

No. 09-2290

**IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT**

IN RE MEDTRONIC, INC. SPRINT FIDELIS LEADS PRODUCTS LIABILITY LITIGATION

ANNA BRYANT, et al.,

Plaintiffs–Appellants

v.

MEDTRONIC, INC., et al.,

Defendants–Appellees

On Appeal From The United States District Court
For The District Of Minnesota, MDL No. 08-1905 (RHK/JSM)

BRIEF FOR THE APPELLEES

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RESPONSIVE SUMMARY OF THE CASE

Pursuant to Local Rule 28A(f)(1), appellees offer the following clarifications of appellants' summary of the case.

First, the district court held that *all* of plaintiffs' claims were expressly preempted under *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), and that none was parallel (*i.e.*, genuinely equivalent) to violations of existing federal requirements. The court *also* held that plaintiffs' manufacturing-defect claims were inadequately pleaded under *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and that their allegations that Medtronic violated FDA regulations and reporting requirements were barred by 21 U.S.C. § 337(a) and impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Second, plaintiffs sought discovery and leave to amend the complaint only *after* the district court granted Medtronic's motion to dismiss. The court denied discovery because plaintiffs had previously disclaimed the need for discovery and had failed to state any viable claims, rendering their belated request an improper fishing expedition. The court denied leave to file plaintiffs' proposed amended complaint as both untimely (because it sought to add information that could have been previously pleaded) and futile (because all claims remained preempted).

Because the appeal poses no unanswered questions of law and involves instead only appellants' disagreement with controlling law, Medtronic believes that 60 minutes for argument—30 minutes per side—would be sufficient.

CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1 and Local Rule 26.1A, defendants–appellees hereby state that:

1. Defendant-appellee Medtronic, Inc. is a publicly held company and has no corporate parent. No other publicly held company owns 10% or more of its stock.

2. Defendant-appellee Medtronic Puerto Rico, Inc. merged into Medtronic International Technology, Inc., a Minnesota corporation, on January 24, 2006. Medtronic Puerto Rico, Inc. no longer exists. Medtronic International Technology, Inc. is owned 9.67% by Medtronic Vascular, Inc. and 90.33% by Medtronic, Inc. Medtronic Vascular, Inc. is owned 100% by Medtronic, Inc.

3. Defendant-appellee Medtronic Puerto Rico Operations Co., a Cayman Island company, is owned 100% by Medtronic Holding Switzerland GmbH, a Swiss company. Medtronic Holding Switzerland GmbH is owned 100% by Medtronic B.V., a Netherlands company. Medtronic B.V. is owned 100% by Medtronic International Technology, Inc., a Minnesota corporation. Medtronic International Technology, Inc. is owned 9.67% by Medtronic Vascular, Inc. and 90.33% by Medtronic, Inc. Medtronic Vascular, Inc. is owned 100% by Medtronic, Inc.

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ISSUES PRESENTED

1. Whether all of plaintiffs' claims are expressly preempted by federal law because they would impose requirements on a Class III medical device with Premarket Approval (PMA) that differ from or add to existing federal requirements.

Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008)

21 U.S.C. § 360k(a)

2. Whether a Class I recall under 21 U.S.C. § 360h(e) invalidates the Food and Drug Administration's (FDA) PMA for a device even though an entirely separate statutory and regulatory procedure under 21 U.S.C. § 360e(e) governs withdrawal of PMA.

Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008)

21 U.S.C. § 360e(e)

21 U.S.C. § 360h(e)

3. Whether plaintiffs have failed to plead manufacturing-defect, failure-to-warn, negligence, and express-warranty claims that fall into the narrow exception to express preemption for state-law claims that are "parallel" to violations of existing federal requirements because, *inter alia*, they have not identified any existing federal requirement for the device at issue that is genuinely equivalent to any of those state-law claims.

Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008)

Bates v. Dow Agrosiences LLC, 544 U.S. 431 (2005)

21 U.S.C. § 360k(a)

4. Whether, in addition to being expressly preempted under 21 U.S.C. § 360k(a), plaintiffs' allegations that Medtronic failed to comply with FDA procedural and reporting requirements are barred by 21 U.S.C. § 337(a) and impliedly preempted because they impermissibly seek to enforce obligations created by (and owed to) the FDA.

Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341 (2001)

21 U.S.C. § 337(a)

5. Whether, in addition to being expressly preempted, plaintiffs' claims were inadequately pleaded because they contained only conclusory assertions and formulaic recitations of various regulatory requirements.

Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007)

Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009)

6. Whether, having failed to challenge the district court's ruling that the proposed amended complaint was untimely, plaintiffs have forfeited any challenge to the denial of their motion to file an amended complaint after the original complaint had been dismissed; and whether, in any event, that denial was within the district court's discretion because plaintiffs sought to add previously available information and new claims that could have been included in the original complaint without any valid excuse for their delay.

Minneapolis Taxi Owners Coal., Inc. v. City of Minneapolis, 572 F.3d 502 (8th Cir. 2009)

United States ex rel. Roop v. Hypoguard USA, Inc., 559 F.3d 818 (8th Cir. 2009)

Drobnak v. Andersen Corp., 561 F.3d 778 (8th Cir. 2009)

Briehl v. Gen. Motors Corp., 172 F.3d 623 (8th Cir. 1999)

7. Whether the district court acted within its discretion by denying plaintiffs' request to conduct unspecified discovery to see if they could find a viable cause of action after the court already had dismissed their complaint.

Bell Atl. Corp. v. Twombly, 550 U.S. 544 (2007)

Ashcroft v. Iqbal, 129 S. Ct. 1937 (2009)

S. Cherry St., LLC v. Hennessee Group LLC, 573 F.3d 98 (2d Cir. 2009)

8. Whether Judge Kyle acted within his discretion by denying plaintiffs' motion to recuse, which was filed after dismissal of the complaint and was based principally on the fact that his son is a shareholder at a law firm that has represented the defendants in matters unrelated to the device at issue in this litigation.

Microsoft Corp. v. United States, 530 U.S. 1301 (2000) (statement of Rehnquist, C.J.)

In re Kan. Pub. Employees Ret. Sys., 85 F.3d 1353 (8th Cir. 1996)

In re Billedeaux, 972 F.2d 104 (5th Cir. 1992)

28 U.S.C. § 455(a)

28 U.S.C. § 455(b)(5)(iii)

STATEMENT OF THE CASE

In February 2008, the Judicial Panel on Multidistrict Litigation (JPML) consolidated all federal cases raising claims involving Medtronic's Sprint Fidelis defibrillator leads before the Honorable Richard Kyle of the District of Minnesota. Judge Kyle subsequently appointed a lead counsel and Plaintiffs' Steering Committee (PSC) that he noted was "made up of more than a dozen experienced products liability lawyers." AA35. On July 2, 2008, the PSC filed a 60-page Master Consolidated Complaint (MCC) "suffused with immense detail regarding the Sprint Fidelis leads." *Id.*

Medtronic moved to dismiss the MCC on the basis of federal preemption. After considering the MCC, the "voluminous submissions" by the parties (AA2), and the arguments presented during a nearly two-hour hearing, Judge Kyle dis-

missed the MCC with prejudice on January 5, 2009. He held that (i) each of plaintiffs' claims was expressly preempted by 21 U.S.C. § 360k; (ii) some also were barred by 21 U.S.C. § 337(a) and impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001); and (iii) some also were inadequately pleaded. AA1-37.

In a January 20 letter, plaintiffs sought permission to move for reconsideration of the January 5 order and requested leave to conduct certain (unspecified) discovery. Judge Kyle declined to entertain a motion for reconsideration, finding that plaintiffs were “merely seek[ing] to relitigate issues” that they had lost. AA38. He held that the request for discovery was an improper “fishing expedition” and that plaintiffs had not explained “how further discovery [would] aid [their] cause.” AA40-44. He also found that plaintiffs' request was untimely because the “purported ‘need’ for discovery ... [had] appear[ed] nowhere in their Opposition to Medtronic's Motion to Dismiss” (AA43) and “Plaintiffs' lead counsel [had] made clear from the outset of this case that no discovery was necessary in order to resolve the preemption issue” (AA42). Indeed, the Court had entered a stay of discovery on June 5, 2008 (Dkt. 115), and plaintiffs never sought to lift that stay prior to the Court's dismissal of their claims. Accordingly, Judge Kyle denied plaintiffs' requests on February 5. AA38-46. In the same order, however, Judge Kyle authorized plaintiffs to seek leave to file an amended complaint based on plaintiffs' rep-

resentations that they recently had learned new facts that would place their claims beyond the scope of the court's preemption ruling. AA39-40.

Plaintiffs moved for leave to file an Amended Master Consolidated Complaint (AMCC) on February 27. Judge Kyle thereafter granted plaintiffs' request to substitute a proposed Revised Amended Master Consolidated Complaint (RAMCC) for the proposed AMCC. Following another round of briefing, Judge Kyle held that the motion to amend was untimely because "many of th[e] so called 'new' facts [in the RAMCC] were available to plaintiffs before the MCC was filed." AA73. Judge Kyle also held that the proposed amendments were futile because "the flaws endemic to the MCC are equally endemic to the Proposed [RAMCC]." AA72-74. Accordingly, on May 12, 2009, Judge Kyle denied plaintiffs' motion for leave to amend. AA71-78.

After Judge Kyle dismissed the original MCC, plaintiffs filed a motion asking Judge Kyle to recuse himself based principally on his son's status as a shareholder in a firm that has represented Medtronic in matters unrelated to this litigation. Judge Kyle denied that motion on March 9, 2009 (AA68) and denied the plaintiffs' request for leave to file a motion for reconsideration on April 1, 2009 (AA69-70).

When Judge Kyle denied plaintiffs’ motion for leave to amend, he also entered judgment against those plaintiffs who had adopted the MCC as the operative complaint. AA77. This Court consolidated the resulting appeals.

STATEMENT OF FACTS

A. Statutory And Regulatory Background

Until 1976, the FDA generally lacked authority to regulate medical devices. That year, Congress enacted the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.* The MDA extended the FDA’s regulatory authority to medical devices. PUB. L. No. 94-295, 90 Stat. 539 (1976).

In enacting the MDA, Congress sought to ensure that safe and effective medical devices would be readily available to treat patients in need of lifesaving care. To that end, Congress crafted a regulatory framework striking a careful balance between regulation and innovation. Hence, the MDA “provide[s] for the safety and effectiveness of medical device[s]” (90 Stat. 539), while simultaneously “encourag[ing] the[] research and development” of “sophisticated, critically important” devices. S. REP. No. 94-33, at 2 (1975); *see also* H.R. REP. No. 94-853, at 12 (1976) (MDA “reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research”); *Riegel v. Medtronic, Inc.*,

128 S. Ct. 999, 1003 (2008) (MDA created comprehensive “regime of detailed federal oversight”).

An important purpose of the new federal regime was to ensure that innovations in medical device technology would not be “stifled by unnecessary restrictions” (H.R. REP. NO. 94-853, at 12), and to avoid the “undu[e] burden[]” imposed by differing state regulation. *Id.* at 45. Accordingly, Congress incorporated an express-preemption clause—a “general prohibition on non-Federal regulation” (*id.*)—specifying that no state may impose “any requirement” relating to the safety or effectiveness of a medical device or any other matter regulated by the MDA that “is different from, or in addition to, any requirement applicable ... to the device” under federal law. 21 U.S.C. § 360k(a); *see generally* AA4-5.

In *Riegel*, the Supreme Court confirmed that, by enacting 21 U.S.C. § 360k(a), Congress expressly preempted any state-law claim that challenges the design, manufacturing process, or labeling of a premarket-approved medical device. 128 S. Ct. at 1009. Such claims necessarily would involve a jury second-guessing the FDA’s determination that the device was safe and effective and could be marketed as approved. *Id.*

1. The rigorous Premarket Approval process for Class III devices

The MDA establishes three classes of medical devices. 21 U.S.C. § 360c. For Class I devices (for example, tongue depressors), generally applicable design,

manufacturing, and labeling standards established by the MDA “are sufficient to provide reasonable assurance of ... safety and effectiveness.” *Id.* § 360c(a)(1)(A)(i). For Class II devices (for example, hearing aids), the “general controls” applicable to all devices are insufficient to provide a reasonable assurance of safety and effectiveness. *Id.* § 360c(a)(1)(B). Accordingly, although such devices may be marketed without advance FDA approval, they must comply with additional federal performance regulations known as “special controls.” *Id.* Class III devices are those devices that either “present[] a potential unreasonable risk of illness or injury” or that are “represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,” and for which neither general nor special controls would provide a reasonable assurance of safety and effectiveness. *Id.* § 360c(a)(1)(C).

Medtronic’s Fidelis leads are Class III medical devices. *See* JA24 (MCC¶21). As such, they “incur the FDA’s strictest regulation” (*Buckman*, 531 U.S. at 344), and must receive FDA approval before they may be sold. To obtain FDA approval via the PMA process, a manufacturer “must submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance

standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information.” *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 109 (2d Cir. 2006) (citing 21 U.S.C. § 360e(c)), *aff’d*, 128 S. Ct. 999 (2008).

The FDA closely and rigorously scrutinizes PMA applications, ““weigh[ing] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.”” *Riegel*, 128 S. Ct. at 1004 (quoting 21 U.S.C. § 360c(a)(2)(C)). If the Agency is not satisfied with the information provided, it may demand more. *See id.* (citing 21 U.S.C. § 360e(c)(1)(G)). The FDA also may refer the application to a panel of outside experts. *See id.* (citing 21 C.F.R. § 814.44(a)).

As part of the PMA process, the FDA must review the device’s proposed labeling to “evaluate[] safety and effectiveness under the conditions of use set forth on the label, ... and must determine that the proposed labeling is neither false nor misleading.” *Id.* (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). If the FDA decides that the device’s design, manufacturing methods, or labeling should be revised, it may require such revisions prior to approval. *See id.* at 1005 (citing 21 C.F.R. § 814.44(e)).

“The FDA spends an average of 1,200 hours reviewing each application” and “grants premarket approval only if it finds there is a ‘reasonable assurance’ of

the device’s ‘safety and effectiveness.’” *Id.* (quoting 21 U.S.C. § 360e(d)). The Supreme Court has observed that obtaining “[p]remarket approval is a ‘rigorous’ process.” *Riegel*, 128 S. Ct. at 1004 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996)).

The FDA’s regulatory role does not end with approval of the initial PMA application. “Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.” *Id.* (citing 21 U.S.C. § 360e(d)(6)(A)(i)). If a manufacturer wishes to make such changes, it must submit a supplementary application for Premarket Approval (PMA-Supplement) and may implement the proposed changes only after FDA approval. *See Riegel*, 451 F.3d at 110 (citing 21 C.F.R. § 814.39(a)). A PMA-Supplement is subject to exactly the same standard of review as an initial PMA application. *See Riegel*, 128 S. Ct. at 1005 (citing 21 C.F.R. § 814.39(c)); *see also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000). *See generally* AA3-4. Medtronic’s Fidelis leads received the FDA’s Premarket Approval after being subjected to this rigorous and exacting process. *See* page 12, *infra*.

2. Ongoing post-approval reporting for approved devices

The MDA also imposes post-approval reporting obligations on the manufacturer of an approved device. FDA regulations require a manufacturer “to inform

the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, ... and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred.” *Riegel*, 128 S. Ct. at 1005 (citing 21 C.F.R. §§ 803.50(a), 814.84(b)(2)). *See generally* AA4.

3. Enforcement of FDA requirements for approved devices

Congress has specified that all actions to enforce the FDCA “shall be by and in the name of the United States.” 21 U.S.C. § 337(a). Accordingly, the FDA has exclusive authority to enforce the requirements imposed on devices via the PMA process. *See, e.g., Buckman*, 531 U.S. at 352 (“Congress intended that the MDA be enforced exclusively by the Federal Government”); Brief for United States as *Amicus Curiae*, *Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2007) (No. 06-1498), 2007 WL 4218889, at *4 (Nov. 28, 2007) (“The United States has *exclusive* authority to enforce the [FDCA’s] provisions.”) (emphasis added). Although “citizens may report wrongdoing and petition the agency to take action” (*Buckman*, 531 U.S. at 349 (citing 21 C.F.R. § 10.30)), the FDCA does not provide a private right of action (*id.* at 349 n.4). Consistent with the Agency’s exclusive power to enforce the FDCA, the FDA has the authority “to investigate violations of the Act, and to pursue a wide range of sanctions for any fraud it uncovers” (Brief for United

States, *Warner-Lambert*, 2007 WL 4218889, at *3 (citation omitted)), including “injunctive relief, 21 U.S.C. 332, civil money penalties, 21 U.S.C. 333(f)(1)(A), seizure of the device, 21 U.S.C. 334(a)(2)(D), and criminal prosecution, 21 U.S.C. 333(a), 18 U.S.C. 1001 (1994 & Supp. IV 1998).” Brief for United States as *Amicus Curiae*, *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001) (No. 98-1768), 2000 WL 1364441, at *22 (Sept. 13, 2000).

B. The Fidelis Leads

The Fidelis leads are defibrillator leads designed and manufactured by Medtronic. Implantable defibrillators treat abnormal heart rhythms by shocking the heart back into normal rhythm with an electric pulse delivered through an insulated wire called a “lead.” AA9. The FDA approved the Fidelis leads through PMA-Supplements to Medtronic’s original PMA for the Transvene Lead System. AA9-10. Over time Medtronic’s leads “have grown progressively smaller” because, as Judge Kyle noted, “a smaller lead takes up less space in a coronary vein, and therefore restricts less blood flow to the heart.” AA10 & n.7. As plaintiffs admit, the FDA granted Premarket Approval to four Fidelis leads—Models 6930, 6931, 6948, and 6949—on June 8, 2004, following a six-month-long evaluation of Medtronic’s PMA-Supplement applications. JA24 (MCC¶21); *see also* AA10.

On October 15, 2007, Medtronic announced a voluntary withdrawal of the Fidelis leads. AA12. The FDA classified that action as a Class I recall, pursuant to

21 C.F.R. § 7.41. As the FDA explained, “[a] recall is an action taken when a medical device is defective, when it could be a risk to health, or when it is both defective and a risk to health.” FDA, *Medtronic Recalls Sprint Fidelis Cardiac Leads: Questions and Answers for Consumers* (last updated July 10, 2009).¹ The Agency observed that withdrawal was appropriate here because the leads were “slightly more prone to fracture” than a predecessor lead, but noted that they “continue to function properly in the vast proportion of patients.” FDA, *Statement on Medtronic’s Voluntary Market Suspension of Their Sprint Fidelis Defibrillator Leads* (Oct. 15, 2007).

In their brief, plaintiffs try to paint a picture of a manufacturer recklessly rushing a device to market and concealing information from the FDA. Medtronic strongly disagrees with that account, but recognizes—as did Judge Kyle (*see* AA13-14)—that plaintiffs’ factual allegations, as opposed to bare conclusions, must be taken as true for purposes of a motion to dismiss. That said, neither the MCC nor the RAMCC identifies any FDA finding that even theoretically could provide a plausible basis for plaintiffs’ allegations about fraud and concealment.²

¹ This and all other FDA documents discussed in this brief are available on the FDA’s web site; http addresses are included in the Table of Authorities, *supra*.

² For example, plaintiffs do not even identify so much as an FDA “Warning Letter” related to the leads. The FDA’s publicly available records confirm that there are no such Warning Letters (though even Warning Letters would not necessarily be sufficient to state a claim). *See* <http://www.fda.gov/ICECI/>

More importantly, as Judge Kyle found (AA17-34, 73-76), even with the benefit of the liberal standard on a motion to dismiss, none of the vague and conclusory allegations in the MCC brings any of plaintiffs’ state-law claims into the narrow class of claims that can avoid preemption following *Riegel*. The allegations in the RAMCC—which are not properly before this Court in any event—do not remedy that fatal defect.³ *See* Parts III, IV, *infra*.

SUMMARY OF THE ARGUMENT

The device at issue in this litigation—an FDA-approved Class III medical device—by definition “support[s] or sustain[s] human life” or “presents a potential unreasonable risk of illness or injury.” 21 U.S.C. § 360c(a)(1)(C)(ii). As the Supreme Court made clear in *Riegel*, the decision to market such a device requires a “cost-benefit analysis”—a balancing of the potential public benefits of the device with its potential to cause harm. 128 S. Ct. at 1008. *Riegel* further observed that juries are ill-equipped to perform this cost-benefit analysis because, *inter alia*, they

EnforcementActions/WarningLetters/default.htm. *See* notes 14 & 15, *infra*.

³ Plaintiffs treat the RAMCC as “the operative complaint” for purposes of this appeal. Plaintiffs’ Brief (PB) 7 n.1. But Judge Kyle denied their request to file the RAMCC because, *inter alia*, it was untimely. By failing to challenge this finding in their brief, plaintiffs have forfeited any challenge to this aspect of Judge Kyle’s denial of their motion to amend, which, in any event, was not an abuse of the district court’s discretion. *See* Part III, *infra*. Accordingly, the RAMCC is not the operative complaint and plaintiffs’ statement of facts—which cites almost exclusively to the rejected RAMCC and makes no effort to distinguish between the versions of the complaint—does not accurately portray the record before this Court or the issues on appeal.

“see[] only the cost of a more dangerous design” and are “not concerned with its benefits; the patients who reaped those benefits are not represented in court.” *Id.*

Because Congress found that it is in the public interest to encourage the development of these life-saving devices even though they may pose a risk of injury to some people, it placed exclusive responsibility for conducting that “cost-benefit analysis” in the hands of an expert federal agency, the FDA. Furthermore, to ensure that manufacturers would not be subjected to inconsistent or additional standards and to create a climate that encourages innovation and development of these devices, Congress explicitly prohibited any state-law claim that would impose a standard that is “different from or in addition to” the standards imposed by the FDA. *Id.* at 1006-09.

In the two years since *Riegel* was decided, courts across the country have consistently enforced this explicit statutory prohibition and dismissed claims—just like those here—that “would impose requirements that are ‘different from, or in addition to’ those imposed by the PMA (or other federal law).” AA17 n.11 (quoting 21 U.S.C. § 360k(a)). As Judge Kyle found (*id.*), the dispositive issue in this case is whether plaintiffs’ claims fall into the “narrow window left open by *Riegel* for ‘parallel’ claims” that do not differ from or add to existing federal requirements (AA14). Remarkably, plaintiffs make only a perfunctory argument on this issue and almost completely ignore the growing body of case law rejecting their conten-

tions. *See* PB40-48. In any event, plaintiffs' cursory attempts to show that a few of their claims escape preemption as "parallel" claims fail because plaintiffs have either misrepresented the relevant federal requirements or elided the significant differences between those requirements and the requirements they seek to impose under state law. *See* Part IV, *infra*.

The remainder (and great bulk) of plaintiffs' brief is devoted to scattershot arguments attempting to avoid the dispositive force of *Riegel*. In what amounts to a series of distractions from the controlling legal principles, plaintiffs argue that (1) preemption does not apply to a recalled device; (2) they should have been allowed to file an amended pleading; (3) the district court's interpretation of *Buckman* is overbroad; (4) the district court's alternative holding that the manufacturing-defect claims were inadequately pleaded was error; (5) they should have been permitted to take discovery; and (6) Judge Kyle should have recused himself. These assertions lack any basis in law and should be rejected.

First, courts have consistently rejected the argument that the MDA's express-preemption clause does not apply to a device that has been recalled, and plaintiffs have not identified a single case accepting it. Given the clear statutory and regulatory distinction between an FDA recall classification on the one hand and a withdrawal of PMA on the other, the uniform rejection of plaintiffs' argument is not surprising. In any event, because plaintiffs do not dispute that their de-

vices were marketed and sold prior to the recall and at a time when they were subject to valid PMAs, this argument is simply irrelevant. *See Part II, infra.*

Second, Judge Kyle did not err by denying plaintiffs' request to file an amended complaint after Medtronic's motion to dismiss their original complaint had been briefed, argued, and granted. As an initial matter, plaintiffs have forfeited this issue because they do not challenge Judge Kyle's ruling that the motion to amend was untimely. The holding of untimeliness was in any event far from an abuse of Judge Kyle's discretion because much of the information plaintiffs sought to add in the proposed RAMCC was available to them prior to their filing of the original MCC. *See Part III, infra.* And even if the allegations in the RAMCC were before this Court, Judge Kyle correctly held that none of the proposed amendments would have cured the fatal defects in the MCC. *See Part IV, infra.*

Third, Plaintiffs miss the mark when criticizing Judge Kyle's interpretation of *Buckman*. As Judge Kyle recognized, *Buckman* held that claims based on allegations that a manufacturer failed to comply with reporting or procedural requirements created by (and duties owed to) the FDA are impliedly preempted and barred by 21 U.S.C. § 337(a), which vests in the federal government the exclusive authority to enforce the FDCA and its implementing regulations. Other courts consistently have agreed with that interpretation. Indeed, plaintiffs' own description of *Buckman*—as barring state-law claims for which the federal requirements are a

“critical element”—essentially confirms that Judge Kyle’s holding was correct. FDA-created procedural or reporting regulations indisputably are a “critical element” of those claims that Judge Kyle found to be impliedly preempted. *See* Part V, *infra*.

Fourth, plaintiffs’ effort to circumvent the pleading standards established by *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and now *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), is even more of an attempt at distraction. *See* PB49-54. As an initial matter, this argument is relevant only to plaintiffs’ manufacturing-defect claims. Judge Kyle held those claims to be inadequately pleaded only in the alternative, however, *after* holding that they were expressly preempted. Thus, the Court need not even reach this issue. But even if the Court were to address the adequacy of plaintiffs’ pleadings, the examples that plaintiffs offer to show that they have met federal pleading requirements are precisely the type of formulaic recitations and naked assertions that the Supreme Court has held to be insufficient to plead a viable claim. *See* Part VI, *infra*.

Fifth, Judge Kyle did not abuse his discretion by denying plaintiffs’ belated request to conduct discovery after holding that plaintiffs had failed to plead any viable claims. The law does not allow plaintiffs to conduct fishing expeditions in an effort to find a cause of action. As *Twombly* and *Iqbal* make clear, plaintiffs must present a well-pleaded, viable cause of action *before* they can impose the signifi-

cant burden of discovery on a defendant. Moreover, contrary to plaintiffs' insinuation that relaxed pleading and discovery standards should apply to claims involving medical devices, the very concerns that led Congress to protect manufacturers of complex life-saving devices from the impact of different or additional state requirements counsel against a rule that would give every device recipient license to impose significant litigation costs on manufacturers before pleading a viable claim. *See Part VII, infra.*

Finally, Judge Kyle did not abuse his discretion by denying plaintiffs' motion for recusal, filed after Judge Kyle had granted Medtronic's motion to dismiss. Plaintiffs principally argue that recusal is required because Judge Kyle's son, Richard H. Kyle, Jr. (Kyle Jr.), is a shareholder at Fredrikson & Byron, P.A. (Fredrikson), a law firm that has represented Medtronic in various matters. But Fredrikson has never represented Medtronic in litigation involving Fidelis leads, and Kyle Jr. has never represented Medtronic in any matter. Courts have uniformly rejected recusal based on a family member's partnership at a law firm that represented a party in unrelated matters. Judge Kyle did not abuse his discretion by applying that settled law to deny recusal here. *See Part VIII.A, infra.*

Nor did Judge Kyle abuse his discretion by denying recusal based on his brief responses to three press inquiries about plaintiffs' announcement that they intended to move for recusal. Judge Kyle merely informed the media that, based on

the facts initially alleged by plaintiffs, he did not think he had a conflict. Judge Kyle's comments did not suggest that he would be unable to consider the arguments made in plaintiffs' ensuing motion with anything but an open mind. *See* Part VIII.B, *infra*.

STANDARDS OF REVIEW

This Court reviews the decision to grant a motion to dismiss *de novo* and will affirm if dismissal was appropriate on any ground. *Firstcom, Inc. v. Qwest Corp.*, 555 F.3d 669, 674, 681 (8th Cir. 2009).

Generally, the Court reviews the denial of leave to file an amended complaint for abuse of discretion, but “the narrow issue of futility [is reviewed] *de novo*.” *In re Acceptance Ins. Co. Sec. Litig.*, 423 F. 3d 899, 904 (8th Cir. 2005).

The decision whether to allow discovery is reviewed “utilizing an abuse of discretion standard.” *Johnson v. United States*, 534 F.3d 958, 964 (8th Cir. 2008).

Finally, the Court reviews a judge's refusal to recuse himself for abuse of discretion. *Am. Prairie Constr. Co. v. Hoich*, 560 F.3d 780, 789 (8th Cir. 2009).

ARGUMENT

I. The MDA's Express-Preemption Clause Preempts State-Law Causes Of Action Such As Those Pleaded By Plaintiffs.

The MDA's preemption clause, 21 U.S.C. § 360k(a), establishes a two-step procedure for determining if state-law claims are preempted. First, a court must determine whether “the Federal Government has established requirements applicable

to” the particular medical device. *Riegel*, 128 S. Ct. at 1006; *see also* AA7. If it has, the court then must determine whether the plaintiffs’ state-law claims would impose “requirements with respect to the device that are ‘different from, or in addition to’” the federal requirements (*Riegel*, 128 S. Ct. at 1006), and that relate to either (i) “safety or effectiveness” or (ii) “any other matter included in a requirement applicable to the device under [the MDA].” 21 U.S.C. § 360k(a)(2). If both these conditions are satisfied, then the claim is preempted.

1. Claims involving a device that has received PMA automatically satisfy the first condition of the test for preemption. *See Riegel*, 128 S. Ct. at 1007 (“[p]remarket approval ... imposes [federal] ‘requirements’” as that term is used in § 360k(a)); *see also* AA7.⁴

Plaintiffs criticize the approval process for Fidelis leads and insinuate that the FDA did not conduct a “rigorous” review of the leads. *See* PB9-12. These allegations are legally irrelevant (in addition to being factually baseless). Under *Riegel*, the MDA’s express-preemption clause applies to every device that has received approval through the PMA process. Courts may not second-guess the FDA’s approval of a device by conducting their own evaluation of whether the re-

⁴ Because the device in *Riegel* was approved through the PMA-Supplement process, the Court’s holding applies equally to specifications imposed by an original or a supplemental approval (as in this case). *Riegel*, 128 S. Ct. at 1005; *see also, e.g., Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Wolicki-Gables v. Arrow Int’l, Inc.*, 2009 WL 2190069, at *9 (M.D. Fla. July 22, 2009).

view process was sufficiently rigorous to justify preemption. *See, e.g., Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009) (“nothing in *Riegel* even hints that whether a state-law claim is expressly preempted by § 360k(a) turns on the nature or extent of the information made available to the FDA at the time it approved a device”). The only material question for purposes of preemption is whether the FDA approved the device through the PMA process. There is no dispute on that issue here.⁵

2. *Riegel* also held that state common-law and statutory duties imposed through litigation are requirements “with respect to devices” as that term is used in Section 360k(a). 128 S. Ct. at 1009-10 (internal quotation marks omitted); *see also* AA7. The Court specifically rejected the proposition that, to be preempted, a common-law duty “must apply *only* to the relevant device,” or even “only to medical devices and not to all products and all actions in general.” *Riegel*, 128 S. Ct. at 1010.

Thus, *Riegel* stands unequivocally for the proposition that the MDA expressly preempts state-law causes of action that seek to impose a requirement on a device with PMA that is “different from, or in addition to” the requirements imposed by federal law. *Id.* at 1009 (quoting 21 U.S.C. § 360k(a)).

⁵ Moreover, to the extent that plaintiffs are suggesting that Medtronic obtained PMA for the leads by misleading the FDA, that claim is barred by 21 U.S.C. § 337(a) and *Buckman*. *See* Part V, *infra*.

Recognizing that *Riegel* and § 360k(a) are fatal to their claims, plaintiffs repeatedly misstate this clear test, suggesting instead that claims are preempted under the MDA only if they “conflict” with federal requirements. *See, e.g.*, PB35-36, 38-39, 45-48. But *Riegel* made clear that the MDA’s express-preemption clause preempts any state-law requirement that would “*add to or differ from* federal requirements.” AA9 (emphasis in original); *see also Riegel*, 128 S. Ct. at 1009-10. In other words, a “conflict” is not required because a state-law requirement may be *consistent* with existing federal requirements and yet be preempted because it would differ from—or even just add to—those requirements.⁶

As Judge Kyle observed, since *Riegel*, “courts across the country have applied Section 360k(a) broadly, preempting all manner of claims from strict products liability and negligence, to breach of warranty, to failure to warn and manufacturing- and design-defect, to negligence per se.” AA8 (citations omitted); *see*

⁶ To support this erroneous standard, plaintiffs cite *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996)—a case that did not involve a medical device approved through the PMA process—and *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001)—a pre-*Riegel* case applying *Lohr*. *See* PB35. But *Riegel* makes clear that the standard discussed in those cases does not apply to devices with PMA. Similarly unavailing is plaintiffs’ invocation of 21 C.F.R. § 808.1 to support the contention that claims of “general applicability” are not preempted by the MDA. PB35 n.7. The Supreme Court considered that regulation in *Riegel* and concluded that it “can add nothing to our analysis but confusion.” 128 S. Ct. at 1010-11.

also AA75 (citing later cases).⁷ As shown below, all of plaintiffs' claims are similarly preempted by Section 360k(a). See Part IV, *infra*.

Before turning to that issue, however, we address two of plaintiffs' collateral attacks: the argument that an FDA recall classification negates preemption (which logically precedes a claim-by-claim analysis), and the assertion that Judge Kyle should have allowed plaintiffs to file their proposed amended complaint (which affects what claims are before this Court).

⁷ Cases postdating Judge Kyle's two opinions include, *e.g.*, *Williams v. Cyberonics, Inc.*, 2009 WL 2914414 (E.D. Pa. Sept. 10, 2009) (MDA preempted claims for manufacturing defect and implied warranty); *Covert v. Stryker Corp.*, 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009) (MDA preempted claims for failure-to-warn, defective design, defective manufacture, negligence, express warranty, and implied warranty); *Wolicki-Gables*, 2009 WL 2190069 (MDA preempted claims for design defect, negligence, and failure-to-warn); *Bencomo v. Guidant Corp.*, 2009 WL 1951821 (E.D. La. June 30, 2009) (MDA preempted express-warranty claim); *Riley*, 625 F. Supp. 2d at 769 (MDA preempted claims for failure-to-warn, manufacturing defect, implied warranty, express warranty, misrepresentation, and fraud); *Miller v. DePuy Spine, Inc.*, 2009 WL 1767555 (D. Nev. May 1, 2009) (MDA preempted claims for strict products liability, negligence, implied warranty, and express warranty); *Adkins v. Cytoc Corp.*, 2008 WL 2680474 (W.D. Va. July 3, 2008) (MDA preempted claims for implied warranty, express warranty, negligent design, and failure-to-warn); *Colombini v. Westchester County Health Care Corp.*, 2009 WL 2170230 (N.Y. Sup. Ct. July 6, 2009) (MDA preempted claims for negligent design, negligent manufacture, negligent failure-to-warn, breach of warranty, and strict products liability); *Mullin v. Guidant Corp.*, 970 A.2d 733, 735 (Conn. App. Ct. 2009) (MDA preempted claims "relating to the [device's] safety, design, manufacture and distribution, including breach of implied and expressed warranties, failure to evaluate the safety of the [device], and subjecting [the plaintiff] to unreasonable danger"); *Lake v. Kardjian*, 874 N.Y.S.2d 751 (N.Y. Sup. Ct. 2008) (MDA preempted claims for failure-to-warn, negligence, implied warranty, and express warranty).

II. The Recall Classification Is Irrelevant.

Plaintiffs attempt to avoid preemption entirely by contending that, because the FDA designated Medtronic's voluntary action a recall, "there are no federal requirements [for the leads]." PB36. But, like Judge Kyle (AA14-16), every court to consider this argument has held that recall neither invalidates PMA nor negates the federal requirements applicable to a device with PMA. *See, e.g., Moore v. Sulzer Orthopedics, Inc.*, 337 F. Supp. 2d 1002 (N.D. Ohio 2004); *Steele v. Depuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439 (D.N.J. 2003); *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1023 (E.D. Mich. 1993); *Mitaro v. Medtronic, Inc.*, 2009 WL 1272398, at *5 (N.Y. Sup. Ct. Apr. 9, 2009); *Blanco v. Baxter Healthcare Corp.*, 70 Cal. Rptr. 3d 566, 579-80 (Cal. Ct. App. 2008); *Bausch v. Stryker Corp.*, 2008 WL 5157940, at *1, *3 (N.D. Ill. Dec. 9, 2008); *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127 (Tex. App. 2005), *cert. denied*, 128 S. Ct. 1441 (2008); *cf. Colombini v. Westchester County Health Care Corp.*, 2009 WL 2170230, at *3-*4 (N.Y. Sup. Ct. July 6, 2009) (preemption applies despite reclassification of device to Class II because it "did go through the premarket approval process" and reclassification "does not negate the approval, or the preemption").

A. Recall does not invalidate Premarket Approval.

The fact that courts have unanimously rejected plaintiffs' argument is unsurprising because the regulatory structure draws a clear distinction between recall

and the withdrawal of PMA. Recalls of Class III medical devices are governed either by 21 C.F.R. §§ 7.40-7.59 (for voluntary manufacturer actions that the FDA classifies as recalls, such as here), or by 21 U.S.C. § 360h(e) and 21 C.F.R. §§ 810.10-810.18 (for mandatory recalls). Nothing in these regulations even remotely suggests that a recall results in the withdrawal of a device's PMA.

To the contrary, an entirely separate statutory and regulatory process governs withdrawal of PMA. *See* 21 U.S.C. § 360e(e); 21 C.F.R. § 814.46. Indeed, the standards for withdrawal of PMA are distinct from those governing recalls. *Compare* 21 U.S.C. § 360e(e)(1) *with* 21 C.F.R. §§ 7.40(a), 7.41(a), 7.46(a). And the revocation of PMA requires explicit FDA action pursuant to a specific statutory and regulatory procedure. *See, e.g.,* 21 C.F.R. § 814.46(c) (manufacturer has the right to a hearing “[b]efore [the agency issues] an order withdrawing approval of a PMA”); 21 C.F.R. §§ 16.62, 16.80, 16.95(b)(2) (any decision to revoke PMA must result in “a written decision stating the reasons for the ... administrative action and the basis in the record”); 21 U.S.C. §§ 360e(e)(2), 360e(g)(1)(A) (orders revoking PMA are subject to internal FDA review); 21 C.F.R. §§ 16.120, 10.45 (a final FDA order revoking PMA is subject to judicial review pursuant to the APA).

Here, although the FDA characterized Medtronic's voluntary action as a recall, the agency has not withdrawn—or even initiated proceedings to withdraw—PMA of the Fidelis leads. Plaintiffs do not allege otherwise. Accordingly, even

though the leads no longer are being marketed, the PMAs remain valid and 21 U.S.C. § 360k(a) still preempts any state-law claim that would impose additional or different requirements. *See* AA14-17; *cf. Talbott v. C.R. Bard, Inc.*, 63 F.3d 25, 28 (1st Cir. 1995) (holding that preemption applies as long as the FDA has not revoked PMA, even if the FDA has determined that the manufacturer submitted fraudulent data during the PMA process).⁸

Plaintiffs attempt to avoid this controlling law by asserting that there are no federal requirements for an “adulterated” device. PB37. But, as Judge Kyle held, “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.’” AA29 n.18 (quoting *Gile v. Optical Radiation Corp.*, 22 F.3d 540, 544 (3d Cir. 1994)). Yet plaintiffs have not identified or even alleged an FDA finding that the Fidelis leads were adulterated (because there is none). In any event, plaintiffs fail to cite any au-

⁸ The stock language that plaintiffs quote from a form letter sent to Medtronic regarding the Fidelis recall (*see* PB37) did not constitute an official FDA determination that the Fidelis leads violated federal requirements in general, much less any specific requirement that could support a state common-law claim for plaintiffs here. In fact, the FDA’s public statements on the Fidelis recall contain not even a suggestion that the agency found a violation of FDA regulations, let alone a violation of any particular regulation. *See* pages 12-13, *supra*. Accordingly, neither the recall classification itself nor the letter that plaintiffs cite supports plaintiffs’ attempt to identify an alleged violation of a federal requirement that is parallel to one of their state-law claims. *See* Part IV, *infra*.

thority to support their naked assertion that there are no requirements for an adulterated device.

Plaintiffs are equally mistaken when they contend that PMA is automatically revoked whenever a manufacturer allegedly violates one of the standard “conditions of approval” for devices with PMA. PB38. Again, revocation of PMA requires explicit FDA action, and there are specific statutory and regulatory procedures that must be followed before an order revoking PMA can issue. *See* page 26, *supra*. Plaintiffs have not alleged that the FDA invoked those procedures here, and they identify no support for their assertion that the “conditions of approval” that are included with PMAs effectively undo the statutory and regulatory regime by which the FDA is bound. In any event, allegations that Medtronic improperly maintained approval for the leads by violating the reporting obligations described in the “conditions of approval” are precisely the type of claims that the Supreme Court found to be impliedly preempted in *Buckman*. *See* Part V, *infra*.

B. Plaintiffs’ claims would be preempted even if recall did invalidate Premarket Approval.

Plaintiffs’ contention that recall invalidates the PMA for a device not only is wrong as a matter of law; it also is irrelevant. As Judge Kyle found, “Plaintiffs’ argument ignores that PMA for the Sprint Fidelis leads was in place *at the time the leads were implanted,*” which “is what matters.” AA16; *see also Kemp*, 835 F. Supp. at 1023 (preemption applied despite recall because, “when the [device] was

implanted ..., [it] had received pre-market approval”); *Blanco*, 70 Cal. Rptr. 3d at 580-81. In other words, because plaintiffs contend that the leads they received should have been designed, manufactured, or labeled differently, their claims necessarily relate to events that took place before the recall and while the leads indisputably were subject to federal requirements under the PMAs. Accordingly, plaintiffs’ claims seek to impose requirements that add to or differ from the federal requirements that existed *at the relevant time*, regardless of any (counterfactual) later change in PMA status.

Plaintiffs dispute Judge Kyle’s conclusion by again conflating the general constitutional doctrine of conflict preemption with the statutory express preemption at issue here (*see* page 23, *supra*) and baldly asserting that “the operative time for consideration of preemption issues” is “when this litigation began.” PB38-39. That argument is inconsistent with the language of § 360k(a), which makes no such distinction, and contrary to the uniform case law identified in the trial court and above (at 25). There is no logical reason why preemption of plaintiffs’ claims would be related to, much less determined by, the dates that they happened to commence litigation rather than the dates the devices were sold and implanted, which typically is the time at which a plaintiffs’ claims are evaluated. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) (“A product is defective when, *at the time of sale or distribution*, it contains a manufacturing de-

fect, is defective in design, or is defective because of inadequate instructions or warnings.”) (emphasis added).

III. Allegations In The Proposed RAMCC Are Not Before This Court.

After Judge Kyle dismissed the MCC, plaintiffs filed a motion for leave to amend the complaint, accompanied by a proposed AMCC (which later was replaced with the RAMCC). *See* page 5, *supra*. Judge Kyle denied that motion because the proposed amendments in the RAMCC were *both* untimely *and* futile. AA71-78. This Court reviews Judge Kyle’s conclusion that the proposed amendments were futile *de novo*. *See* page 20, *supra*. Accordingly, Medtronic addresses that rationale below, in the context of plaintiffs’ contention that they have pleaded “parallel claims” in the RAMCC that avoid preemption. *See* Part IV, *infra*. But the Court need not consider that rationale because plaintiffs have failed to preserve a challenge to the first basis for denying their motion to amend—untimeliness. Furthermore, even if plaintiffs had preserved the issue, Judge Kyle acted within his “considerable discretion” (*Drobnak v. Andersen Corp.*, 561 F.3d 778, 788 (8th Cir. 2009) (quoting *United States ex rel. Roop v. Hypoguard USA, Inc.*, 559 F.3d 818, 824 (8th Cir. 2009))), in finding that the motion to amend was untimely.

A. Plaintiffs have forfeited any challenge to the denial of their motion to amend as untimely.

In deciding plaintiffs’ motion for leave to amend, Judge Kyle considered the proposed RAMCC, a redline comparing it with the MCC, and a full round of brief-

ing. *See* AA71; JA285. Based on that detailed review, he concluded that the motion was “untimely” because “many of [the] so-called ‘new’ facts [in the RAMCC] were available to plaintiffs before the MCC was filed,” and plaintiffs “failed to explain why those facts were omitted from the MCC.” AA73. Plaintiffs try to minimize this basis for Judge Kyle’s ruling, claiming that he merely “implied” that the motion was untimely. PB60. To the contrary, he relied on several cases for the proposition that a motion to amend is appropriately denied when untimely and reached that conclusion as to the RAMCC. AA73. He then went on to hold that “*even if not untimely* the Court would deny plaintiffs’ Motion because the proposed amendments would be futile.” *Id.* (emphasis added). In other words, the first basis for denying the motion was its untimeliness; futility was an alternative basis on which the court “would” have relied had the motion been timely.

In a footnote, plaintiffs state that they “disagree” with Judge Kyle, asserting that “[d]espite the district court’s statement to the contrary, [the “new”] information was *not* available to plaintiffs prior to the deadline to file the MCC.” PB60 n.15. That cursory statement is insufficient to preserve a challenge to Judge Kyle’s denial of plaintiffs’ motion to amend.⁹ *See, e.g., Minneapolis Taxi Owners Coal., Inc. v. City of Minneapolis*, 572 F.3d 502, 506 n.2 (8th Cir. 2009) (“inclusion of a

⁹ To the extent that plaintiffs attempt to incorporate the arguments from their district court briefs (*see* PB60 n.15), they have violated Local Rule 28A(g).

footnote hinting at [an argument] ... is inadequate to preserve the claim” because an appellants’ brief must “contain ... appellant’s contentions and the reasons for them, with citations to the authorities and parts of the record on which the appellant relies”) (quoting Fed. R. App. P. 28(a)(9)(A)); *Koehler v. Brody*, 483 F.3d 590, 599 (8th Cir. 2007) (finding forfeiture because appellant “failed to argue the point in his opening brief in anything more than a conclusory manner”). Accordingly, plaintiffs have forfeited any challenge to this basis for the denial of their motion to amend the complaint, leaving the MCC as the only complaint before this Court.

B. The district court did not abuse its “considerable discretion” by denying plaintiffs’ motion to amend as untimely.

This Court has stated in “numerous cases” that “[a]lthough leave to amend a complaint should be granted liberally when the motion is made pretrial, different considerations apply to motions filed after dismissal.” *Roop*, 559 F.3d at 823 (internal quotation marks omitted). Indeed, district courts have “considerable discretion” to deny such “disfavored” motions. *Drobnak*, 561 F.3d at 788 (quoting *Roop*, 559 F.3d at 824).

Judge Kyle acted well within his “considerable discretion” in denying plaintiffs’ motion as untimely. “A district court does not abuse its discretion in denying a plaintiff leave to amend the pleadings to change the theory of their case after the complaint has been dismissed under Rule 12(b)(6).” *Briehl v. Gen. Motors Corp.*,

172 F.3d 623, 629 (8th Cir. 1999). It also is appropriate to deny leave to amend when the court finds undue delay. *United States ex rel. Joshi v. St. Luke's Hosp. Inc.*, 441 F.3d 552, 557 (8th Cir. 2006). This is particularly true where “no valid reason is shown for the failure to present the new theory at an earlier time.” *Humphreys v. Roche Biomedical Labs., Inc.*, 990 F.2d 1078, 1082 (8th Cir. 1993) (internal quotation marks omitted); *see also Freeman v. Busch*, 349 F.3d 582, 589 (8th Cir. 2003) (affirming denial of leave to amend even before dismissal of original complaint because plaintiff provided “no good cause” why proposed amendment “could not have earlier been alleged”) (internal quotation marks omitted); *Bausch v. Stryker Corp.*, 2009 WL 2827954, at *1-*3 (N.D. Ill. Aug. 31, 2009) (denying motion for leave to amend following dismissal under *Riegel* as untimely: “To allow plaintiffs to have ‘repeated bites,’ ... after the parties have expended resources, would result in an endless cycle of litigation and would be a travesty of justice.”).

Here, plaintiffs did not indicate a desire to amend the MCC until the status hearing on their request to file a motion for reconsideration of Judge Kyle’s order dismissing the MCC. At that hearing, plaintiffs “indicated that they intend[ed] to seek leave to file a Motion to Amend the [MCC]” because they “recently became aware of additional facts that, if added to the Complaint, would render plaintiffs’ claims beyond the reach of the Court’s preemption ruling.” AA39 (citing JA211-

17). Judge Kyle allowed plaintiffs to file a motion for leave to amend based on that representation. But the proposed RAMCC that plaintiffs submitted attempted to incorporate publicly available information that could have been included in the MCC and to recast allegations already contained in the MCC as new claims. Judge Kyle did not abuse his discretion by rejecting this untimely attempt to amend the complaint.¹⁰

Plaintiffs' assertion that the "new" information in the RAMCC "was *not* available ... prior to the deadline to file the MCC" (PB60 n.15) is demonstrably untrue. For example, plaintiffs sought to add a list of alleged regulatory issues at Medtronic's Villalba manufacturing facility (none of which involved the Fidelis leads and all of which date back long prior to the MCC). They compiled that list of events from the FDA's public website, which has always been available to them . JA300-01 (RAMCC¶49). Plaintiffs plainly could have searched that website before filing the MCC, and they have offered no excuse for failing to do so.

Similarly, plaintiffs cited the FDA's publicly available MAUDE database in seeking to add information allegedly showing that some adverse-event reports re-

¹⁰ It is worth remembering that the MCC was itself an amended complaint. It consolidated the complaints that were originally filed by the individual plaintiffs whose cases were transferred to Judge Kyle by the JPML and became the amended complaint for those cases unless specifically disclaimed. *See* Dkt. 115. Moreover, the MCC 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." AA35.

garding the Fidelis leads were untimely. JA324 (RAMCC¶¶134-35). Again, plaintiffs offer no excuse for their failure to discover and incorporate these public records from periods prior to when they filed the MCC. Plaintiffs also sought to reproduce the text of Medtronic's express limited warranty for the Fidelis leads. JA348-49 (RAMCC¶249). But this was included with all Fidelis leads, and thus plaintiffs obviously had access to it when they filed the MCC.

Equally unavailing is plaintiffs' attempt to recast the legal theories and allegations contained in the MCC. For example, plaintiffs sought to expand and rewrite the sections of the MCC alleging that Medtronic violated various provisions of the FDA's Good Manufacturing Practices/Quality System Regulation (GMP/QSR), 21 C.F.R. §§ 820 *et seq.* But they did so by relying on a laundry list of regulations that were available to them (in the Code of Federal Regulations and on the FDA's web site) at the time they filed the MCC. JA315-19 (RAMCC¶¶106-13). Similarly, while the MCC asserted claims for failure to warn, negligence, and negligence per se, the RAMCC added separate causes of action purporting to attack "post-approval" and "post-recall" conduct under those theories of liability. *See* JA329-34, 340-43, 345-47. Plaintiffs provided no justification for including these "new" theories, which were simply an attempt to reargue the issues that Judge Kyle had decided against plaintiffs when dismissing the MCC.

In sum, plaintiffs did not offer Judge Kyle (and have not offered this Court) any legitimate excuse for failing to include these factual allegations and legal theories in the MCC. Accordingly, Judge Kyle did not abuse his “considerable discretion” by denying as untimely plaintiffs’ motion to file an amended complaint after the MCC had been dismissed.¹¹

IV. Plaintiffs’ Claims Do Not Fall Into The Narrow Exception To Preemption For Parallel Claims.

Federal law and the PMA for Fidelis leads imposed (and continue to impose) federal requirements that control the design, manufacture, testing, marketing, labeling, and post-market surveillance of the devices. *See* Part I, *supra*. Accordingly, as Judge Kyle recognized, “[t]he only issue [in this case] 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).” AA17 n.11. Recognizing this, plaintiffs briefly suggest that several of their claims fall into the narrow exception to preemption for state-law causes of action that are parallel to alleged violations of federal regulations. *See Riegel*, 128 S. Ct. at 1011. Contrary to plaintiffs’ cursory arguments (PB42-48), however, Judge Kyle correctly found that plaintiffs’ vague assertions about violations of various federal requirements in the MCC and

¹¹ As Judge Kyle correctly found, *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), did not provide plaintiffs with any new basis to amend the complaint because it “addressed implied preemption of claims concerning prescription drugs, which are treated differently than medical devices.” AA76.

RAMCC were inadequate to show that any of plaintiffs' state-law causes of action properly pleaded a true "parallel claim."

In order to state a "parallel" claim, a plaintiff must identify with particularity both a pre-existing state cause of action and a federal requirement applicable to the device that each prohibit the same conduct. As the Supreme Court explained in *Bates v. Dow Agrosiences LLC*, 544 U.S. 431, 454 (2005), to survive preemption as a "parallel" claim, a requirement under state law must be "*genuinely equivalent*" to a requirement under federal law. *See also Lohr*, 518 U.S. at 496-97 (suggesting that state-law requirement must be "equal to, or substantially identical to" federal requirement to avoid preemption). In other words, the term "parallel claim" simply refers to state-law claims that do not meet the MDA's "different from, or in addition to" standard for preemption. True parallel claims are not expressly preempted because, as Judge Kyle explained, "they do not add to or differ from federal requirements." AA8-9.

Plaintiffs' discussion of parallel claims continues to conflate generic conflict preemption with the MDA's explicit statutory standard. *See* page 23, *supra*. But even plaintiffs eventually admit that, "[t]o escape preemption by § 360k(a), ... a state-law claim must be premised on the breach of a state-law duty that is *the same as* a duty imposed under [federal law]." PB39-40 (emphasis added) (quoting *Riley*, 625 F. Supp. 2d at 776).

Once a manufacturer establishes that the preemption doctrines in *Riegel* apply to a device because it was approved through the PMA process, it is the plaintiff's burden to identify an existing federal requirement applicable to the device that affirmatively imposes a duty on the manufacturer that is "the same as" the duty that would be imposed by the plaintiff's state-law claim. If a plaintiff fails to identify "any such specified requirement," then he "necessarily seek[s] to impose requirements that differ from" those imposed by federal law. AA20; *see also Riley*, 625 F. Supp. 2d at 776 ("To escape preemption by § 360k(a) ... a state-law claim must be premised on the breach of a state-law duty that is the same as a duty imposed under the FDCA (or one of its implementing regulations).").¹²

Moreover, "to proceed with [his] claim, [a] plaintiff must demonstrate that the particular federal violation [that he has alleged] led to the injuries [he] sustained." *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009); *see also Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301-02 (D. Colo. 2008); *Bausch*, 2008 WL 5157940, at *4.¹³ In other words, a plaintiff must *link* the breach

¹² With this standard in mind, it is plain that many claimed violations of federal requirements can never support a parallel claim because there simply is no state common law analog to the federal requirement. For example, no state common or statutory law imposes a duty to report information to the FDA. This type of requirement exists solely by virtue of the FDCA, and the FDA alone may enforce it. *See Buckman*, 531 U.S. at 352.

¹³ Of course, even if a plaintiff has shown that a state-law claim does not differ from or add to existing federal requirements, "that is not the end of the inquiry, for

of a federal requirement (that is the same as a state law duty) to his alleged and legally cognizable injuries.

Here, plaintiffs have failed to show that any of their claims are “parallel” to existing federal requirements applicable to the Fidelis leads. On the contrary, as Judge Kyle held, each of plaintiffs’ state-law claims would impose requirements on the leads that either differ from or add to the existing requirements under federal law.

A. Manufacturing defect

1. The MCC does not state a parallel claim.

The only purported manufacturing defect that plaintiffs alleged with any particularity in the MCC is Medtronic’s use of spot-welding instead of a “crimped coupler.” *See* JA26-27 (MCC ¶¶31-35). But plaintiffs never identified an existing federal requirement that prohibited the use of spot-welding (because there is none), and do not even attempt to do so here.

Instead, plaintiffs contend that their manufacturing-defect claims escape preemption because they are parallel to an alleged failure to comply with the FDA’s GMP/QSR. *See, e.g.*, PB43. As Judge Kyle explained, this allegation cannot state a “parallel claim” because the duties that plaintiffs seek to impose on Medtronic un-

even if a claim is not expressly preempted by § 360k(a), it may be impliedly preempted under [*Buckman*].” *Riley*, 625 F. Supp. 2d at 776. *See generally* Part V, *infra*.

der state law are not the same as the duties that are imposed by the GMP/QSR. AA18-20.

As an initial matter, the MCC did not allege an FDA finding that Medtronic violated the GMP/QSR with respect to the manufacture of Fidelis leads, even though the Agency “monitors device problem data and inspects the operations and records of device developers and manufacturers to determine compliance with the GMP requirements.” FDA, *Medical Device Quality Systems Manual: A Small Entity Compliance Guide*, at 1-1 (1st ed. 1996) (HHS Pub. FDA 97-4179) (FDA, *QS Manual*). This gap in the MCC is unsurprising because there has been no such finding.

Without a specific finding of a violation by the FDA, no state-law cause of action based on the GMP/QSR could even be evaluated as a potential “parallel claim” because the GMP/QSR “allow[] some leeway in the details of quality system elements” (*id.* at 1-2). As Judge Kyle found, the GMP/QSR “are simply too generic, standing alone, to serve as the basis for plaintiffs’ manufacturing-defect claims” because they “require manufacturers to develop *their own* quality-system controls” and “are inherently flexible.” AA18 (quoting FDA, *QS Manual*, at 1-2); *see also id.* (“In most cases, *it is left to the manufacturer to determine the best methods to obtain quality objectives.*”) (quoting FDA *QS Manual*, at 1-2). Even when the regulation “does specify the particular type of method to be used, ... [t]his does

not mean ... that manufacturers cannot vary from the method specified if the intent of the GMP requirement can be met by another method.” FDA, *QS Manual*, at 1-2.¹⁴

Thus, a jury verdict on the question whether Medtronic complied with the GMP/QSR could not “parallel” an existing federal requirement in any meaningful sense. *See* AA18. For example, “Plaintiffs allege that Medtronic’s welding techniques were ‘defective,’ but they have not pleaded how that welding technique violated the CGMPs or QSR ... 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).” AA20. Accordingly, Judge Kyle concluded, “holding Medtronic liable for such a welding ‘defect’ would impose requirements ‘different

¹⁴ *See generally* FDA, *Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation*, 61 Fed. Reg. 52,602, 52,603 (Oct. 7, 1996) (“[T]he 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 FDA has made changes to the [prior draft of the regulation] ... to provide manufacturers with even greater flexibility in achieving the quality requirements.”).

Thus, post-*Riegel* cases suggest that, in order to state a true parallel claim related to these regulations, a plaintiff must have concrete evidence that a manufacturer has violated federal requirements *as they are interpreted by the FDA*. *Compare Purcel v. Advanced Bionics Corp.*, 2008 WL 3874713, at *1 (N.D. Tex. Aug. 13, 2008) (allowing a parallel claim based on FDA Warning Letters and *litigation against the manufacturer*) with *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090, 1095 (D. Minn. 2008) (“Because plaintiff’s claims are not based on a breach of the MDA *as enforced by the FDA*, the claims are not grounded in state laws that ‘parallel’ federal requirements.”) (emphasis added).

from, or in addition to' those under federal law." *Id.* Each of the other allegations that plaintiffs raise under the GMP/QSR is subject to the same fatal defect: The intentionally flexible federal regulations simply do not impose the same requirements that plaintiffs seek to impose under state law.

The fact that plaintiffs' GMP/QSR allegations do not state parallel claims is evident not only from the FDA's interpretation of the regulations but also from plaintiffs' own description of their claims, which consistently use the qualifier "adequate" when describing (in conclusory terms) the alleged failings in Medtronic's manufacturing process. *See generally* JA27-29 (MCC ¶¶37-39). For example, plaintiffs allege that "Medtronic failed to perform adequate electrical and mechanical testing." PB46. But they do not identify any federal regulation specifying what electrical and mechanical testing was required for manufacture of the Fidelis leads, and likewise do not allege what was the claimed "inadequacy" of Medtronic's actions. It follows that plaintiffs' version of the testing Medtronic should have done (*i.e.*, whatever plaintiffs think would have been "adequate" testing) necessarily would impose requirements on the manufacturing process for the leads that do not exist under the GMP/QSR. Because plaintiffs' claims seek to impose their own idiosyncratic interpretation of intentionally flexible federal standards, those

claims cannot be parallel to the existing federal requirements. In each instance they necessarily would impose *additional or different* requirements on the leads.¹⁵

2. The allegations in the proposed RAMCC would have been futile.

Although plaintiffs recount a long list of allegations from the RAMCC, they have not even attempted to show how the great majority of those allegations help to demonstrate that their manufacturing-defect claim (or any other claim) is identical to the violation of an existing federal requirement for the leads. *See* PB42-44. Given plaintiffs' failure—both below and on appeal—to explain why these “new”

¹⁵ The cases that plaintiffs cite (PB41-42) do not help their cause. In *Purcel*, the FDA had instituted legal action against the manufacturer for violations of the GMP/QSR and, under the particular circumstances of that case, that was found sufficient to state a claim that the manufacturer's conduct fell outside the range of options authorized by the flexible GMP/QSR standards. *See* 2008 WL 3874713, at *1. That unique situation has no relevance to plaintiffs' attempt to impose their own interpretation of the GMP/QSR on the Fidelis leads. *Miller* (cited at PB42), stands only for the unremarkable proposition that some manufacturing-defect claims “could conceivably escape preemption” if the plaintiff's particular device “was manufactured out of conformity with the materials or manufacturing specifications approved by the FDA in the PMA granted for the [device].” 2009 WL 1767555, at *3. Judge Kyle also recognized this possibility, but properly found it inapplicable here. *See* AA20-22. The final two opinions that plaintiffs cite, *Medtronic submits*, were wrongly decided, but in any event shed no light on the arguments made by plaintiffs concerning the GMP/QSR. The first case, *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009), has been rejected not only by Judge Kyle but also by two other federal courts as fundamentally inconsistent with *Riegel*. *See* AA75; *Covert*, 2009 WL 2424559, at *5, *12-*13; *Horowitz*, 613 F. Supp. 2d at 284-85. The second, *Mitaro*, 2009 WL 1272398, at *3, is a cursory New York state court opinion that did not consider whether the GMP/QSR are sufficiently definite and specific to form the basis of a parallel claim, but simply found the plaintiff's bare allegation of a deviation from federal requirements to be sufficient to state a parallel claim under New York law.

allegations should change the preemption analysis, it is ironic that they accuse Judge Kyle of making “no effort to determine whether the newly alleged facts [in the RAMCC] supported a parallel violation.” PB61. Regardless, that accusation is simply untrue. Judge Kyle considered plaintiffs’ proposed amendments and their briefing in support before correctly holding that the RAMCC might be “suffused with some greater detail than the MCC,” but still “largely reiterates and rehashes the allegations previously made” and thus “would not survive a motion to dismiss on preemption grounds.”¹⁶ AA74-76.

Plaintiffs also protest that Judge Kyle misconstrued their claims because he did not acknowledge their allegation “that Medtronic failed to comply with the FDA’s requirements.” PB61. On the contrary, Judge Kyle recognized that plaintiffs tried to *describe* their claims—both those in the MCC and those in the RAMCC—as based on a violation of federal requirements. *See, e.g.*, AA18. He correctly held, however, that the *actual* federal requirements to which plaintiffs referred would impose different or additional requirements on the leads than plaintiffs’ state-law claims. Plaintiffs have offered no reason to contest that result here. *See, e.g., Iqbal*, 129 S. Ct. at 1949-50 (when deciding a motion to dismiss, courts “are not bound

¹⁶ For the same reason, plaintiffs’ contention that Judge Kyle inappropriately refused to give them a chance to cure the defects in the MCC (PB62) is frivolous. Judge Kyle gave plaintiffs an additional opportunity and properly found the RAMCC would not cure those defects.

to accept as true a legal conclusion couched as a factual allegation”) (quoting *Twombly*, 550 U.S. at 555).

Even though plaintiffs have forfeited any challenge to the denial of their motion to amend (*see* Part III, *supra*), and have made no effort to show how the “new” allegations in the RAMCC would have rendered their claims parallel to existing federal requirements, a few clarifications are warranted.

First, contrary to plaintiffs’ representation (PB15, 25-27), the FDA’s Establishment Inspection Reports (EIR) following recall of the Fidelis leads did not find violations of the GMP/QSR. Although plaintiffs allege various questions, concerns, observations, and potential violations purportedly noted by the FDA inspector in those documents (JA312-15 (RAMCC ¶¶93-105)), they fail to acknowledge that EIRs and any accompanying FDA Form 483 reports, by their very terms, “do not represent a final Agency determination regarding [a device manufacturer’s] compliance.” FDA, *Inspection of Medical Device Manufacturers*, at Part III.A.2.a (June 15, 2006). For that reason alone, allegations about the EIRs cannot circumvent preemption by showing that plaintiffs’ manufacturing-defects claims are parallel to an actual violation of an existing federal requirement.

Moreover, the various areas of concern allegedly noted by the FDA’s inspector in the EIRs involve either sterilization procedures, which are irrelevant here because plaintiffs have not claimed that they received or were injured by non-

sterile leads, or Medtronic’s efforts to document certain aspects of its post-market surveillance of leads. For example, plaintiffs allege that Medtronic did not timely complete an “FPIR” report in connection with its Corrective and Preventive Action (CAPA) investigation regarding Fidelis leads. *See, e.g.*, JA306, 312-13 (RAMCC¶¶70, 94-96). Plaintiffs have never identified a federal regulation regarding “FPIRs,” but even assuming that purported failure violated a federal requirement applicable to the leads, it could not be parallel to one of plaintiffs’ state-law claims because it implicated only a documentation or reporting obligation owed *to the FDA*, not any required disclosure *to patients or physicians*. Accordingly, this alleged violation finds no parallel in any of the common-law duties invoked by plaintiffs, and it also cannot be (and is not even alleged as) the cause of plaintiffs’ alleged injuries (*see* pages 37-38 and note 12, *supra*). Furthermore, any claims based on Medtronic’s alleged failure to comply with these purported FDA reporting obligations are impliedly preempted under *Buckman* and barred as impermissible attempts to enforce FDA regulations contrary to Section 337(a).¹⁷ *See* Part V, *infra*.

¹⁷ The RAMCC also mentions (at ¶46) a purported comment to the FDA (from an anonymous source) during the inspections that the manufacturing process was a possible cause of lead fractures. *See* PB15. But that is irrelevant because there is no allegation that the comment was referring to a *deviation* from FDA-approved manufacturing requirements as opposed to indicating that the FDA-approved process *itself* was “a possible cause of lead fractures.”

In sum, the RAMCC’s “new” allegations—many of which have nothing to do with Fidelis leads—do not show that any of plaintiffs’ state-law manufacturing-defect claims are parallel to the violation of an existing federal requirement applicable to the Fidelis leads. Accordingly, they could not have cured the fatal defects in the MCC and were thus futile.¹⁸

¹⁸ Plaintiffs’ brief focuses on a March 2009 FDA document, “The Enforcement Story,” which contains a cursory overview of several FDA activities involving Medtronic—including the Fidelis recall. PB18-19. This document was published over a month before Judge Kyle ruled on plaintiffs’ motion to amend but plaintiffs never brought it to his attention. Regardless, the passage plaintiffs identify jumbles together a variety of FDA actions, most of which have nothing to do with the Fidelis leads. Indeed, although plaintiffs suggest otherwise, the references in the document to violations of the GMP/QSR and to Warning Letters concern not Fidelis leads but entirely unrelated Physio-Control external defibrillators manufactured by another Medtronic subsidiary, which are discussed at the end of the document. *See FDA, News Release: Manufacturer of Heart Defibrillator Signs Consent Decree of Permanent Injunction* (April 30, 2008) (FDA press release using exact language found in “Enforcement Story” publication to describe violations and Warning Letters for the Physio-Control defibrillators). Furthermore, an FDA inspection and Warning Letter discussed in the “Enforcement Story” dates from 2000, three years *before* Medtronic even proposed the Fidelis leads for approval.

That plaintiffs would seek to rely on this document now is surprising given the official FDA record. Of note, the “Purpose” section of the “Enforcement Story” reveals that it is not an official record of FDA actions, but simply an attempt to compile material “from various sources within the [FDA]” to give a “practical presentation of the actual FDA enforcement actions ... in a summary form to convey the significance” of those actions. The FDA also has noted that the document “may not contain all significant information on any cited account.” <http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM130094.pdf>. In any event, the Enforcement Story provides no support for plaintiffs’ claims.

B. Failure to warn

1. The MCC does not state a parallel claim.

Although *Riegel* did not involve a cause of action for failure to warn, the Supreme Court observed that “the MDA would pre-empt a jury determination that the FDA-approved labeling for a [device] violated a state common-law requirement for additional warnings.” 128 S. Ct. at 1011.¹⁹ Here, as Judge Kyle found, “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 leads’ product label—a label that was specifically approved by the FDA as part of the PMA process.” AA22-23. Thus, plaintiffs’ failure-to-warn claims would “impose requirements ‘different from or in addition to’ those approved by the FDA.” *Id.*

Plaintiffs’ own description of their failure-to-warn claims confirms Judge Kyle’s conclusion. Plaintiffs contend that, under FDA regulations, Medtronic “could have” given an additional warning, that the FDA “permits” label changes in certain limited circumstances, and that a manufacturer “may” add to or strengthen

¹⁹ See also, e.g., *Brooks*, 273 F.3d at 796-98; *King v. Collagen Corp.*, 983 F.2d 1130, 1136 (1st Cir. 1993); *Horowitz*, 613 F. Supp. 2d at 277; *Covert*, 2009 WL 2424559, at *3-*4; *Wolicki-Gables*, 2009 WL 2190069, at *9, *11; *Riley*, 625 F. Supp. 2d at 786; *Adkins*, 2008 WL 2680474, at *2-*3; *Colombini*, 2009 WL 2170230, at *2-*5; *Parker*, 584 F. Supp. 2d at 1300; *Lake*, 874 N.Y.S.2d at 754-55; *Kemp*, 835 F. Supp. at 1021; *Talbott v. C.R. Bard, Inc.*, 865 F. Supp. 37, 51-52 (D. Mass. 1994), *aff’d* 63 F.3d 25 (1st Cir. 1995); *Blanco*, 70 Cal. Rptr. 3d at 579.

the label in certain situations. PB45. But plaintiffs do not identify any federal statute or regulation that *required* Medtronic to give additional warnings—let alone required it to give the (unspecified) warnings that plaintiffs allege should have been given.

Accordingly, plaintiffs’ failure-to-warn claims are preempted because they would impose a requirement *in addition to* existing federal requirements—turning a permitted action into a mandatory one.²⁰ *See, e.g.,* AA74 (““where a federal requirement permits a course of conduct and the claim alleged would make it obligatory, the claim is preempted”” because it imposes a different or additional requirement) (quoting AA23-24); *see also, e.g., McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489-90 (7th Cir. 2005) (state-law claims alleging that a manufacturer had a duty to make post-sale warnings regarding information discovered after a device was approved are preempted because they “would impose on [the manufacturer] a requirement that is in addition to federal requirements” which, at most, “permit[],

²⁰ Because plaintiffs have never specified what additional warnings or instructions they claim should have been given, it is impossible to tell whether such warnings would have even been *permissible* under FDA regulations. Thus, plaintiffs fail to meet the standards even of their own misguided theory of parallel claims. Regardless, there is nothing in the regulations that would *require* the warnings that plaintiffs’ state-law claims would mandate.

but [do] not require” such warnings); *id.* at 489 n.3 (“An agency’s urging ... does not change a permissive provision into a mandatory one.”).²¹

Similarly, there is no federal requirement equivalent to plaintiffs’ state-law claim that “Medtronic had a duty, once it received FDA approval of its design that corrected some of the Fidelis Leads’ defects[,] to inform physicians and patients that it fixed the defective Leads.” PB45. As discussed in more detail below (*see* page 55-56), the federal regulations do not require a manufacturer to stop selling a device, or to “warn” consumers before selling it, merely because it has obtained approval to market a modified version of the device.

Plaintiffs also suggest that *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), “rejected arguments nearly identical to the one that Medtronic made to the district court.” PB46-47. But the arguments were not “nearly identical”; as *Wyeth* expressly recognized, the critical difference between them is the very express-preemption clause that is at issue here. *Wyeth*, 129 S. Ct. at 1195-96 (noting that “when Congress enacted an express pre-emption provision for medical devices ... it declined to enact such a provision for prescription drugs”). Under Section

²¹ Plaintiffs ambiguously state that “federal regulations and conditions of approval ... require label changes by PMA Supplement.” PB47. In fact, the regulations and conditions of approval mandate only that a manufacturer seek FDA approval *if* it is going to make certain changes to the label for a device with PMA. *See, e.g.*, 21 C.F.R. § 814.39; JA294-96. Plaintiffs’ state-law claims, on the other hand, would require Medtronic to have sought approval to make specific (though unspecified) changes at specific times.

360k(a), state-law claims are preempted if they impose a requirement that *differs from or adds to* federal requirements. The conflict-preemption doctrines at issue in *Wyeth*, on the other hand, come into play only if it is *impossible* for a drug manufacturer to comply with both the state-law and federal requirements. *Id.* at 1199.²² *Wyeth* is thus irrelevant here and does not spare plaintiffs' failure-to-warn claims from preemption under Section 360k(a).

2. The allegations in the proposed RAMCC would have been futile.

Without even attempting to show how these aspects of the RAMCC would have saved their failure-to-warn claims from preemption (*see* PB44-47), plaintiffs cite the RAMCC's allegation that Medtronic was late in filing various reports with the FDA (PB20-21). But an allegation that Medtronic violated a federal requirement for filing *a report with the FDA* could not be parallel to any of plaintiffs' state-law claims, which would require additional (unspecified) *warnings to physicians or patients*.²³ Once again, plaintiffs have identified nothing in the federal

²² Remarkably, plaintiffs contend that, “[a]lthough implied and express preemption differ, these distinctions are not pivotal here.” PB46. In fact, the distinctions are critical: an additional state-law warning might not be *inconsistent* with existing federal warnings but would still, by definition, *differ from or add to* them.

²³ Notably, the FDA clearly states that the information in these reports “is not intended to be used either to evaluate rates of adverse events or to compare adverse event occurrence rates across devices.” FDA, *Manufacturer and User Facility Device Experience Database (MAUDE)* (September 14, 2009); *see also* 21 C.F.R. § 803.16 (these reports “do[] not necessarily reflect a conclusion by the party submitting the report or by the FDA that ... the reporting entity or its employees,

regulations that required such additional warnings. In any event, the allegation that Medtronic violated FDA reporting requirements by failing to timely submit these reports is barred by Section 337(a) and impliedly preempted under *Buckman*. See Part V, *infra*.

Plaintiffs also cite allegations from the RAMCC that Medtronic failed to submit PMA-Supplement applications for certain changes to the manufacturing process for the Fidelis leads. See PB44. It is not clear how this allegation is related to their failure-to-warn claims (or, indeed, any of their claims), but it is insufficient to state a parallel claim in any event.

Specifically, the RAMCC would have listed a number of changes that Medtronic allegedly made over the years to the manufacturing procedures associated with the Fidelis leads, and alleged that Medtronic should have submitted a PMA-Supplement for each of these changes—even though Medtronic reported each such change to the FDA in annual reports. JA296-98 (RAMCC ¶¶30-41). But, contrary to plaintiffs’ allegations, FDA regulations state that a manufacturer may make a change “without submitting a PMA supplement if the change does not affect the device’s safety or effectiveness and the change is reported to FDA in postapproval periodic reports.” 21 C.F.R. § 814.39(b). Moreover, the regulations specify that “the burden for determining whether a supplement is required is primarily on the

caused or contributed to the reportable event”).

PMA holder.” 21 C.F.R. § 814.39(a). The proposed allegations in the RAMCC confirmed that Medtronic complied with the periodic reporting requirements for these changes. *See* JA296-98 (RAMCC¶¶30-41). In addition, with one possible exception discussed below, plaintiffs have not alleged that the FDA challenged Medtronic’s submission of these changes via post-approval periodic reports. Accordingly, plaintiffs’ conclusory assertion that Medtronic should have submitted a PMA-Supplement for these changes would impermissibly seek to second guess the FDA and to enforce plaintiffs’ view of FDA regulations via a private action barred by 21 U.S.C. § 337(a).

Plaintiffs identify one change for which the FDA—after the company had suspended distribution of the leads—advised Medtronic that it believed a PMA-Supplement should have been submitted. *See* JA298 (RAMCC¶40). But Medtronic’s reporting of that change via an annual report—far from being parallel to one of plaintiffs’ state-law claims—has nothing to do with plaintiffs’ allegations that Medtronic should have given additional warnings to patients or physicians.²⁴ Furthermore, plaintiffs’ effort to enforce compliance with this FDA reporting obli-

²⁴ Here, as in much of their brief, plaintiffs appear to be operating under the false assumption that if they can allege even one regulatory violation, of any form, they have stated a “parallel” claim. As noted above (at 37-39), however, to state a parallel claim, plaintiffs must not only allege a violation of a federal requirement, but must also plead in sufficient detail both how that alleged violation is identical to one of their preexisting state-law claims and that it caused their alleged injuries.

gation not only fails to state a parallel claim, it also is impliedly preempted under *Buckman*. See Part V, *infra*.

C. Negligence

None of the allegations that plaintiffs cite in an effort to show that their negligence claims escape preemption was pleaded in the MCC. Accordingly, if the Court agrees that only the MCC is properly before the Court (*see* Part III, *supra*), it need not consider plaintiffs' attempt to save their negligence claims. In any event, plaintiffs' arguments are meritless.

Plaintiffs contend that their negligence claims avoid preemption because they allege that Medtronic should have stopped selling the original version of the Fidelis lead when it received approval to manufacture a modified version. According to plaintiffs, this requirement is "consistent with FDA's approval of Medtronic's altered design for the Leads and do[es] not conflict with federal requirements." PB48. Once again, plaintiffs have misstated the relevant standard. Whether or not a state-law requirement is "consistent with" or "do[es] not conflict with" existing federal requirements (according to plaintiffs), it is preempted by Section 360k(a) if it would *add to* existing federal requirements. Plaintiffs identify no existing federal source for the requirements that they seek to impose on Medtronic through this negligence claim.

In fact, the requirements that plaintiffs would impose are contrary to federal law. A new version of a product does not per se render an earlier version obsolete (and certainly does not revoke prior PMA approvals). Subject to FDA procedures, manufacturers often make a variety of improvements and modifications to products approved via the PMA process, and lawfully continue to market earlier iterations of these products. Indeed, plaintiffs acknowledge that the FDA approved the Fidelis leads as the 29th and 30th supplemental applications following the original Transvene Lead PMA. *See* PB10. But not even plaintiffs suggest that, upon receiving approval to market the Fidelis Leads, Medtronic was required to cease marketing all prior approved lead models (including the Quattro model that plaintiffs now cite as the standard by which the Fidelis leads should be judged (*see* JA36 (MCC¶70))). Indeed, the FDA has publicly explained that manufacturers need not stop marketing a device simply because they have requested PMA for a “modified (and presumably improved) model[.]” FDA, *Medical-Device Safety and the FDA*, 359 NEW ENG. J. MED. 88 (July 3, 2008). *See, e.g., Blunt v. Medtronic, Inc.*, 760 N.W.2d 396, 407 (Wis. 2009) (finding similar claim preempted because “[w]e have found nothing in the comprehensive federal regulatory scheme that suggests a change in device-specific premarket approval of a Class III medical device occurs

simply because a subsequent device has received supplemental premarket approval”).²⁵

D. Express warranty

1. The MCC does not state a parallel claim.

Plaintiffs contend that their express-warranty claims avoid preemption to the extent that the warranties were voluntary rather than required by the FDA. PB55. As Judge Kyle explained, this contention ignores the fact that plaintiffs’ express-warranty claim is “based on an allegation that the leads were represented as safe ... but were not.” AA33; *see also* JA54 (MCC ¶¶149-50) (“Defendants expressly warranted to Plaintiffs ... that the Sprint Fidelis Leads were safe, effective, fit and proper for their intended use,” but “[t]hese warranties and representations were false” because the “Leads were not safe and were unfit for the uses for which they were intended”); PB57 (quoting MCC).

Although neither the MCC nor the RAMCC identify any statements by Medtronic that allegedly gave rise to such an express warranty, Judge Kyle correctly noted that this claim necessarily would require a jury “to conclude that the Sprint Fidelis leads were unsafe” whereas “the FDA determined that the leads were

²⁵ Similarly, plaintiffs have not identified any federal requirement that manufacturers “seek necessary modifications” to a device at any particular time. PB48. To the extent that plaintiffs are suggesting that Medtronic misrepresented information in a PMA-Supplement application, that claim is impliedly preempted under *Buckman*. *See* Part V, *infra*.

safe and effective when granting PMA.” AA33. Accordingly, whether or not the alleged warranty was voluntary or compelled by the FDA, this type of warranty claim is expressly preempted.

Indeed, numerous courts have recognized that “[w]here ... an essential element of a plaintiff’s claim of breach of express ... warranty will be proof that a device granted a PMA is not safe or effective, such a contention necessarily conflicts with the FDA’s contrary finding and ... is directly preempted by *Riegel*.” *Miller v. DePuy Spine, Inc.*, 2009 WL 1767555, at *3 (D. Nev. May 1, 2009). *See Parker*, 584 F. Supp. 2d at 1303; *Lake v. Kardjian*, 874 N.Y.S.2d 751, 754 (N.Y. Sup. Ct. 2008); *Bencomo v. Guidant Corp.*, 2009 WL 1951821, at *5 (E.D. La. June 30, 2009); *see also Riegel*, 128 S. Ct. at 1009; *cf. Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 932 (5th Cir. 2006) (MDA preempts express warranty claims when “[a] jury hearing [the] state-law breach of express warranty claim would have to decide whether [the defendant’s] representations about the [product] were true. Because those representations”—including the label and warnings—“were approved by the FDA through the PMA process, the duties arising under the [state] breach of warranty statute relate to, and are potentially inconsistent with, the federal regulatory scheme.”).²⁶

²⁶ Because the express warranty alleged by plaintiffs relates to the safety and effectiveness of the device, their claim is distinct from the express-warranty claims dealing with collateral issues that courts have found are not preempted. *Compare*

2. The allegations in the proposed RAMCC would have been futile.

Far from curing the fatal defects in plaintiffs' express-warranty claim, the RAMCC sought to reproduce the text of Medtronic's express limited warranty for the Fidelis leads, which completely undermines that claim. The limited warranty that plaintiffs sought to include in their claims does *not* include a warranty that the lead is safe and effective. Instead, that limited warranty (a) promises to take certain corrective action if the lead is determined to be defective in materials or workmanship, and (b) disclaims all other warranties. *See* JA348-49 (RAMCC¶249). Plaintiffs have never alleged that Medtronic violated *that* limited warranty.

E. Plaintiffs have forfeited any challenge to the dismissal of their implied-warranty, negligence-per-se, fraud, and misrepresentation claims.

Plaintiffs do not offer any substantive challenge to Judge Kyle's finding that their implied-warranty, negligence-per-se, misrepresentation, and fraud claims failed to state a parallel claim and thus were preempted. In a footnote, they assert

Mitchell v. Collagen Corp., 126 F.3d 902, 915 (7th Cir. 1997).

Plaintiffs' reliance on pre-*Riegel* cases and cases decided under regulatory regimes that do not have an express-preemption clause analogous to Section 360k (PB55-56) is misplaced. Plaintiffs also cite *Riley* (PB56), but that opinion did not consider whether the warranty alleged might impermissibly require a finding that the device at issue was not safe or effective (625 F. Supp. 2d at 787-88). To the extent that *Riley* can be construed as allowing such a claim, it is at odds with *Riegel's* holding that Section 360k(a) "bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the [FDA]." 128 S. Ct. at 1002.

that their “claims rooted in theories of negligence, strict products liability or fraud similarly allege parallel violations” (PB48 n.9), but that cursory and unsupported statement is inadequate to preserve a challenge related to those causes of action.²⁷ *See e.g., Minneapolis Taxi Owners Coal.*, 572 F.3d at 506 n.2; *Koehler*, 483 F.3d at 599.

In sum, as Judge Kyle correctly found, each of the claims that plaintiffs attempt to defend here would impose requirements on the Fidelis leads that differ from or add to the existing requirements under federal law. Furthermore, although the RAMCC is not properly before this Court, it too failed to identify any alleged violations of federal requirements that were truly parallel to plaintiffs’ pre-existing state-law claims—even though Judge Kyle had explained this fatal flaw in his order dismissing the MCC. Because plaintiffs’ claims do not fall into the narrow remaining exception to preemption under the MDA, they were appropriately dismissed.

V. The District Court Correctly Applied *Buckman*.

The MCC and RAMCC contain a number of conclusory allegations that Medtronic concealed information regarding the Fidelis leads from the FDA or failed to comply with various reporting obligations under FDA regulations. *See*,

²⁷ Accordingly, plaintiffs also have forfeited any challenge to those “derivative” claims that, as Judge Kyle explained, depend on these claims. *See* AA33-34.

e.g., JA42-43, 59 (MCC¶¶95-96, 174); JA296-98, 323-26 (RAMCC¶¶30-41, 130-139). These spurious allegations do not save plaintiffs' claims from dismissal on preemption grounds. As Judge Kyle correctly held, any claim that depends on the allegation that Medtronic obtained or maintained PMA for the Fidelis leads through conduct that violated FDA reporting or procedural requirements is barred by 21 U.S.C. § 337(a) and impliedly preempted by *Buckman*. See AA25-27.

In *Buckman*, the Supreme Court held that the MDA impliedly preempts state-law claims for personal injuries that allegedly were caused by the manufacturer's fraud in connection with approval of a device under Section 510(k) (an approval process that is much less rigorous than the PMA process). 531 U.S. at 343, 348. The Court noted that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used ... to achieve a somewhat delicate balance of statutory objectives" under Section 510(k). *Id.* at 348. Thus, claims alleging that a manufacturer violated FDA disclosure regulations "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id.* at 350. Such claims therefore are preempted under the Supremacy Clause of the United States Constitution.

The Court's analysis in *Buckman* applies with even greater force in the PMA context. The PMA process seeks to achieve a "balance of statutory objectives" that

is even more “delicate” than that of Section 510(k). *See Riegel*, 128 S. Ct. at 1004. Allowing varying state-law standards to govern applicants’ conduct in seeking or maintaining PMA could easily upset that balance. Moreover, were applicants “to submit a deluge of information” out of “fear that their disclosures to the FDA, although deemed appropriate by the Administration, w[ould] later be judged insufficient in state court,” the FDA’s already complicated task would be rendered all the more difficult. *Buckman*, 531 U.S. at 351. As Congress found when amending the MDA in 2002, “prompt approval and clearance of safe and effective devices is critical to the improvement of the public health so that patients may enjoy the benefits of devices to diagnose, treat, and prevent disease.” Medical Device User Fee and Modernization Act of 2002, PUB. L. No. 107-250, 116 Stat. 1589, title I, § 101 (Oct. 26, 2002).

Furthermore, permitting private litigants to bring a cause of action that would void the preemptive effect of a device’s PMA based on an allegation that the manufacturer withheld “material” information from the FDA would be tantamount to allowing a private action seeking to rescind a PMA. As Judge Kyle correctly concluded, such an action is expressly prohibited under 21 U.S.C. § 337(a) and would conflict with Congress’s intent that “the MDA be enforced exclusively by the Federal Government.” *Buckman*, 531 U.S. at 352; AA25-27.²⁸

²⁸ Indeed, a finding of fraud in connection with FDA submissions would not

In any event, as the expert agency charged with balancing all considerations of safety and efficacy, the FDA—not a jury—should determine whether a manufacturer has complied with FDA disclosure and reporting requirements, and, if not, what response is appropriate given the competing interests at stake.²⁹ Under plaintiffs’ view, juries could (i) interpret FDA reporting regulations (in ways that might vary from jury to jury and substantially depart from the FDA’s interpretation); (ii) decide whether a manufacturer had complied with those regulations (according to the jury’s non-expert understanding of the medical and scientific processes, norms, and information at issue); and (iii) decide what response is appropriate for a viola-

automatically invalidate PMA. *See* 21 C.F.R. § 814.46; *see also Talbott*, 63 F.3d at 28-30 (preemption applies even when the FDA has determined that the manufacturer submitted fraudulent data during the PMA process). Rather, federal law commits the decision whether to revoke PMA in the face of fraud to the FDA’s “discretion.” FDA, *Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy*, 56 Fed. Reg. 46,191, 46,193 (Sept. 10, 1991); *see also id.* at 46,200 (upon a finding of fraud, “the agency intends ordinarily [*i.e.*, not automatically] to exercise its authority, under applicable statutes and regulations . . . to proceed to withdraw approval”). Accordingly, no showing of fraud under state law—much less a mere allegation thereof—could undo the preemptive effect of a valid PMA unless and until the FDA takes discretionary action to withdraw approval. As noted above (at Part II), no such action has been taken, or even alleged, with respect to the Fidelis leads.

²⁹ *See Riegel*, 128 S. Ct. at 1008 (“A jury . . . sees only the cost of a more dangerous design, and is not concerned with its benefits; the patients who reaped those benefits are not represented in court.”); *see also Talbott*, 63 F.3d at 29 (“Allowing an exception for noncompliance would disturb the balance Congress struck between the competing goals of protecting individuals from unreasonably dangerous medical devices and spurring innovation by ensuring that device manufacturers are subject to uniform, nationwide standards.”).

tion (perhaps turning what the FDA would see as a technical violation into a multi-million dollar judgment that could force a needed medical device from the market). That would impermissibly usurp the FDA's powers and interfere with the proper functioning of the regulatory scheme created by Congress.³⁰

For all of these reasons, courts have consistently agreed with Judge Kyle (*see* AA25-27) that Section 337(a), as interpreted in *Buckman*, impliedly preempts claims alleging that a manufacturer violated FDA reporting obligations or otherwise made misrepresentations to the agency. *See, e.g., Talbott*, 63 F.3d at 28 (“Congress did not intend to provide for an exception to the MDA’s preemption clause where a manufacturer fails to comply with the provisions of the MDA by fraudulently obtaining approval of its device from the FDA.”); *Riley*, 625 F. Supp. 2d at 777 (“a state-law claim that the defendant made misrepresentations to the FDA is preempted [under *Buckman*] because such a claim would not exist absent the federal regulatory scheme” and such claims are thus an inappropriate attempt to enforce the FDCA “in substance (even if not in form)”); *Miller*, 2009 WL

³⁰ This result does not leave a plaintiff who suspects fraud without recourse. As the Supreme Court has emphasized, “citizens may report wrongdoing and petition the agency to take action.” *Buckman*, 531 U.S. at 349 (citing 21 C.F.R. § 10.30). If the FDA, in its expert opinion, agrees with the complaint, it “may respond to fraud by seeking injunctive relief” or “civil penalties,” “seizing the device,” and/or “pursuing criminal prosecutions.” *Id.* “The FDA thus has at its disposal a variety of enforcement options that allow it to make a measured response to suspected fraud” *Id.*

1767555, at *4 (“any claim ... based on a contention that [the manufacturer] provided inaccurate or incomplete information to the FDA would be preempted ... under the implied preemption principles stated in *Buckman*”); *see also* *Covert v. Stryker Corp.*, 2009 WL 2424559, at *7-*8 (M.D.N.C. Aug. 5, 2009); *Delaney v. Stryker Orthopaedics*, 2009 WL 564243, at *4 (D.N.J. Mar. 5, 2009); *McCutchen v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008); *Link v. Zimmer Holdings Inc.*, 604 F. Supp. 2d 1174, 1179 (N.D. Ill. 2008); *Mitaro*, 2009 WL 1272398, at *4; *Lake*, 874 N.Y.S.2d at 754-55.

Once again, plaintiffs ignore the case law against them and fail to identify a single case supporting their position.³¹ Instead, plaintiffs argue that Judge Kyle’s interpretation “stretches *Buckman* too far” and effectively abrogates the parallel claims exception to express preemption under Section 360k. PB58. But Judge Kyle held only that *Buckman* preempts the subset of plaintiffs’ claims that alleged viola-

³¹ Plaintiffs cite *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2007), *aff’d per curiam by an equally divided Court sub nom. Warner-Lambert Co. v. Kent*, 128 S. Ct. 1168 (2008), but that case involved a Michigan statute that barred claims against a drug manufacturer unless the manufacturer had defrauded or bribed the FDA in connection with the drug at issue. *Id.* at 86-87. Thus, the question in *Desiano* was whether *Buckman* prevents a plaintiff from invoking a fraud-on-the-FDA exception to a state-law bar on claims. The Second Circuit held that it did not, in part because the plaintiff was actually pursuing “preexisting common law liability based on other wrongs” and only using the allegation of fraud in order to establish an exception to the state statute. *Id.* at 95-96. Indeed, *Desiano* stated that *Buckman* would preempt a claim that “derives from, or is based on, a newly-concocted duty between a manufacturer and a federal agency.” *Id.* at 94-95.

tions of FDA reporting requirements. AA25-27. Even plaintiffs concede that *Buckman* preempts claims for which “the ‘existence of ... federal enactments [is] a critical element.’” PB58 (quoting *Buckman*, 531 U.S. at 353). Many of plaintiffs’ allegations fall under that description. For example, there is no pre-existing common-law duty to file an adverse event report with the FDA (let alone to file it within the time period specified by the regulations). Neither is there a pre-existing common-law duty to follow CAPA documentation procedures or to file PMA-Supplement applications. Because the existence of the FDCA and MDA is “a critical element” in claims based on those allegations, such claims necessarily infringe upon the FDA’s authority to police its own regulations and are impliedly preempted under Section 337(a) and *Buckman*—even according to plaintiffs’ account of that case.

In sum, Judge Kyle correctly held that, “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.” AA26-27. Claims that are *not* equivalent to existing federal requirements are expressly preempted under Section 360k(a); claims that *are* equivalent to existing federal requirements are impliedly preempted under Section 337(a) if the federal regulation itself is “a critical element” in the claim (*i.e.*, if the claim cannot be stated without reference to the regulations). None of plaintiffs’ claims falls into the

narrow remaining exception for pre-existing state-law claims that can be stated without reference to the federal requirements but that are equivalent to those requirements.³²

VI. The District Court Correctly Applied The Federal Pleading Standard Under *Twombly* And *Iqbal*.

If the Court agrees that plaintiffs' manufacturing-defect claims are preempted (*see* Part IV.A, *supra*), then it need not address plaintiffs' challenge to Judge Kyle's application of *Twombly*. The only substantive reference to *Twombly* in Judge Kyle's decision was as an *alternative* basis for dismissing plaintiffs' manufacturing-defect claims; Judge Kyle first determined that those claims are preempted before noting that "Plaintiffs' failure to allege in detail the federal requirement(s) purportedly violated by Medtronic *also* raises the specter of *Twombly*." AA20-21 (emphasis added).

Regardless, Judge Kyle was correct that *Twombly*, and now *Iqbal*, require plaintiffs to plead more than the conclusory statements they included in support of their manufacturing-defect claims. To plead a parallel claim, plaintiffs must iden-

³² Plaintiffs protest that their claims "for failure to timely warn of adverse events or defects, or to change labels to provide adequate warnings, are traditional state law causes of action" that "would arise regardless of whether the FDCA or any federal requirements were ever enacted." PB59-60. To the extent that plaintiffs are referring to common-law claims that Medtronic should have warned *patients* of adverse events or made changes to the labeling for the leads, Judge Kyle did not find such claims to be impliedly preempted under *Buckman*. Rather, Judge Kyle correctly held that such claims are expressly preempted under *Riegel* because they would add to or differ from existing federal requirements. *See* Part III, *supra*.

tify an existing federal requirement applicable to the leads that is genuinely equivalent to one of their pre-existing state-law claims. Each of the “examples” that plaintiffs offer in an effort to show that they have provided sufficient detail (PB50-51) fails this test.

In particular, some of plaintiffs’ examples have no connection to federal requirements at all, and thus cannot form the basis of a parallel claim. For example, plaintiffs state that Medtronic’s “welding techniques ... were inadequate” (PB50), but they do not identify any federal requirements that dictate the type of welding techniques that Medtronic was required to use. As Judge Kyle held, “Plaintiffs were required to point to something in the CGMPs/QSR precluding the use of spot welding” or else their assertion that they had pleaded a parallel claim is not “plausible on its face.” AA21 (quoting *Twombly*, 550 U.S. at 570).

Plaintiffs’ other examples—which simply identify various federal regulations and assert that Medtronic violated them—are stereotypical “bare assertions” that “amount to nothing more than a ‘formulaic recitation of the elements’ of a [violation of a federal requirement applicable to the Fidelis leads].” *Iqbal*, 129 S. Ct. at 1951 (quoting *Twombly*, 550 U.S. at 555). For example, plaintiffs assert that Medtronic “failed to adhere to, and otherwise comply with FDA regulations in the manufacture, inspection, distribution, shipment and sale of Sprint Fidelis Leads.” PB51. This is precisely the type of formulaic pleading that is insufficient to meet

federal standards. As the Supreme Court explained in *Iqbal*, “[a] pleading that offers ‘labels and conclusions’ or ‘a formulaic recitation of the elements of a cause of action,’” or “‘naked assertion[s]’ devoid of ‘further factual enhancement,’” “‘will not do.’” 129 S. Ct. at 1949 (quoting *Twombly*, 550 U.S. at 555, 557). As Judge Kyle put it: “Plaintiffs cannot simply incant the magic words ‘Medtronic violated FDA regulations’ in order to avoid preemption.” AA20.

Plaintiffs also suggest that they have “pleaded as much as the ‘model’ [manufacturing-defect claim] cited by the district court” (PB52), but that is demonstrably false. As an example of a manufacturing-defect claim that appears to be sufficiently pleaded under *Twombly*, Judge Kyle cited *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790 (W.D. La. 2008). AA21-22. In *Rollins*, the plaintiff did not simply allege that the manufacturer “violated the PMA packaging requirements” for the device or “failed to adequately package the device.” Instead, she alleged that the PMA required the device to be packaged in a clearly specified way but that it was packaged in a different way, leading to her injuries.³³ As Judge Kyle noted, that type of pleading may be sufficient to state a parallel claim—but there is nothing approaching it here.

³³ The plaintiff in *Rollins* identified requirements in the PMA specifying that the device be packaged in a specific orientation with a .035-inch guide wire, and alleged that her device was packaged in a different orientation with a .038-inch guide wire, which rendered the product defective and caused her injuries. *See* 583 F. Supp. 2d at 794, 800.

Rollins also shows that plaintiffs are wrong when they claim that Judge Kyle’s “interpretation of *Twombly* ... is tantamount to requiring that Plaintiffs *prove* their allegations at the pleading stage.” PB52. In *Rollins*, the plaintiff did not prove that her device was packaged in the wrong orientation and with the wrong guide wire. Neither did she prove that this alleged deviation from the PMA requirements caused her injuries. Instead, she identified an existing federal requirement for the manufacture and packaging of the device; pleaded facts that, if true, might plausibly establish that that requirement had been violated; and alleged a plausible inference that this deviation caused her injuries. The sharp contrast to the complaint in this case is apparent.

VII. The District Court Acted Within Its Discretion In Rejecting Plaintiffs’ Request To Conduct Discovery Before Pleading A Viable Cause Of Action.

A. Plaintiffs’ request sought an improper fishing expedition, and was untimely and conclusory.

In seeking permission to move for reconsideration of Judge Kyle’s order dismissing the MCC, plaintiffs asked the court to authorize discovery. Judge Kyle concluded that the request was an improper “fishing expedition” that “put the proverbial cart before the horse” by using discovery to try to find a cause of action rather than to investigate a well-pleaded claim. AA40-41. He also noted that “Plaintiffs’ lead counsel made clear from the outset of this case that no discovery was necessary in order to resolve the preemption issue.” AA42-44. And he stressed that

“Plaintiffs’ purported ‘need’ for discovery appear[ed] nowhere in their Opposition to Medtronic’s Motion to Dismiss” but was instead an “eleventh hour” request for a “‘get out of jail free’ card.”³⁴ *Id.* Judge Kyle’s rejection of plaintiffs’ request was far from an abuse of discretion.

Putting aside the untimeliness of plaintiffs’ request for discovery, Judge Kyle was surely correct in labeling it a fishing expedition. Allowing plaintiffs to impose the significant burdens of discovery on Medtronic based on nothing but speculation that they might find evidence that would allow them to plead a claim that meets all the criteria necessary to avoid both express and implied preemption (*see* Parts IV and V, *supra*) would be highly improper.

Even before *Twombly* and *Iqbal*, courts consistently held that “the price of entry, *even to discovery*, is for the plaintiff to allege a *factual* predicate concrete enough to warrant further proceedings, which may be costly and burdensome.” *DM Research, Inc. v. Coll. of Am. Pathologists*, 170 F.3d 53, 55 (1st Cir. 1999). That is all the more so now that the Supreme Court has emphasized twice in the last several years that “a district court must retain the power to insist upon some specific-

³⁴ Plaintiffs try to distance themselves from their initial rejection of discovery by suggesting that Judge Kyle changed the game when he went outside the pleadings in ruling on Medtronic’s motion to dismiss. PB54 n.11. As Judge Kyle explained, however, the only materials outside the pleadings that played a role in his decision were official FDA statements interpreting the regulations that plaintiffs had invoked in an effort to avoid preemption. AA42-43 & n.2.

ity in pleading *before* allowing a potentially massive factual controversy to proceed.” *Twombly*, 550 U.S. at 558 (emphasis added; internal quotation marks omitted); *see also Iqbal*, 129 S. Ct. at 1950 (“Rule 8 ... does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions”).

Furthermore, even when plaintiffs finally did request discovery, Judge Kyle noted that they “only vaguely asserted what it is they intend[ed] to discover” and did not make “any substantial showing how further discovery will aid [their] cause.” AA42. In such circumstances, it is not an abuse of discretion to refuse discovery. *See, e.g., Casazza v. Kiser*, 313 F.3d 414, 421 (8th Cir. 2002) (holding that “the District Court did not abuse its discretion by denying further discovery and ruling on the motion to dismiss” given, *inter alia*, “the conclusory nature of [the plaintiff’s] request for a continuance”).

B. There is no basis for a relaxed pleading or discovery rule for claims involving Class III devices with PMA.

Plaintiffs imply that relaxed rules should govern claims involving preemption under the MDA because they cannot meet the federal pleading standard without “access to the defendant’s secret FDA’s [*sic*] documents.” PB54. This argument fails for several reasons.

First, as the Second Circuit recently held, a plaintiff’s “confessed inability” to adequately plead a claim without discovery “underscores, rather than cures, the deficiency in the Complaint.” *S. Cherry St. LLC v. Hennessee Group LLC*, 573

F.3d 98, 113-14 (2d Cir. 2009). It is not the role of courts or discovery to help people “find out if [they] ha[ve] any basis for a claim,” but only to help them gather information once they have pleaded a viable claim. AA40 (quoting *Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1327 (Fed. Cir. 1990)).

In fact, Congress’s expressed intent to encourage the development and production of innovative life-saving devices by shielding device manufacturers from different or additional state requirements counsels strongly against a special rule that would give every device recipient license to impose substantial discovery costs on the device manufacturer without first stating a viable claim. *See, e.g., Parker*, 584 F. Supp. 2d at 1302 n.6 (argument that discovery is necessary to meet federal pleading standard “is not unique to claims under the MDA and provides no compelling reason for ignoring the clear holding of *Twombly* ... that the complaint must provide adequate factual substantiation in order to state a plausible claim for relief”); *cf. Iqbal*, 129 S. Ct. at 1953-54 (declining to impose a “relax[ed] ... pleading requirement” to allow “minimally intrusive discovery” because doing so would contravene the purposes of the qualified-immunity doctrine).

Second, plaintiffs have failed to support the proposition underlying their argument—that the information they claim to need is unavailable because “Medtronic’s [unspecified] FDA submissions” are “secret.” PB53. On the contrary, plaintiffs appear to admit that they have the documents they are looking for as a

result of a FOIA request, but complain that certain portions have been redacted. *See* PB54 & n.12. Yet plaintiffs make no effort to show why it is reasonable to believe that these unidentified redactions—which the FDA presumably made pursuant to 5 U.S.C. § 552(b)(4) to preserve Medtronic’s trade secrets³⁵—conceal a requirement that meets all of the criteria necessary to provide the basis for a parallel claim. Indeed, it is telling that plaintiffs specifically asked Judge Kyle to ensure that the magistrate’s order denying their request to compel production of unredacted versions of these documents not be a part of this appeal. *See* Dkt. 298.

Third, the implication of plaintiffs’ argument is that questions of preemption with respect to medical devices cannot be resolved under Rule 12(b)(6), but must proceed through discovery to summary judgment. In fact, courts regularly grant motions to dismiss on the basis of federal preemption under Section 360k(a). *See, e.g., Horowitz*, 613 F. Supp. 2d 271; *Covert*, 2009 WL 2424559; *Parker*, 584 F. Supp. 2d 1298; *Riley*, 625 F. Supp. 2d 769; *Adkins v. Cytoc*, 2008 WL 2680474 (W.D. Va. July 3, 2008); *Bausch*, 2008 WL 5157940; *Talbott*, 63 F.3d at 25. That plaintiffs have failed to meet the relevant standard does not mean that Judge Kyle has “established an impossible standard for plaintiffs on a motion to dismiss.” PB53-54. Indeed, Judge Kyle and other courts have identified circumstances in

³⁵ Plaintiffs suggest that *Medtronic* redacted the material they received through FOIA requests. *See* PB12 n.2. In fact, *the FDA* is statutorily required to redact certain information it produces in response to FOIA requests. *See* 5 U.S.C. § 552(b).

which a plaintiff may be able to plead a parallel claim, *see* AA21-22, 27 n.17, but those circumstances simply are not present here.

Finally, plaintiffs have once again failed to identify any cases adopting the position that they urge on this Court or that support the conclusion that Judge Kyle abused his discretion. They cite *Walker v. Medtronic, Inc.*, 2008 WL 4186854 (S.D. W. Va. Sept. 9, 2008). *See* PB55. But *Walker* already had proceeded to discovery before *Riegel* was decided (2008 WL 4186854, at *1), and involved the unrelated question whether the plaintiff was entitled to discovery to challenge an affidavit establishing that his individual device was manufactured according to federal requirements (*id.* at *3). Similarly unavailing is plaintiffs' reliance on *In re Celexa & Lexapro Products Liability Litigation*, 2008 WL 2906713 (E.D. Mo. July 24, 2008). *See* PB55. That case involved drugs, not medical devices. As explained above (at pages 50-51), the Supreme Court has clearly distinguished between drugs and devices in applying the law of preemption. Specifically, preemption in the drug context—which turns on the existence of a conflict between federal and state regulations—may require a much more fact-intensive investigation into the extent and nature of the FDA's involvement with the drug at issue. *See Wyeth*, 129 S. Ct. at 1200-03. Thus, the *In re Celexa* court's decision to allow discovery “on the preemption issue” (2008 WL 2906713, at *1), has no relevance here.

In sum, Judge Kyle did not abuse his broad discretion by denying plaintiffs' belated and unjustified request to ignore the normal requirement of a well-pleaded cause of action and instead allow them to use the discovery process in the hope of stumbling upon a viable claim.

VIII. The District Court Did Not Abuse Its Discretion By Denying Recusal.

Just weeks after Judge Kyle denied reconsideration of his order dismissing the MCC, plaintiffs moved for Judge Kyle's recusal. First, plaintiffs argued that recusal was required under 28 U.S.C. §§ 455(a) and 455(b)(5)(iii) because Judge Kyle's son, Kyle Jr., is a shareholder at Fredrikson, a law firm that has represented Medtronic in various matters unrelated to this litigation. Second, plaintiffs sought recusal based on Judge Kyle's brief responses to press inquiries about plaintiffs' intent to move for recusal. Judge Kyle did not abuse his discretion by holding that neither ground required his recusal and that he was therefore "obliged" to preside. *Sw. Bell Tel. Co. v. FCC*, 153 F.3d 520, 523 (8th Cir. 1998) (Hansen, J., in chambers) ("There is as much obligation for a judge not to recuse when there is no occasion for him to do so as there is for him to do so when there is") (quoting *Hinman v. Rogers*, 831 F.2d 937, 939 (10th Cir. 1987)).

A. Kyle Jr.'s status as a shareholder at Fredrikson does not mandate recusal.

The Supreme Court has stated that where "one of those aspects addressed in [Section 455](b) *is* at issue, ... it is poor statutory construction to interpret (a) as

nullifying the limitations (b) provides.” *Liteky v. United States*, 510 U.S. 540, 553 n.2 (1994). Because Section 455(b)(5)(iii) is “at issue” here, Judge Kyle properly began his analysis with that “more specific subsection.” AA52; accord *In re Apex Oil Co.*, 981 F.2d 302, 303 (8th Cir. 1992) (Loken, J., in chambers).

1. Section 455(b)(5)(iii) does not require recusal.

Section 455(b)(5)(iii) requires recusal if “a person within the third degree of relationship” to the judge “[i]s known by the judge to have an interest that could be substantially affected by the outcome of the proceeding.” Judge Kyle applied settled law in rejecting recusal under Section 455(b)(5)(iii) based on his son’s status as a shareholder at a law firm that has represented Medtronic in unrelated matters.

a. This litigation could not “substantially affect” Kyle Jr.’s interests.

Plaintiffs offer two arguments why Kyle Jr.’s interests could be “substantially affected” by this litigation. First, plaintiffs argue without explanation that this litigation could substantially affect Kyle Jr.’s “financial interests.” PB75. To the extent plaintiffs claim that Medtronic would steer its legal business away from Fredrikson if Judge Kyle ruled against Medtronic, that is preposterous. As Judge Kyle noted, the purportedly “close association” between Fredrikson and Medtronic makes it “particularly unlikely that *any* ruling the Court might make ... would have an impact on the quantum of business [Fredrikson] receives.” AA52-53. Regardless, plaintiffs’ argument “is little more than a hypothetical house of cards: [Kyle

Jr.] *could* be affected *if* the Court were to rule against Medtronic, *if* Medtronic then ‘retaliated’ by withdrawing business from Fredrikson, *if* the removal of that business were to impair [Kyle Jr.’s] financial interests, and *if* that impairment were ‘substantial.’” AA53-54. This “‘unsupported, irrational, or highly tenuous speculation’ will not do.” AA54 (quoting *Hinman*, 831 F.2d at 939).

To the extent plaintiffs claim that this litigation could threaten Medtronic’s ability to pay Fredrikson’s fees, that too is preposterous. “Given Medtronic’s sheer size,” Judge Kyle observed, “such an outcome is highly unlikely.” AA53 n.3. Moreover, Fredrikson’s fortunes do not rise and fall with Medtronic’s. In 2008, Fredrikson’s approximately 240 lawyers represented more than 5,000 clients, with Medtronic matters generating only a small percentage of the firm’s revenue. Dkt. 258, Exh. B ¶¶ 4, 6, 10.³⁶ None of Fredrikson’s engagements for Medtronic is contingent on the outcome of this litigation, and there is no relationship between Medtronic’s success or failure in litigation handled by other firms and the amount of work Medtronic assigns to Fredrikson. *Id.* ¶ 9.

Even if this litigation adversely impacted Medtronic and Fredrikson, there is no basis to presume that it would substantially affect Kyle Jr. He owns a miniscule interest in Fredrikson’s profits. *Id.* ¶ 16. Moreover, because Fredrikson bases

³⁶ Medtronic submitted an unredacted version of this affidavit under seal to Judge Kyle in chambers.

shareholder compensation primarily on individual performance, Kyle Jr.'s compensation could increase or remain constant even if firm revenues decline. *Id.* ¶ 17. Plaintiffs are therefore incorrect in asserting that “[w]hat substantially affects Medtronic ... necessarily has an effect on Fredrikson, and in turn, its shareholders.” PB72-73. As Judge Kyle noted, “[s]omething that substantially affects Medtronic need not substantially affect Fredrikson—let alone my son—*ipso facto*, particularly given my son’s relatively small stake in the firm’s profits.” AA54 n.4.

Second, citing *Potashnick v. Port City Construction Co.*, 609 F.2d 1101 (5th Cir. 1980), plaintiffs assert that this litigation could substantially affect Kyle Jr.’s “business relationships and reputation[.]” PB75. But, as Judge Kyle noted, “Plaintiffs fail to explain” how this litigation could substantially affect Kyle Jr.’s reputation “when neither he, nor the firm, is counsel of record in this case.” AA57. Nor do plaintiffs explain how this litigation could substantially affect Kyle Jr.’s “business relationships” given that he has never represented Medtronic. Dkt. 258, Exh. B ¶ 14. Even if Fredrikson’s business relationships were relevant, Judge Kyle correctly stated that “[l]arge law firms like Fredrikson gain and lose clients—even ‘material’ clients—all the time, and ‘the reputation and good will of those firms has not been affected substantially.’” AA58 (quoting *Diversifoods, Inc. v. Diversifoods, Inc.*, 595 F. Supp. 133, 139 (N.D. Ill. 1984)). Thus, “it is ‘impossible to do more than speculate that [Kyle Jr.] might someday reap a [non-pecuniary] benefit

as an indirect result of the success of’ Medtronic here.’ *Id.* (quoting *Scott v. Metro Health Corp.*, 234 Fed. App’x 341, 357 (6th Cir. 2007), *cert. denied*, 128 S. Ct. 1225 (2008)).

Potashnick is plainly distinguishable. In that case, the district judge—the son of a senior partner at plaintiff’s law firm—“was involved in business dealings” and “was being personally represented” by plaintiff’s attorney. 609 F.2d at 1104, 1106. Nothing remotely similar is alleged in this litigation, in which Fredrikson is not even involved. *See Huff v. Standard Life Ins. Co.*, 683 F.2d 1363, 1369-70 (11th Cir. 1982) (distinguishing *Potashnick*); *see also Pashaian v. Eccelston Props., Ltd.*, 88 F.3d 77, 83 (2d Cir. 1996). Moreover, the same court that decided *Potashnick* subsequently made clear that recusal is improper under facts like those presented here. *In re Billedeaux*, 972 F.2d 104 (5th Cir. 1992).

b. Judge Kyle’s decision follows settled law.

As Judge Kyle noted, “arguments like those asserted by Plaintiffs have been repeatedly rejected.” AA54. In *Microsoft Corp. v. United States*, 530 U.S. 1301 (2000) (statement of Rehnquist, C.J.), for example, Chief Justice Rehnquist declined to recuse himself under Section 455(b)(5)(iii) from considering Microsoft’s appeal in antitrust litigation brought by the government even though his son was a law firm partner who personally represented Microsoft in related private antitrust litigation. Chief Justice Rehnquist explained that his son’s financial interest would

not be “substantially affected” by the governmental litigation because Microsoft had retained his son’s firm “on an hourly basis at the firm’s usual rates.” 530 U.S. at 1302. He also found that “it would be unreasonable and speculative to conclude that the outcome of any Microsoft proceeding in this Court would have an impact on [his son’s nonpecuniary] interests when neither he nor his firm would have done any work on the matters here.” *Id.*³⁷; see also *In re Digital Music Antitrust Litig.*, 2007 WL 632762, at *13 & n.19 (S.D.N.Y. Feb. 27, 2007) (denying recusal under “virtually identical” 28 U.S.C. § 455(b)(4) where judge’s husband was law firm partner who personally represented defendants in related litigation).

While Chief Justice Rehnquist was faced with the more difficult question of whether to recuse when his son was a partner who *personally* represented a party in *related* litigation, it is no surprise that courts have consistently rejected recusal under Sections 455(b)(4) and 455(b)(5)(iii) when faced with more attenuated scenarios like the one presented here. *E.g.*, *Hook v. McDade*, 89 F.3d 350, 353, 356 (7th Cir. 1996) (district judge’s wife was law firm partner who represented defendant’s co-defendant in unrelated matters); *In re Nat’l Union Fire Ins. Co.*, 839 F.2d 1226, 1229 (7th Cir. 1988) (district judge’s son represented party in unrelated litigation); *Canino v. Barclays Bank, PLC*, 1998 WL 7219, at *4 (S.D.N.Y. Jan. 7,

³⁷ Although recusal is arguably more problematic for Supreme Court justices than for lower court judges (*Microsoft*, 530 U.S. at 1303), the lower court cases cited above provided similar reasons in rejecting recusal.

1998) (judge’s husband was partner at law firm that represented defendant in unrelated litigation); *Diversifoods*, 595 F. Supp. at 138-39 (same); cf. *Jenkins v. Ark. Power & Light Co.*, 140 F.3d 1161, 1165 (8th Cir. 1998) (district judge’s child had accepted associate position at defendant’s law firm); *In re Kan. Pub. Employees Ret. Sys.*, 85 F.3d 1353, 1364 (8th Cir. 1996) (same).

Citing *Diversifoods*, plaintiffs attempt to distinguish this settled law by arguing that Medtronic is a “material” client of Fredrikson. PB76. But Judge Kyle correctly rejected a “bright-line rule” requiring recusal “if a judge’s child is a partner in a law firm that derives substantial revenue from a client.” AA56-57. Such a rule would be “contrary” to this Court’s “admonition that a ‘relationship between a party and a judge’s son or daughter does not *per se* necessitate a judge’s disqualification.’” AA57 (quoting *Kan. Pub. Employees Ret. Sys.*, 85 F.3d at 1364).

In any event, *Diversifoods* denied recusal, and the *dictum* plaintiffs cite is inapposite. Plaintiffs have not shown that Medtronic is a “material” client of Fredrikson—as Judge Kyle put it, “there is simply nothing in the record to indicate that Medtronic is Fredrikson’s *raison d’etre*” (AA57 n.6)—much less that this litigation could substantially affect Kyle Jr.

2. Section 455(a) does not require recusal.

Section 455(a) requires recusal where the judge’s “impartiality might reasonably be questioned.” This Court applies “an objective standard of reasonable-

ness in determining whether recusal is required” under Section 455(a). *Fletcher v. Conoco Pipe Line Co.*, 323 F.3d 661, 664 (8th Cir. 2003). The test is whether “the judge’s impartiality might reasonably be questioned by the average person on the street who knows all the relevant facts.” *Kan. Pub. Employees Ret. Sys.*, 85 F.3d at 1358. “‘Because a judge is presumed to be impartial, a party seeking recusal bears the substantial burden of proving otherwise.’” *Scenic Holding, LLC v. New Bd. of Trustees*, 506 F.3d 656, 662 (8th Cir. 2007).

“Courts have uniformly rejected the argument that an appearance of impropriety exists” under Section 455(a) where “(i) a judge’s [family member] is a partner in a law firm that represents a litigant in matters other than the case before the judge; and (ii) the [family member] did not perform any work at the law firm for the litigant or worked for the litigant on unrelated matters.” *Digital Music Antitrust Litig.*, 2007 WL 632762, at *12. In *Billedeaux*, for example, the Fifth Circuit affirmed the denial of plaintiff’s motion to recuse the district judge under Section 455(a) based on the judge’s husband’s partnership in a law firm that represented the defendant in other matters. The court held that “any interest that could be attributed to [the judge] in the fate of her husband’s law firm’s sometime client is so remote and speculative as to dispel any perception of impropriety.” 972 F.2d at 106.

As Judge Kyle observed, *Billedeaux* is consistent with “legions of cases” that have rejected recusal under Section 455(a) where a judge’s family member, or the law firm at which the family member was a partner, represented a party in unrelated matters. AA59; e.g., *Hook*, 89 F.3d at 355; *Diversifoods*, 595 F. Supp. at 138-40; *Canino*, 1998 WL 7219, at *3; cf. *Transportes Coal Sea de Venezuela C.A. v. SMT Shipmanagement & Transp. Ltd.*, 2007 WL 62715, at *10 (S.D.N.Y. Jan. 9, 2007). In fact, courts have rejected recusal under Section 455(a) even when a family member was a law firm partner who, unlike here, *personally* represented a party in *related* litigation. See *Microsoft*, 530 U.S. at 1302; *Digital Music Antitrust Litig.*, 2007 WL 632762, at *12.

This settled law governs here. Fredrikson, which primarily counsels Medtronic in corporate transactions and intellectual property, has never represented Medtronic in litigation concerning Fidelis leads. Dkt. 258, Exh. B ¶¶ 7-8. Kyle Jr., whose practice consists primarily of white collar defense, has never represented Medtronic in any matter. *Id.* ¶¶ 13-14. No reasonable person apprised of these facts would harbor doubts about Judge Kyle’s impartiality. See *Sw. Bell Tel. Co.*, 153 F.3d at 523 (“A judge who cannot be expected to remain impartial through trivial matters such as this should not be sitting even when his family is unaffected.”) (quoting *Nat’l Union Fire Ins. Co.*, 839 F.2d at 1230).

Plaintiffs ignore the uniform authority rejecting their interpretation of Section 455(a). Instead, they “largely parrot[] their argument under Section 455(b)” — an argument that should be rejected under Section 455(a) for the same “reasons set forth above.” AA59. Plaintiffs’ additional arguments fare no better.

First, plaintiffs suggest that Fredrikson has represented Medtronic in matters related to this litigation, asserting that “Medtronic *never* clearly states whether Fredrikson or any of its shareholders were actually involved in the development of or regulatory aspects related to the Leads.” PB73. In fact, Medtronic submitted an affidavit from Fredrikson’s President averring that “the firm has not represented Medtronic in any regulatory matter concerning Sprint Fidelis leads and had no role in advising Medtronic during the design, development, testing, premarket approval or post-market surveillance of the performance of Sprint Fidelis leads.” Dkt. 268, Exh. B ¶ 8. As Judge Kyle noted, “[i]t is hard to see how Medtronic could have been any clearer.” Dkt. 15 at 2.

Similarly, plaintiffs speculate that “former Medtronic employees, now Fredrikson shareholders, worked on regulatory and compliance matters including aspects of the PMA or exemption from PMA, of the very product or the root devices in question.” PB71-72. Plaintiffs apparently rely on nine-year old correspondence between Robert Klepinski—then an in-house lawyer at Medtronic and now a Fredrikson shareholder—and the FDA concerning “temporary pacemaker electrodes.”

Dkt. 247, Exh. D. But as Judge Kyle noted, “there is no obvious connection between such devices and the Sprint Fidelis leads, ... nor do Plaintiffs point to any.” AA61 n.7. Moreover, Fredrikson’s President “specifically” rejected plaintiffs’ speculation in a sworn affidavit. *Id.*

Second, plaintiffs argue that Judge Kyle should not have analyzed the potential impact of this litigation on Fredrikson because “the actual financial impact on Fredrikson cannot be known by third persons and is irrelevant.” PB74. To the contrary, Section 455(a) asks whether “the judge’s impartiality might reasonably be questioned by the average person ... *who knows all the relevant facts.*” *Kan. Pub. Employees Ret. Sys.*, 85 F.3d at 1358 (emphasis added).

Finally, plaintiffs assert (PB71) that Judge Kyle’s decision is inconsistent with *United States v. Miell*, 2008 WL 974843 (N.D. Iowa Apr. 8, 2008). In *Miell*, the district judge’s husband was a shareholder in a law firm that represented an insurer alleging fraud in a civil action against Robert Miell. Acting “out of an abundance of caution,” the district judge recused herself from a criminal action against Miell alleging the same fraud that formed the basis for the insurer’s civil action because the two cases were not “unrelated.” *Id.* at *3. As Judge Kyle recognized, this case is “markedly different” from *Miell* because Fredrikson does not represent Medtronic in related litigation. AA62.

3. Plaintiffs' motion was untimely.

a. Plaintiffs delayed seeking recusal for over a year.

Motions for recusal “will not be considered unless timely made.” *Tri-State Fin., LLC v. Lovald*, 525 F.3d 649, 653 (8th Cir. 2008), *cert. denied*, 129 S. Ct. 630 (2008); *see also Kan. Pub. Employees Ret. Sys.*, 85 F.3d at 1360 (“our circuit has consistently required timely action as to § 455 in general, *i.e.*, as to both (a) and (b)”). Although Judge Kyle denied recusal on the merits, he noted that “the timing of Plaintiffs’ Motion—coming not long after the Court issued a major ruling adverse to Plaintiffs—suggests, to be charitable, that it is an exercise in judge shopping.” AA66. Indeed, the MDL was pending before Judge Kyle for over a year before plaintiffs sought recusal, during which time “the Court (and the parties) invested substantial time, effort, and expense.” AA66 n.12.

Plaintiffs concede that they have long been aware that Kyle Jr. is a shareholder at Fredrikson. PB69. However, plaintiffs claim that they only became aware of Fredrikson’s relationship with Medtronic in February 2009. *Id.* Although plaintiffs do not explain how they first learned about Fredrikson’s relationship with Medtronic, “their evidence of that relationship consists almost entirely of articles posted on Fredrikson’s website.” AA64. “The age of the[se] sources,” Judge Kyle noted, “belies Plaintiffs’ assertion that they lacked awareness of the connections between Fredrikson and Medtronic.” AA65.

But even if plaintiffs were not actually aware of Fredrikson’s relationship with Medtronic, they should be charged with such knowledge. As Judge Kyle correctly stated, “Plaintiffs seeking recusal cannot claim ignorance of key facts easily discoverable—they are ‘charged with knowledge of all facts known or knowable, if true, with due diligence, from the public record or otherwise.’” AA65 (citing, *inter alia*, *Kan. Pub. Employees Ret. Sys.*, 85 F.3d at 1363 n.8).

Information about Medtronic’s relationship with Fredrikson has been “easily discoverable” from Fredrikson’s website since this litigation began. Dkt. 268, Exh. B ¶ 11. Plaintiffs’ own review of Fredrikson’s website “demonstrates that apparently it is not very difficult to perform such a search.” *Digital Music Antitrust Litig.*, 2007 WL 632762, at *9. Charging plaintiffs with knowledge is particularly appropriate because plaintiffs were well aware of the fact that they say caused them to review Fredrikson’s website—that Kyle Jr. is a shareholder at the firm—from the outset of the litigation. While Judge Kyle’s dismissal order appears to have motivated plaintiffs to pursue potential bases for recusal, it does not provide good cause for their delay.³⁸

³⁸ Plaintiffs assert that they “are not required to ‘pore through the judge’s private affairs’ to discover potential conflicts.” PB65. But as Judge Kyle noted, “the facts Plaintiffs alleged to have recently discovered have nothing to do with [Judge Kyle’s] ‘private affairs’—they concern only the links between Fredrikson and Medtronic.” AA66 n.12.

b. Neither Judge Kyle nor Medtronic violated any disclosure obligations.

Plaintiffs ask to be excused from their failure to timely seek recusal by asserting that Judge Kyle and Medtronic should have disclosed Medtronic's relationship with Fredrikson at the inception of the MDL. Plaintiffs' assertion is irrelevant because, as described above, they knew or are deemed to know about that relationship. In any event, plaintiffs' request finds no support in the law and would make bad public policy.

First, plaintiffs suggest (PB63-64) that Judge Kyle violated the directive, pursuant to 28 U.S.C. § 455(c), that MDL judges "promptly review" the litigation for "conflicts that may require recusal." *Manual for Complex Litigation* § 10.121 (4th ed. 2004). In fact, Section 455(c) requires only that the "judge ... make a reasonable effort to inform himself about the personal financial interests of his spouse and minor children." Because Kyle Jr. is not a "minor" child, Section 455(c) did not require Judge Kyle to monitor his son's financial interests, much less the interests of Fredrikson's clients.

Second, plaintiffs note that judges should disclose information that is "relevant" to recusal. PB65-66. But there was no need for Judge Kyle to disclose his son's connection to Fredrikson because plaintiffs were well aware of that fact. And even had he known of Fredrikson's relationship with Medtronic, Judge Kyle would not have needed to disclose that relationship because it is irrelevant to his ability to

preside. *See Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 882 F.2d 1556, 1569 (Fed. Cir. 1989) (“the trial judge was not required to disclose to [defendant] that the son was employed by [plaintiff]”); *accord Datagate, Inc. v. Hewlett-Packard Co.*, 941 F.2d 864, 871 (9th Cir. 1991).

Third, plaintiffs assert that Pretrial Order No. 1 (“PTO No. 1”) required Medtronic to disclose its relationship with Fredrikson. PB64. PTO No. 1 required only that the parties provide “a list of all companies affiliated with the parties and all counsel associated in the litigation.” PTO No. 1, § 3(d). Fredrikson is not a “compan[y] affiliated” with Medtronic and does not represent Medtronic “in the litigation.” *Id.* As Judge Kyle noted, “Plaintiffs nowhere explain (and the Court fails to see) how [PTO No. 1] somehow required the disclosure of ‘Fredrikson’s relationship with Medtronic.’” AA70 n.1.

Moreover, Judge Kyle correctly recognized that “[a]ccepting Plaintiffs’ logic would require judges to run conflict checks through the law firms employing their children, spouses, parents, aunts and uncles, and other family members within the circle of consanguinity.” AA67; *see* 28 U.S.C. § 455(b)(5)(iii) (requiring recusal if “a person within the third degree of relationship” to judge or judge’s spouse “could be substantially affected by the outcome of the proceeding”). “Such a system would be wholly unworkable” and “would push the Court down a slippery slope

that could require recusal in many situations well beyond the carefully crafted parameters of Section 455.” AA67-68.

The burden on litigants would also be substantial. Litigants would have to try to identify, for each case in which they are a party, all individuals “within the third degree of relationship” to the judge and the judge’s spouse. 28 U.S.C. § 455(b)(5)(iii). They would then have to try to investigate every one of the hundreds of law firms and other entities with which they have relationships to determine whether those entities employ any of the judge’s family members. If an entity with which a litigant does business employed one of the judge’s relatives, the litigant would have to try to determine whether that entity could be substantially affected by the litigation. This “daunting task”—particularly so for large companies like Medtronic—“outweighs any benefit of eliminating the remote possibility of consequential bias.” *Kan. Pub. Employees Ret. Sys.*, 85 F.3d at 1362.

B. Judge Kyle’s comments to the press do not require recusal.

Plaintiffs also seek recusal based on Judge Kyle’s brief responses to press inquiries about plaintiffs’ intent to move for recusal. Plaintiffs do not suggest that a judge’s comments to the press per se require recusal. To the contrary, courts have repeatedly rejected recusal based on such comments. *See In re Monsanto Co.*, 862 So. 2d 595, 632 (Ala. 2003) (collecting cases).

Instead, plaintiffs argue that Judge Kyle’s comments “suggest[] predetermination of the outcome.” PB79. That argument is baseless. According to the press reports cited by plaintiffs, Judge Kyle merely stated that—based on the facts vaguely described in the February 12, 2009 conference call during which plaintiffs announced their intent to seek recusal—he did not think he had a conflict and was “not sure that it is an issue.” Dkt. 247, Exhs. A-C. These comments, as Judge Kyle later explained, “accurately reflected the state of affairs as [it] existed at the time.” AA62; *see also Philips v. Joint Legislative Comm. on Performance & Expenditure Review*, 637 F.2d 1014, 1019 n.6 (5th Cir. 1981) (judge is obligated to recuse himself even without a formal motion if grounds for recusal exist). Judge Kyle never suggested that he “would ignore the facts Plaintiffs intended to present” in their ensuing motion. AA62.

Moreover, “opinions formed by the judge on the basis of facts introduced ... in the course of the current proceedings ... do not constitute a basis for a bias or partiality motion unless they display a deep-seated favoritism or antagonism.” *Litky*, 510 U.S. at 555. Judge Kyle based his comments to the press on facts alleged by plaintiffs during the February 12 call. Because Judge Kyle’s comments do not “display deep-seated favoritism or antagonism,” recusal based on those comments would be improper.

In re Boston's Children First, 244 F.3d 164 (1st Cir. 2001), cited by plaintiffs (PB79), “is readily distinguishable.” AA63. *Boston's Children* is a “highly idiosyncratic case” where recusal was required because the district judge wrote a letter to a newspaper and spoke with a reporter to defend her delay in resolving class certification. 244 F.3d at 166, 171. In this case, by contrast, Judge Kyle merely provided a brief comment on plaintiffs’ initial assertion of conflict. Moreover, unlike *Boston's Children*, Judge Kyle did not affirmatively contact the press to defend any ruling. To the contrary, the press contacted Judge Kyle “within hours of [the February 12] call, even though no transcript or other public record of that call had yet been filed.” AA62 n.9.

Caperton v. A.T. Massey Coal Co., 129 S. Ct. 2252 (2009), also cited by plaintiffs (PB79-80), is even further afield. Addressing facts that were “extreme by any measure,” *Caperton* held that the Due Process Clause required a state judge to recuse himself from an appeal filed by a litigant who had contributed \$3 million to the judge’s campaign while the appeal was pending. 129 S. Ct. at 2263-65. *Caperton* has no conceivable relevance here.

CONCLUSION

The judgment of the district court should be affirmed in all respects.

Respectfully submitted.

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September 21, 2009

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Case No. 09-2290

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CERTIFICATE OF SERVICE

I hereby certify that on this 21st day of September, 2009, I served a total of six copies of the foregoing Brief for the Appellees by overnight delivery on Appellants herein, two to each of the following addresses:

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