UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

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

Multidistrict Litigation
No. 08-1905 (RHK/JSM)

This document relates to:
ALL CASES

ORDER

This matter is before the Court on Plaintiffs' Motion for Leave to File an Amended Master Consolidated Complaint for Individuals (Doc. No. 248). For the reasons set forth below, the Court will deny the Motion.

The background of this case is set forth in detail in the Court's January 5, 2009 Order dismissing Plaintiffs' Master Consolidated Complaint for Individuals (the "MCC") and will not be repeated here. See In re Medtronic, Inc. Sprint Fidelis Prods. Liab. Litig., 592 F. Supp. 2d 1147 (D. Minn. 2009). In short, the Court previously concluded that all of the claims alleged in the MCC were preempted under 21 U.S.C. § 360k(a), and it dismissed those claims with prejudice. With the Court's approval, however, Plaintiffs later filed the instant Motion, seeking leave to file an Amended MCC; Plaintiffs also submitted a proposed Amended MCC to the Court, which they subsequently revised. Medtronic opposes Plaintiffs' Motion to Amend, arguing the proposed amendments are futile and that many are untimely.

Amendment generally is governed by Federal Rule of Civil Procedure 15. Under that Rule, courts "should freely give leave [to amend] when justice so requires." Fed. R.

Civ. P. 15(a)(2). But "different considerations apply to motions [to amend] filed after dismissal," United States *ex rel.* Roop v. Hypoguard USA, Inc., 559 F.3d 818, 823 (8th Cir. 2009) (quoting Briehl v. Gen. Motors Corp., 172 F.3d 623, 629 (8th Cir. 1999)), because "[a]fter a complaint is dismissed, the right to amend under Fed. R. Civ. P. 15(a) terminates." Parnes v. Gateway 2000, Inc., 122 F.3d 539, 550 (8th Cir. 1997) (citation omitted). Courts have "considerable discretion" to deny such "disfavored" motions. Drobnak v. Andersen Corp., 561 F.3d 778, 788 (8th Cir. 2009) (quoting Roop, 559 F.3d at 824).

Plaintiffs argue they should be permitted to amend, and that the Court erred in dismissing the MCC with prejudice, because "dismissal with prejudice is a drastic sanction." (Pl. Mem. at 3 (quoting Omaha Indian Tribe v. Tract I-Blackbird Bend Area, 933 F.2d 1462, 1468 (8th Cir. 1991)).) But as the quoted language suggests, Omaha Indian Tribe addressed dismissal as a *sanction* for failing to comply with court orders, not (as here) dismissal for failure to state a claim under Rule 12. There is simply no support for Plaintiffs' assertion that dismissals under Rule 12 "should be" without prejudice. See Pet Quarters, Inc. v. Depository Trust & Clearing Corp., 559 F.3d 772, 782 (8th Cir. 2009) (no abuse of discretion in dismissing complaint with prejudice and without opportunity to amend); 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 pleadings must automatically be given leave to amend when the court finds that the opposing party's Rule 12(b)(6) motion should be granted").

Indeed, plaintiffs do not enjoy an absolute or automatic right to amend. E.g., United States *ex rel.* Lee v. Fairview Health Sys., 413 F.3d 748, 749 (8th Cir. 2005); Meehan v. United Consumers Club Franchising Corp., 312 F.3d 909, 913 (8th Cir. 2002). That is particularly true where, as here, a plaintiff does not request leave to amend before an adverse ruling. See Drobnak, 561 F.3d at 787 ("A district court does not abuse its discretion in failing to invite an amended complaint when plaintiff has not moved to amend and submitted a proposed amended pleading.") (quoting Meehan, 312 F.3d at 913).

In addition, the basis for Plaintiffs' Motion is a host of allegedly "newly discovered" facts they claim add substance to their allegations. But many of those so-called "new" facts were available to Plaintiffs before the MCC was filed on July 2, 2008. (See, e.g., Proposed Revised Amended MCC ¶¶ 49, 134.) Plaintiffs have failed to explain why those facts were omitted from the MCC. See, e.g., United States *ex rel.* Joshi v. St. Luke's Hosp., Inc., 441 F.3d 552, 557 (8th Cir. 2006) (appropriate to deny amendment for undue delay). Moreover, Plaintiffs seek to assert several new claims, but "a post-judgment motion for leave to assert an entirely new claim is untimely." Roop, 559 F.3d at 825. A litigant cannot simply lie in wait with plans to amend his or her complaint and change the theory of the case should it be dismissed. See Briehl, 172 F.3d at 629.

In any event, even if not untimely the Court would deny Plaintiffs' Motion because the proposed amendments would be futile. "Futility is a valid basis for denying leave to amend." Roop, 559 F.3d at 822. In the Court's view, all of the claims in the Proposed

Revised Amended MCC (including the newly asserted ones) are preempted for the reasons stated in the January 5, 2009 Order. While suffused with some greater detail than the MCC, the Proposed Revised Amended MCC largely reiterates and rehashes the allegations previously made. For instance, Plaintiffs continue to adhere to the view that "[b]ecause the Sprint Fidelis leads have been recalled, the FDA approval no longer exists" (Proposed Revised Amended MCC ¶ 1), a proposition the Court has squarely rejected. See In re Medtronic Sprint Fidelis, 592 F. Supp. 2d at 1155. Similarly, Plaintiffs repeat their assertion that Medtronic was negligent in failing to change the Sprint Fidelis Leads' product label after adverse events were reported. (See Proposed Revised Amended MCC ¶¶ 68, 228.) Yet, federal law merely *permits*, but does not *require*, such product-label changes. As the Court previously held, "[w]here a federal requirement permits a course of conduct and the [claim alleged would] make[] it obligatory, the [claim] is preempted." In re Medtronic Sprint Fidelis, 592 F. Supp. 2d at 1160 (citation omitted).

Simply put, the Court believes that the flaws endemic to the MCC are equally endemic to the Proposed Revised Amended MCC because the very premise underlying Plaintiffs' claims is faulty. As the Court noted when it dismissed the MCC:

> 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 use 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. . . . [S]uch claims are by their very nature preempted under Section 360k(a).

Id. at 1166.

Plaintiffs, however, argue that the Court's preemption ruling misapplied 21 U.S.C. § 360k(a) (the express preemption provision for medical devices in the Federal Food, Drug, and Cosmetic Act) and Riegel v. Medtronic, Inc., __ U.S. __, 128 S. Ct. 999 (2008). They cite a recent decision from the United States District Court for the Southern District of Indiana, Hofts v. Howmedica Osteonics Corp., No. 1:08-CV-855, 2009 WL 331470, at *3 (S.D. Ind. Feb. 11, 2009), in which the medical-device defendant's motion to dismiss on preemption grounds was denied. Of course, Hofts is not binding on this Court, and the undersigned respectfully disagrees with that decision. See also Horowitz v. Stryker Corp., __ F.R.D. __, 2009 WL 436406, at *9 n.5 & *10 n.6 (E.D.N.Y. Feb. 20, 2009) (favorably citing this Court's preemption decision and concluding that Hofts wrongly applied Riegel and Bell Atlantic Corp. v. Twombly, 550 U.S. 544 (2007)). Since the preemption decision in January, several other courts have confirmed Riegel's teaching that Section 360k(a) broadly preempts tort and other claims concerning FDA-approved medical devices. See, e.g., Heisner v. Genzyme Corp., No. 08-C-593, 2009 WL 1210633, at *3 (N.D. Ill. Apr. 30, 2009); Dorsey v. Allergan, Inc., No. 3:08-0731, 2009 WL 703290, at *5-7 (M.D. Tenn. Mar. 11, 2009); Horowitz, 2009 WL 436406, at *8-12; Blunt v. Medtronic, Inc., 760 N.W.2d 396, 403-09 (Wis. 2009). The Court remains of the view that Plaintiffs' claims are preempted, notwithstanding Hofts. See In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig., 455 F. Supp. 2d 709, 716 (N.D. Ohio 2006) (case law "reveal[s] that § 360k(a) preempts almost every type of state law claim that

seeks to hold a defendant liable for a PMA- approved medical device").[1]

For all of these reasons, the Court concludes that Plaintiffs' proposed amendments would not survive a motion to dismiss on preemption grounds and, hence, are futile. See, e.g., Cornelia I. Crowell GST Trust v. Possis Med., Inc., 519 F.3d 778, 782 (8th Cir. 2008) ("[W]hen the court denies leave on the basis of futility, it means the district court has reached the legal conclusion that the amended complaint could not withstand a motion to dismiss."). Accordingly, the Court will deny Plaintiffs' Motion for Leave to Amend.

The foregoing begs the question: What now? Previously, the Court had suggested it might certify its preemption decision to the Eighth Circuit for review under 28 U.S.C. § 1292(b). Upon reflection, the Court concludes that certification would be improper for several reasons. First, certification is rarely appropriate. See Caraballo-Seda v. Municipality of Hormigueros, 395 F.3d 7, 9 (1st Cir. 2005). Moreover, as Medtronic has previously noted, there are at least 229 cases pending in this MDL that have simply adopted the MCC without any additional claims. (See Doc. No. 237 & Ex. B.) Because the MCC has been dismissed and the Court has denied Plaintiffs leave to amend, each of those 229 cases is subject to outright dismissal. And, were the Court to dismiss those

[1] In a letter seeking reconsideration of the January 5, 2009 Order, Plaintiffs suggest that the preemption landscape has changed due to the Supreme Court's recent decision in Wyeth v. Levine, __ U.S. __, 129 S. Ct. 1187 (2009). But Wyeth addressed implied preemption of claims concerning prescription drugs, which are treated differently than medical devices. See id. at 1200 ("[D]espite its 1976 enactment of an express pre-emption provision for medical devices, Congress has not enacted such a provision for prescription drugs.") (citations omitted). In the Court's view, Wyeth does not alter the preemption analysis.

cases, the preemption decision could be brought to the Eighth Circuit via appeal. If this Court were to certify the preemption decision, however, there is no guarantee that the appellate court would accept it for review. See 28 U.S.C. § 1292(b) (court of appeals "may . . . in its discretion" accept certified question); Caraballo-Seda, 395 F.3d at 9 (review of interlocutory order certified to appellate court is discretionary). Therefore, the Court determines that the appropriate action at this juncture is to dismiss the 229 cases that have adopted the MCC for the operative Complaint. Because the Court believes that at least some of the plaintiffs in those cases will appeal, and because the Eighth Circuit's decision in those cases will impact the remaining cases in this MDL, it is the Court's view that the remaining cases comprising this MDL should be stayed in the interim.

Based on the foregoing, and all the files, records, and proceedings herein, **IT IS ORDERED** as follows:

1. Plaintiffs' Motion for Leave to File an Amended Master Consolidated Complaint for Individuals (Doc. No. 248) is **DENIED**;

2. Plaintiffs' March 6, 2009 letter request to file a Motion for Reconsideration of the Court's January 5, 2009 Order is **DENIED**;

3. The Complaints in each of the 229 cases listed in the attachment hereto are **DISMISSED WITH PREJUDICE** and **JUDGMENT SHALL BE ENTERED ACCORDINGLY** in each of those cases; and

4. The remaining cases comprising this MDL, including any cases subsequently transferred here by the Judicial Panel on Multidistrict Litigation, are

STAYED pending further Order of the Court. The parties shall promptly notify the Court (1) when one or more plaintiffs in the 229 dismissed cases have filed a notice of appeal to the Eighth Circuit or (2) the time for doing so has expired without any plaintiff having appealed.

Dated: May 12, 2009

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