why Plaintiffs' manufacturing-defect claims are not "parallel." Plaintiffs allege that Medtronic's welding techniques were "defective," but they have not pleaded how that welding technique violated the CGMPs or QSR. This is likely because the CGMPs and QSR do not provide such a fine level of detail concerning the manufacture of defibrillator leads (or most other medical devices). In the absence of any specific requirement in the CGMPs/QSR that Medtronic weld the Sprint Fidelis leads in a certain fashion, holding Medtronic liable for such a welding "defect" would impose requirements "different from, or in addition to" those under federal law. This is equally true of Plaintiffs' allegation that Medtronic used inadequate testing and quality-assurance methods – Plaintiffs simply have not identified any specific requirements in the CGMPs/QSR that were purportedly violated by Medtronic. Without any such specified requirement, Plaintiffs necessarily seek to impose requirements that differ from the CGMPs/QSR.

Plaintiffs' failure to allege in detail the federal requirement(s) purportedly violated by Medtronic also raises the specter of Twombly. Plaintiffs cannot simply incant the magic words "Medtronic violated FDA regulations" in order to avoid preemption. See Parker, 2008 WL 4716879, at *2 (conclusory allegation that device "was sold in direct

violation of the Code of Federal Regulations" insufficient under Twombly to save claim from FDCA preemption). Hence, their assertion that the Sprint Fidelis leads did not comply with the CGMPs/QSR is insufficient, without more, to save their claims. See Heisner, 2008 WL 2940811, at *5-6 (claims preempted under FDCA where plaintiff failed to provide factual basis for assertion that defendant failed to comply with FDA regulations); Cottengim v. Mentor Corp., Civ. No. 05-161, 2007 WL 2782885, at *5 (E.D. Ky. Sept. 24, 2007) (rejecting argument that "mere allegations that a manufacturing defect exists is enough to avoid preemption"). Under Twombly, Plaintiffs were required to provide enough factual detail in the Complaint to alert Medtronic of the "grounds" upon which their manufacturing-defect claim rests. 127 S. Ct. at 1964-65. Merely alleging that Medtronic failed to comply with the CGMPs/QSR by using spot welding is insufficient without some factual detail about *why* that violates federal standards. Id. Instead, Plaintiffs were required to point to something in the CGMPs/QSR precluding the use of spot welding in order to state a manufacturing-defect claim that is "plausible on its face." Id. at 1974.[13]

Rollins v. St. Jude Medical, __ F. Supp. 2d __, 2008 WL 4661622 (W.D. La. Oct. 20, 2008), provides an example of the types of allegations sufficient to survive preemption under Twombly. There, the plaintiff alleged that the defendant had failed to

[13] Plaintiffs' conclusory allegation that Medtronic "failed to manufacture and inspect the Sprint Fidelis Leads in a manner consistent with, and as prescribed by the FDA-approved specifications for manufacture and inspection of the Sprint Fidelis Leads" (Compl. ¶ 103) similarly fails to pass muster.

comply with the device's PMA specifications requiring the device to be "packaged with [its] anchor in vertical position with the bypass tube, neither extending beyond the end of the tube nor inserted deeply within it," by "incorrectly pack[ing] [it] with a .038" guidewire as opposed to the required .035" guidewire." Id. at *8. No similarly detailed allegations appear in the Complaint here.[14]

B. Failure-to-warn claims

In their failure-to-warn claims, Plaintiffs allege that Medtronic "failed to provide adequate and timely warnings or instructions regarding the Sprint Fidelis [l]eads." (Compl. ¶ 121.) Specifically, Plaintiffs allege that Medtronic failed to warn physicians and patients of the defects in the leads prior to announcing the recall on October 15, 2007. (Mem. in Opp'n at 25.) This is a "parallel" claim, Plaintiffs argue, because the FDA "encourages voluntary recalls and unilateral changes to warning labels" and "FDA regulations specifically permit manufacturers to make labeling changes to enhance product safety, without pre-approval from the FDA." (Id. (citing 21 C.F.R. § 814.39).)

But Plaintiffs cannot escape that under their theory of liability, Medtronic would have been required to provide warnings above and beyond those on the Sprint Fidelis

[14] At oral argument, Plaintiffs asserted for the first time that they could not plead the specifications contained in the leads' PMA because they have not yet conducted discovery. But the Court anticipated this at the outset of the case, and Plaintiffs' counsel represented to the Court at that time that no discovery was necessary to resolve the preemption issue. Indeed, at the initial status conference held on May 28, 2008, the Court specifically asked Plaintiffs' counsel whether discovery was needed before addressing preemption. (See 5/28/08 Tr. at 53-54.) Counsel made abundantly clear that "for purposes of a [Rule] 12(b)(6) motion [on preemption], no discovery is necessary." (Id. at 54.)

leads' product label – a label that was specifically approved by the FDA as part of the PMA process. See 21 U.S.C. § 360c(a)(2)(B). Mandating that a manufacturer provide warnings beyond those on the device label would impose requirements "different from, or in addition to" those approved by the FDA, and are thus preempted. See King v. Collagen Corp., 983 F.2d 1130, 1136 (1st Cir. 1993).[15] Simply put, Section 360k(a) preempts claims that are, as here, "premised on a 'post-sale duty to warn,' where the plaintiff alleges the defendant was required to provide additional warnings in light of later-received reports of injury to others caused by the same medical device." In re Sulzer Hip, 455 F. Supp. 2d at 717 n.10 (emphasis omitted). For the same reasons, claims alleging that Medtronic should have recalled the Sprint Fidelis leads sooner than it did are similarly preempted. See, e.g., Cupek v. Medtronic, Inc., 405 F.3d 421, 424 (6th Cir. 2005).[16]

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[15] Plaintiffs claim to have "broadly allege[d] that Medtronic . . . entirely failed to provide any warning" concerning the Sprint Fidelis leads, including failing to provide any product label at all. (Mem. in Opp'n at 24.) In support, they cite paragraph 121 of the Complaint, which alleges that Medtronic "failed to provide *adequate* and *timely* warnings or instructions regarding the Sprint Fidelis Leads and the known defects." (emphases added). Even under a generous reading, this allegation in no way suggests that Medtronic failed to provide any warning *whatsoever*. If that is what Plaintiffs intended, they could have easily said so.

[16] Two days before the hearing on Medtronic's Motion, the Supreme Court decided Altria Group, Inc. v. Good, __ U.S. __, 129 S. Ct. 538 (2008). The Altria Court held that claims under the Maine Unfair Trade Practices Act were not preempted by the Federal Cigarette Labeling and Advertising Act. At oral argument, Plaintiffs asserted that, after Altria, their statutory fraud claims are not subject to preemption. But Altria concerned a statute with a much narrower preemption clause than Section 360k(a), as Justice Stevens recognized. See id. at 549 (distinguishing Riegel because Section 360k(a) is "much broader than the operative language of the [Cigarette] Labeling Act"). Accordingly, the Court concludes that Altria did little to alter its analysis.

Furthermore, Medtronic correctly notes that the FDA regulations cited by Plaintiffs *permit* a device manufacturer to give certain warnings, but Plaintiffs' failure-to-warn theory necessarily requires a showing that Medtronic was *required* to give those warnings. And, Plaintiffs have not identified in the Complaint any federal regulation, rule, or other source of obligation that would *require* such a warning to be given. In similar circumstances, the Seventh Circuit held that a failure-to-warn claim was preempted because it was not "parallel" to federal requirements:

> [21 C.F.R.] Section 814.39 permits a manufacturer to temporarily amend a warning pending FDA approval of . . . proposed changes. . . . McMullen discusses at length the fact that Medtronic was "allowed" and "permitted" to issue an interim safety alert while awaiting approval of its amended warning. He argues that state common law requiring a post-sale warning merely "complements" the federal policy of allowing such warnings, and thus is not preempted. Recall, however, that the MDA's preemption clause provides that state requirements that are "in addition to" federal requirements are preempted. 21 U.S.C.. § 360k(a). *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.* Because § 814.39 permits, but does not require, a manufacturer to provide interim supplemental warnings pending approval by the FDA, a common-law duty to provide such a warning imposes an additional obligation.

McMullen v. Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005) (emphasis added); accord King, 983 F.2d at 1139 (Aldrich, J., concurring) ("Plaintiff claims that because [Section 814.39 states] that a manufacturer 'may,' without prior approval, make certain changes that enhance safety, defendant had a duty to make such here. It is sufficient to say that to interpret 'may' as 'should' would unravel the entire garment.").

Plaintiffs attempt to remedy this defect by identifying a source for the "requirement" that Medtronic provide post-PMA warnings: "the FDA approved the Sprint Fidelis Lead PMA Supplements *subject to certain express conditions*." (Mem. in Opp'n at 26 n.13 (emphasis in original) (quoting Compl. ¶ 23).) However, Plaintiffs nowhere specified in their brief what those "express conditions" were, nor did they make any effort to indicate how those conditions mandated the warnings that Plaintiffs claim Medtronic failed to provide. Shortly before the hearing on Medtronic's Motion, however, Plaintiffs finally attempted to supply that information, submitting to the Court the FDA's letter granting PMA to the Sprint Fidelis leads. Plaintiffs now argue that the "express conditions" of pre-market approval required Medtronic to advise the FDA of adverse events in patients using the leads. (See Doc. No. 219, Ex. A.)

But the reporting requirements Plaintiffs point to in the approval letter come from 21 C.F.R. § 803.50 and 21 C.F.R. § 803.53, regulations that were promulgated by the FDA in accordance with the FDCA. Stated differently, the PMA conditions did not impose any *new* reporting requirements on Medtronic, but simply reiterated Medtronic's already-existing obligations under federal law. Hence, what Plaintiffs are really alleging is that Medtronic violated the FDCA by failing to inform the FDA in a timely fashion of adverse lead events. Such a claim necessarily fails, because no private right of action exists under the FDCA. See Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3rd Cir. 1994) ("[V]iolations of the FDCA do not create private rights of action."); Parker, 2008 WL 4716879, at *3; Alexander v. Smith & Nephew, P.L.C., 98 F. Supp. 2d 1310, 1321

(N.D. Okla. 2000). Plaintiffs cannot make an end run around this rule by recasting violations of the FDCA as violations of state common law. See Parker, 2008 WL 4716879, at *3; Lake v. Kardjian, No. 03-1267, 2008 WL 5244823, at *2 (N.Y. Sup. Ct. Dec. 17, 2008).

It might seem inconsistent with Riegel to conclude that a claim alleging a medical-device manufacturer violated the FDCA is preempted. After all, Riegel expressly recognized that "parallel" claims – that is, claims "premised on a violation of FDA regulations" – are not preempted. Id. at 1011. Plaintiffs noted this inconsistency at oral argument, asserting that if they cannot bring state-law claims for violations of the FDCA, then there exist no "parallel" claims that could possibly survive preemption – in essence, "different from, or in addition to" in Section 360k(a) would be rendered meaningless. If Congress had intended that result, Plaintiffs argued, it could have easily said so.

But what this argument overlooks is that claims alleging violations of the FDCA are not preempted because they run afoul of *Section 360k(a)*, which is the type of preemption addressed in Riegel. Rather, such claims are *impliedly* preempted by 21 U.S.C. § 337(a), which states that all proceedings for the enforcement or to restrain violations of the FDCA "shall be by and in the name of the United States." Hence, "the FDCA leaves no doubt that it is the Federal Government rather than private litigants [which is] authorized to file suit for noncompliance with the medical device provisions" in the FDCA. Buckman, 531 U.S. at 349 n.4. As a result, when Sections 337(a) and 360k(a) – as construed in Buckman and Riegel, respectively – are read together, nearly all

types of claims concerning FDA-approved medical devices are preempted, including Plaintiffs' failure-to-warn claims here.[17]

C. Design-defect claims

Plaintiffs' design-defect claims allege that (1) after the FDA approved the Sprint Fidelis leads' "new and improved" design in July 2007, Medtronic should have stopped selling the original, "defective" version, and (2) Medtronic should have used the "new and improved" design prior to July 2007. (See Mem. in Opp'n at 26-27.) The Court concludes that neither is a "parallel" claim.

As an initial matter, Plaintiffs' design-defect claims would require a jury to find that the "older" design of the Sprint Fidelis leads was unsafe. Clearly, such a finding would usurp the FDA's role in evaluating the safety and effectiveness of the leads and would interfere with the PMA process. See Riegel v. Medtronic, Inc., No. 99-CV-649, 2002 WL 34234093, at *6 (N.D.N.Y. Mar. 18, 2002) ("A finding by a jury in this case that this design was defective would necessarily impose a standard on Defendant different from that imposed by the FDA."), aff'd, 451 F.3d 104 (2d Cir. 1996), aff'd, 128 S. Ct. 999 (2008).

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[17] Naturally, this begs the question: what types of claims alleging defects in an FDA-approved medical device are *not* preempted? For one, an adequately pleaded claim that a specific device was not manufactured in accordance with its PMA specifications can survive preemption. See Rollins, 2008 WL 4661622, at *8. Similarly, if a state were to pass a statute providing a remedy for a violation of the FDCA, a claim under such statute would not be preempted. See Bausch, 2008 WL 5157940, at *4. Notably, there is no such statute at issue here – rather, Plaintiffs' claims are based only on "generalized common law theories" such as strict liability, negligence, and breach of warranty. Such claims are preempted. Id.

But in any event, Plaintiffs have nowhere identified a federal requirement mandating a manufacturer to stop selling a device when an "improved" version thereof is granted PMA. Plaintiffs have cited no federal regulation or other requirement suggesting that a previously issued PMA is withdrawn or somehow loses its vitality when a device improvement is granted PMA. Nor does such an assertion make intuitive sense. In many situations, devices may be improved not because they are unsafe, but simply because a newer version is better in some fashion – just as the Sprint Quattro leads purportedly were better than Medtronic's Transvene Leads. (See Compl. ¶¶ 18-20.)

Plaintiffs have similarly failed to identify any federal requirement to support their assertion that "[u]pon receiving notice of the defect, Medtronic had a duty to take reasonable steps to improve the safety of the Sprint Fidelis leads." (Mem. in Opp'n at 27.) They *do* cite in the Complaint a host of regulations concerning Medtronic's post-sale *reporting* requirements. (See Compl. ¶¶ 87-90, 95-96.) But none of those regulations even remotely suggests an obligation on Medtronic's part to *improve* the Sprint Fidelis leads upon learning that patients were experiencing problems. Once again, the best Plaintiffs point to is their allegation that the leads were granted PMA subject to "certain express conditions." (Mem. in Opp'n at 27 (quoting Compl. ¶ 23).) Yet, Plaintiffs have pointed to nothing in those conditions requiring Medtronic to improve the leads. Without any specific federal requirement that Medtronic take steps to improve the safety of the leads upon receiving adverse-event reports, Plaintiffs seek to impose conditions on Medtronic "different from, or in addition to" those under federal law.

Plaintiffs also argue that their design-defect claims are "parallel" because the leads were "adulterated" under federal law. (Mem. in Opp'n at 28.) Such an assertion, however, necessarily rests on Plaintiffs' claim that the leads were negligently manufactured. (See id. (asserting that Medtronic "failed to meet FDA design control requirements").) Indeed, 21 U.S.C. § 351(h) states, in pertinent part, that a Class III medical device is adulterated only if "the methods used in, or the facilities or controls used for, its manufacture, packing, storage, or installation are not in conformity with" the CGMPs/QSR. Because Plaintiffs' manufacturing-defect claims are preempted (see supra at 18-22), this derivative assertion is also preempted. See Gile, 22 F.3d at 544 ("[T]o the extent Gile's adulteration claim is derivative of her other claims for inadequate design, manufacture, and warnings, she cannot overcome a finding of preemption merely by claiming that the product was adulterated."); Parker, 2008 WL 4716879, at *3 (noting that plaintiff's claims were "not saved [from preemption] merely by being recast as violations of the federal adulteration and misbranding statutes").[18]

Simply put, Plaintiffs have not pointed to any federal requirements "parallel" to those they seek to foist onto Medtronic in their design-defect claims. The claims are preempted.

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[18] In any event, it is the FDA's task to determine whether medical devices are adulterated, and only the FDA may "take action with respect to adulterated products." Gile, 22 F.3d at 544. No private cause of action exists against Medtronic for selling "adulterated" devices, no matter how the claim may be styled. See id.; Parker, 2008 WL 4716879, at *3; Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 50 (D. Mass. 1994), aff'd, 63 F.3d 25 (1st Cir. 1995); but see Purcel v. Advanced Bionics Corp., Civ. No. 3:07-CV-1777, 2008 WL 3874713, at *3-4 (N.D. Tex. Aug. 13, 2008).

D. Negligence *per se* claims

Plaintiffs' negligence *per se* claims track their manufacturing-defect claims. Indeed, Plaintiffs admit that these claims "incorporate[] the factual allegations of the ordinary negligence claims" to allege that Medtronic violated "the CGMPs and QSRs," thereby resulting in "defects" in the leads. (Mem. in Opp'n at 29-30.) The claims, therefore, are preempted for the same reasons that the manufacturing-defect claims are preempted.

The negligence *per se* claims are also preempted for another reason. A claim of negligence *per se* simply adopts the standard of care imposed by a statute or regulation as the standard against which the defendant's conduct is evaluated. See Restatement (Second) of Torts § 286 (1965). Stated differently, negligence is the breach of a legal duty, and under a negligence *per se* theory, the measure of that legal duty comes from a statute (rather than the common law). For example, assume that a state statute sets a speed limit of 40 miles per hour, and the defendant violates that speed limit and, as a result, crashes into the plaintiff's car. The plaintiff can press a claim for negligence *per se*, adopting the statutory standard of care (no driving in excess of 40 miles per hour) as the standard to be applied to the defendant's conduct. See, e.g., Elder v. Allstate Ins. Co., 341 F. Supp. 2d 1095, 1099-1100 (D. Minn. 2004) (Kyle, J.).

With this understanding of the foundations for negligence *per se*, it becomes clear why it cannot apply here. "[T]he negligence per se doctrine . . . is not a magic transforming formula that automatically creates a private right of action for the civil

enforcement, in tort law, of every statute." Talley v. Danek Med., Inc., 179 F.3d 154, 158 (4th Cir. 1999). In other words, the doctrine simply sets the standard of care "where an underlying common law cause of action [already] exists." Elder, 341 F. Supp. 2d at 1100. Here, Plaintiffs seek to re-cast their negligence claims as claims for negligence *per se*, relying on the CGMPs/QSR to provide the requisite standard of care. (See Mem. in Opp'n at 29-30.) But all of Plaintiffs' negligence claims are preempted, as discussed above. Accordingly, the negligence *per se* claims cannot stand, because there exists no claim onto which the standard of care from the CGMPs/QSR can be grafted.[19]

E. Breach of warranty

Plaintiffs allege that Medtronic breached implied warranties by selling the Sprint Fidelis leads in a defective condition. (Compl. ¶¶ 145-46.) They further allege that Medtronic expressly warranted that the leads were safe and effective and that Medtronic breached this express warranty because the leads were unsafe. (Id. ¶¶ 149-52.) The Court concludes that these claims, too, are preempted.

As for the implied-warranty claims, Plaintiffs ignore that the Riegel plaintiffs alleged a claim for breach of implied warranty and the Supreme Court affirmed the dismissal of that claim on preemption grounds. 128 S. Ct. at 1005-06. Such a claim would require a jury to determine that Medtronic impliedly warranted that the Sprint

[19] Plaintiffs also allege that Medtronic violated its "obligation not to violate the law" by selling "misbranded" and "adulterated" Sprint Fidelis leads. (Compl. ¶¶ 139-40.) Besides merely paralleling the design-defect and failure-to-warn claims, such claims are also impliedly preempted under 21 U.S.C. § 337(a) and Buckman.

Fidelis leads were safe and effective and that Medtronic breached that implied warranty – *i.e.*, a jury would have to find that the leads were unsafe in their design or manufacture. Such a determination clearly would interfere with the PMA process. See Riegel v. Medtronic, Inc., 451 F.3d at 121 ("We . . . conclude that the Riegels' claim[] for . . . breach of implied warranty . . . would, if successful, impose state requirements that differed from, or added to, the PMA-approved standards for the [device]."), aff'd, 128 S. Ct. 999 (2008); Richman v. W.L. Gore & Assocs., Inc. 988 F. Supp. 753, 758 (S.D.N.Y. 1997) ("[T]he plaintiff's claim for breach of implied warranty [would] impose safety and effectiveness requirements that are different from, or in addition to, those established under FDA regulations."); Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 51 (D. Mass. 1994), aff'd, 63 F.3d 25 (1st Cir. 1995) (same).

Plaintiffs cite 21 C.F.R. § 808.1(d)(1) to argue that their implied-warranty claims are not preempted. That regulation states that requirements of "general applicability" – such as "general electric codes, and the Uniform Commercial Code (*warranty of fitness*)" – are not preempted under Section 360k(a). Id. (emphasis added). But the Riegel plaintiffs made this same argument, and the Supreme Court rejected it, holding that the regulation "fail[ed] to alter [the Court's] interpretation" of Section 360k(a). This Court perceives no reason to deviate from that ruling here.[20]

[20] Plaintiffs note that Lohr and In re Guidant Corp. Implantable Defibrillators Products Liability Litigation, MDL No. 05-1708, 2007 WL 1725289, at *9 (D. Minn. June 12, 2007) (Frank, J.), held that implied-warranty claims were not preempted by the FDCA. The Court concludes that neither case controls in light of the more-recent decision in Riegel.

The Court also believes that the express-warranty claims are preempted for the same reason as the implied-warranty claims.[21] Such claims are based on an allegation that the leads were represented as safe – in both the product label and in "publications, . . . the internet, and other communications intended for physicians, medical patients, and the general public" – but were not. (See Compl. ¶¶ 149-50.) A jury finding in Plaintiffs' favor on such claims, therefore, would be required to conclude that the Sprint Fidelis leads were unsafe. As the safety and effectiveness of the leads are matters solely for the FDA, and because the FDA determined that the leads were safe and effective when granting PMA, these claims are preempted. See, e.g. Gomez v. St. Jude Med. Daig Div. Inc., 442 F.3d 919, 932 (5th Cir. 2006) (express-warranty claim preempted under FDCA); Enlow v. St. Jude Med., Inc., 210 F. Supp. 2d 853, 862 (W.D. Ky. 2001) (same); Lake, 2008 WL 5244823, at *1-2 (same). Simply put, claims such as these, which "require[] a manufacturer's [device] to be safer, but hence less effective, than the model the FDA has approved," necessarily "disrupt[] the federal scheme" and must be preempted. Riegel, 128 S. Ct. at 1008.

F. The remaining claims

While the parties apparently agree that all of Plaintiffs' claims fall into the five categories discussed above, that is not entirely clear to the Court. Claims such as loss of consortium (Count 16) and unjust enrichment (Count 20) do not appear to fit neatly into

[21] The Supreme Court did not opine on express-warranty claims in Riegel, because the plaintiffs did not challenge the dismissal of those claims on appeal.

any of the aforementioned categories. Nevertheless, the Court agrees with Medtronic that any claims in the Complaint not addressed above are derivative of Plaintiffs' other claims and hence cannot stand. See, e.g., Riegel, 128 S. Ct. at 1006 (affirming dismissal of loss-of-consortium claim on preemption grounds because "it was derivative of the pre-empted claims"); Talbott, 865 F. Supp. at 52 (claims for negligent infliction of emotional distress, violation of Massachusetts consumer-protection statute, and fraudulent misrepresentation preempted); see also Pa. Employees Benefit Trust Fund v. Zeneca Inc., 499 F.3d 239, 251-52 & n.12 (3rd Cir. 2007) (FDCA preempted derivative claims under state consumer-protection statute and for unjust enrichment predicated on allegedly misleading advertising of prescription drug).

The analysis above also requires the dismissal of the claims in the Master Consolidated Complaint for Third-Party Payors. The claims in that Complaint parallel those in the Master Consolidated Complaint for Individuals and seek to recover sums paid by insurance companies (and others) on behalf of individuals who had Sprint Fidelis leads implanted. In the absence of any viable claim by the individual Plaintiffs, these claims also fail.

G. The Court will dismiss the Complaints with prejudice

Having concluded that all of Plaintiffs' claims are preempted, the Court must next determine whether to dismiss those claims with or without prejudice. For several reasons, the Court concludes that dismissal with prejudice is appropriate**.**

First, this is not Plaintiffs' only bite at the pleading apple. The Complaint is, in essence, an Amended Complaint filed in each and every one of the cases in this multidistrict litigation. (See supra at 12-13.)

Second, Plaintiffs nowhere requested leave to amend the Complaint in the event the Court were to determine that their claims are preempted. The Court need not grant leave to replead *sua sponte* when Plaintiffs never requested such relief, not even in the alternative. See Confederate Mem'l Ass'n, Inc. v. Hines, 995 F.2d 295, 299 (D.C. Cir. 1993); Gunderson v. ADM Investor Servs., Inc., Nos. C96-3148, C96-3151, 1997 WL 570453, at *11 (N.D. Iowa Apr. 17, 1997) (rejecting "the notion that a party putting forward inadequate pleading must automatically be given leave to amend when the court finds that the opposing party's Rule 12(b)(6) motion should be granted").

Third, the Complaint was filed after extensive preparation by Plaintiffs' steering committee, which is made up of more than a dozen experienced products-liability lawyers well versed in Riegel, Buckman, and the nuances of federal preemption, and only *after* the preemption issue was raised by Medtronic and by the Court. See In re Career Educ. Corp. Sec. Litig., No. 03 C 8884, 2007 U.S. Dist. LEXIS 23635, at *36 (N.D. Ill. Mar. 29, 2007) (dismissal with prejudice appropriate where there have been "ample opportunities to research and plead" sufficient claims). Indeed, the Complaint is suffused with immense detail regarding the Sprint Fidelis leads and sprawls across 59 pages and 252 paragraphs. In the Court's estimation, if Plaintiffs were aware of sufficient facts in order to avoid preemption, they would have already pleaded them.

Fourth, and finally, the Court does not believe that repleading, even with leave to take limited discovery, would remedy the defects in the Complaint. The theory of Plaintiffs' case is that Medtronic did not adequately manufacture the Sprint Fidelis leads, not because it failed to comply with the specifications in the leads' PMA, but rather because the manufacturing methods Medtronic opted to used rendered all of the leads defective. In other words, Plaintiffs' claims are predicated on a defect in the method of manufacture approved by the FDA when it granted the leads PMA. For the reasons set forth above, such claims are by their very nature preempted under Section 360k(a).[22]

CONCLUSION

As in Pacelli, the Court recognizes that at least some Plaintiffs have suffered injuries from using Sprint Fidelis leads, and the Court is not unsympathetic to their plight. But Plaintiffs assert claims for which the Court simply cannot provide a remedy. Congress has decided to limit medical-device manufacturers' liability in order to spur innovation, even though individuals are sometimes injured when using medical devices. Plaintiffs' remedy, therefore, lies with Congress, and not with this Court (or any other court).

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[22] Nor does the Court believe it would be appropriate for Plaintiffs to simply change the theory of their case now by alleging, for example, that Medtronic did not comply with the specifications in the PMA when manufacturing the leads. Cf. Humphreys v. Roche Biomedical Labs., Inc., 990 F.2d 1078, 1082 (8th Cir. 1993) (noting that the right to amend a complaint under Federal Rule of Civil Procedure 15(a) terminates when the complaint is dismissed; "a district court does not abuse its discretion in refusing to allow amendment of pleading to change the theory of a case if the amendment is offered after summary judgment has been granted against the party, and no valid reason is shown for the failure to present the new theory at an earlier time").

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS ORDERED** that Medtronic's Motion to Dismiss the Master Consolidated Complaint for Individuals (Doc. No. 151) and Medtronic's Motion to Dismiss the Master Consolidated Complaint for Third-Party Payors (Doc. No. 149) are **GRANTED**. The Master Consolidated Complaint for Individuals (Doc. No. 129) and the Master Consolidated Complaint for Third-Party Payors (Doc. No. 130) are **DISMISSED WITH PREJUDICE**.

Dated: January 5, 2009

s/Richard H. Kyle
RICHARD H. KYLE
United States District Judge