

No. 2009-04561

*To Be Argued By:*  
Kenneth S. Geller  
*Time Requested: 15 Minutes*

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**New York Supreme Court  
Appellate Division — Second Department**

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NORMA MITARO AND JOSEPH MITARO,

*Plaintiffs-Appellants*

against.

MEDTRONIC, INC., et al.,

*Defendants-Respondents*

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On Appeal From The Supreme Court of Westchester County  
Clerk's Index No. 3642/08

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**BRIEF FOR THE RESPONDENTS**

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## PRELIMINARY STATEMENT

Presently on appeal is an order by the Honorable Francis A. Nicolai dismissing, as preempted by federal law, a number of product-liability claims involving Medtronic's Sprint Fidelis defibrillator leads, Class III medical devices that were approved for sale by the FDA through its Premarket Approval (PMA) process. Judge Nicolai's order follows a long line of preemption decisions by courts across the country in the two years since the Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999, 1008 (2008). *See* pages 15-16 & n.4, *infra*. In particular, it is consistent with orders dismissing identical claims brought on behalf of thousands of plaintiffs in both the federal Multidistrict Litigation and the consolidated Minnesota-state-court proceedings involving the same Fidelis leads. *See In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147 (D. Minn. 2009) (*In re Fidelis I*); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., Multidistrict Litig. No. 08-1905*, 2009 WL 1361313 (D. Minn. May 12, 2009) (*In re Fidelis II*); *In re Medtronic Sprint Fidelis Lead Prods. Liab. State Court Litig.*, No. 27-CV-07-22446, et al., 2009 WL 3417867 (Minn. D. Ct. Oct. 20, 2009) (*In re Fidelis State Court Litig.*). (Indeed, these courts also dismissed manufacturing-defect and express-warranty claims analogous to those that Judge Nicolai did not dismiss.)

As an FDA-approved Class III medical device, the Fidelis leads, by definition, “support[] or sustain[] human life” or “present[] 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, among other things, they “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; 21 U.S.C. § 360k(a).

Accordingly, as Judge Nicolai found (*see* RA9-14) and plaintiffs concede (PB27-31), the dispositive issue in this case is whether any of plaintiffs’ dismissed

claims fall into the narrow window left open by *Riegel* for “parallel claims” that do not differ from or add to existing federal requirements.<sup>1</sup> Plaintiffs attempt to show that their claims escape preemption—on the ground that they are “parallel” to federal requirements—but in so doing 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. Judge Nicolai correctly joined a host of courts that have rejected such transparent attempts to avoid the effect of Section 360k. *See* Part II, *infra*.

Plaintiffs also miss the mark when criticizing Judge Nicolai’s interpretation of *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001). *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 Federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. Other courts consistently have agreed with that interpretation. *See* Part II.D & III, *infra*.

Finally, courts have consistently rejected the argument that Section 360k does not apply to a device that has been recalled, and plaintiffs have not identified

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<sup>1</sup> “RA\_\_” refers to the Record on Appeal; “PB\_\_” refers to the Brief for Plaintiffs-Appellants.

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' position is not surprising. In any event, because plaintiffs do not dispute that Norma Mitaro's device was marketed and sold prior to the recall and at a time when it was subject to valid PMAs, this argument is simply irrelevant. *See Part IV infra.*

### QUESTIONS PRESENTED

1. Did the trial court correctly hold—consistent with a host of courts across the country—that the claims at issue here are expressly preempted by federal law because they would impose requirements on a Class III medical device with Premarket Approval that differ from or add to existing federal requirements?

Yes.

2. Did the trial court correctly hold that plaintiffs' negligence-per-se claim is barred by 21 U.S.C. § 337(a) and impliedly preempted because it impermissibly seeks to enforce obligations created by (and owed to) the FDA?

Yes.

3. Did the trial court correctly hold—consistent with every court to consider the issue—that (i) a Class I recall under 21 U.S.C. § 360h(e) *does not* invalidate the Food and Drug Administration's Premarket Approval for a device because an entirely separate statutory and regulatory procedure under 21 U.S.C. § 360e(e) governs withdrawal of PMA, and, (ii) in any event, a subsequent recall cannot effect the federal requirements and the preemption that attach to a device with PMA at the time it is sold?

Yes.

## 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 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*, 128 S. Ct. at 1003 (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).

In *Riegel*, the Supreme Court confirmed that, by enacting Section 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. 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.* at 1004 (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.* at 1005 (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) and 21 U.S.C. § 360e(d)(6)); *see also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000). Medtronic’s Fidelis leads received the FDA’s Premarket Approval after being subjected to this rigorous and exacting process. *See* pages 11-12, *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)).

### **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 342 (“Congress intended that the MDA be enforced exclusively by the Federal Government”); Brief for United States as *Amicus Curiae* Supporting Petitioners, *Warner-Lambert Co. v. Kent*, 552 U.S. 440 (2008) (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* Supporting Petitioner, *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.” RA9. The FDA approved the Fidelis leads through PMA-Supplements to Medtronic’s original PMA for the Transvene Lead System. RA40-42. Over time Medtronic’s leads have grown progressively smaller because a smaller lead takes up less space in a coronary vein, and therefore restricts less blood flow to the heart. RA44-45. 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. RA42.

On October 15, 2007, Medtronic announced a voluntary withdrawal of the Fidelis leads. RA66. 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).<sup>2</sup> The Agency observed that withdrawal was appropriate here because the leads were “slightly more prone to fracture” than a predecessor lead (the Quattro), 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 that plaintiffs’ factual allegations, as opposed to bare conclusions, must be taken as true for purposes of a motion to dismiss. That said, the complaint does not identify any FDA finding that even theoretically could provide a plausible basis for plaintiffs’ allegations about fraud and concealment. More importantly, as Judge Nicolai found (RA10-13), even with the benefit of the liberal standard on a motion to dismiss, none of the vague and conclusory allegations in the complaint brings any of the state-law claims that were dismissed into the narrow class of claims that can avoid preemption following *Riegel*.

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<sup>2</sup> 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*.

## 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. 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 (*id.*), 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)).<sup>3</sup>

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<sup>3</sup> 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., In re Fidelis I*, 592 F. Supp. 2d at 1153, 1156 n.11; *In re Fidelis State Court Litig.*, 2009 WL 3417867, at \*10 & n.11; *Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Wolicki-Gables v. Arrow Int’l, Inc.*, No. 8:08-CV-151,

Plaintiffs criticize the approval process for Fidelis leads and insinuate that the FDA did not conduct a “rigorous” review of the leads. *See* PB6-12. 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 review 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.

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). 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.

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2009 WL 2190069, at \*9 (M.D. Fla. July 22, 2009).

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.* (quoting 21 U.S.C. § 360k(a)).

As Judge Kyle observed in the federal MDL for *Fidelis* leads, 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.” *In re Fidelis I*, 592 F. Supp. 2d at 1152 (citations omitted).<sup>4</sup>

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<sup>4</sup> In addition to the federal MDL and state-court consolidated proceedings for the *Fidelis* leads (*see* page 1, *supra*), these cases include, *e.g.*, *Ilarraza v. Medtronic, Inc.*, No. CV 09-3264, 2009 WL 5245630 (E.D.N.Y. Dec. 28, 2009) (MDA preempted claim for negligence per se based on alleged manufacturing violations of the FDA’s CGMP/QSR regulation); *Funk v. Stryker Corp.*, No. H:09-00733, 2009 WL 4281389 (S.D. Tex. Dec. 1, 2009) (MDA preempted design-defect, manufacturing-defect, failure-to-warn, and statutory-fraud claims); *McQuiston v. Boston Scientific Corp.*, No. 07-1723, 2009 WL 4016120 (W.D. La. Nov. 19, 2009) (MDA preempted design-defect, manufacturing-defect, failure-to-warn, express-warranty, implied-warranty, and fraud claims); *Hughes v. Boston Scientific Corp.*, No. 2:08cv79, 2009 WL 3817586 (S.D. Miss. Nov. 12, 2009) (MDA preempted negligence, strict-liability, implied-warranty, failure-to-warn, and negligence-per-se claims); *Williams v. Allergan USA, Inc.*, No. CV-09-1160, 2009 WL 3294873 (D. Ariz. Oct. 14, 2009) (MDA preempted claims for negligence and strict liability); *Williams v. Cyberonics, Inc.*, 654 F. Supp. 2d 301 (E.D. Pa. 2009) (MDA preempted claims for manufacturing defect and implied warranty); *Covert v. Stryker Corp.*, No. 01:08CV447, 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.*, No. 06-2473, 2009 WL 1951821 (E.D. La. June

Plaintiffs' contention that Judge Nicolai did not understand what standard should be applied under CPLR 3211 (PB23-25), misses the mark. The fatal flaw in the claims that were dismissed is evident as a matter of law. All of those claims necessarily would impose requirements on the Fidelis leads that differ from or add

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30, 2009) (MDA preempted express warranty claim); *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769 (D. Minn. 2009) (MDA preempted claims for failure-to-warn, manufacturing defect, implied warranty, express warranty, misrepresentation, and fraud); *Miller v. DePuy Spine, Inc.*, 638 F. Supp. 2d 1226 (D. Nev. 2009) (MDA preempted claims for strict products liability, negligence, implied warranty, and express warranty); *Bausch v. Stryker Corp.*, No. 08 C 4248, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008) (MDA preempted claims for strict products liability and negligence); *Despain v. Bradburn*, 282 S.W.3d 814 (Ark. 2008) (MDA preempted claims for strict products liability and negligence); *Link v. Zimmer Holdings, Inc.*, 604 F. Supp. 2d 1174 (N.D. Ill. 2008) (MDA preempted claims for strict liability, negligence, and breach of warranty); *Blanco v. Baxter Healthcare Corp.*, 70 Cal. Rptr. 3d 566 (Cal. Ct. App. 2008) (MDA preempted claims for negligence, strict liability, and breach of implied warranty); *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298 (D. Colo. 2008) (MDA preempted claims for failure to warn and manufacturing-and-design-defect); *Heisner v. Genzyme Corp.*, No. 08-C-593, 2008 WL 2940811 (N.D. Ill. July 25, 2008) (MDA preempted claims of negligence per se); *Adkins v. Cytec, Corp.*, No. 4:07CV00053, 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.*, No. 11101/2002, 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*, 22 Misc. 3d 960 (N.Y. Sup. Ct. 2008) (MDA preempted claims for failure-to-warn, negligence, implied warranty, and express warranty).

to existing federal requirements for the device and thus are preempted by Section 360k(a).

## **II. Plaintiffs' Claims Do Not Fall Into The Narrow Exception To Preemption For Parallel Claims.**

Federal law and the PMA for the Fidelis leads impose federal requirements that control the design, manufacture, testing, marketing, labeling, and post-market surveillance of the devices. Accordingly, the only issue in this case is whether the claims that were dismissed would impose requirements on Medtronic that are “different from, or in addition to” those imposed by the PMA or other federal law. Recognizing this, plaintiffs attempt to show that each of those claims falls into the 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’ arguments (PB31-42), however, Judge Nicolai correctly held that none of the dismissed causes of action pleaded a true “parallel claim.”

In order to state a “parallel claim” that might avoid the preemptive effect of § 360k(a), 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 has explained, to be “parallel,” a state-law requirement must be “*identical*” to the existing federal requirements. *Lohr*, 518 U.S. at 495 (emphasis added); *cf. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 454 (2005) (requirement under state law must be “*genuinely* equivalent” to re-

quirement under Federal Insecticide, Fungicide, and Rodenticide Act to survive preemption as a parallel requirement). For example, if the applicable federal requirements merely *permit* the course of conduct that allegedly is *required* under state law, the state-law requirements would not be “parallel” to the federal requirement, but would be “in addition to the federal requirement and thus ... preempted.” *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 489 (7th Cir. 2005); *see also Cupek.*, 405 F.3d at 424 (“Any [state law] claim ... that Defendant failed to warn patients beyond warnings required by the FDA, or that Defendant failed to recall a product without first going through the PMA supplement process” would “not parallel federal safety requirements.”) (internal quotation marks omitted). 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. *See In re Fidelis Leads I*, 592 F. Supp. 2d at 1152 (true parallel claims are not preempted because “they do not *add to* or *differ from* federal requirements”).

Plaintiffs’ discussion of parallel claims, and their brief generally, at times conflates general conflict preemption with the express statutory preemption under § 360k(a) of the MDA. PB25-27, 36-37, 47-48. To support this erroneous standard, plaintiffs cite *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001)—a pre-*Riegel* case applying *Lohr*. *See* PB47-48. But *Riegel* made clear that the standard discussed in *Lohr* does not apply to devices with PMA and that the MDA’s ex-

press-preemption clause preempts any state-law requirement that would be “different from, or in addition to, federal requirements.” 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. Ultimately, plaintiffs admit that, “state laws which ‘parallel’ federal laws are not preempted, so long as they neither add to nor vary federal requirements.” PB29-30 (internal quotation marks omitted).<sup>5</sup>

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<sup>5</sup> Several aspects of plaintiff’s account of parallel claims either miss the mark or require further explanation. First, they identify *Purcel v. Advanced Bionics Corp.*, No. 03:07-CV-1777, 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008), as a paradigm of a parallel claim. PB30. In *Purcel*, however, the plaintiff’s negligence claim tracked *a lawsuit by the FDA* against the manufacturer for violations of the federal regulations governing the device at issue.

Second, plaintiffs quote extensively from *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009). PB31. But that case has been rejected not only in the Fidelis leads MDL (*see In re Fidelis II*, 2009 WL 1361313, at \*3), but also by several other courts as fundamentally inconsistent with *Riegel*. *See Ilarraza*, 2009 WL 5245630, at \*6; *Covert*, 2009 WL 2424559, at \*5, \*12-\*13; *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 284-85 (E.D.N.Y. 2009).

Third, plaintiffs invoke the 1996 Supreme Court decision in *Lohr*, as well as other cases predating *Riegel* (*e.g.*, *Brooks*, 273 F.3d 785; *In re Medtronic, Inc. Implantable Defibrillators Litig.*, 465 F. Supp. 2d 886 (D. Minn. 2006)). PB28-29. But *Lohr* held that § 360k(a) does not preempt state-law claims involving devices that were approved via the FDA’s “510k,” or “substantial equivalence,” process. *Riegel*, which largely supersedes *Lohr*, held that § 360k(a) *does* preempt state-law claims involving devices approved via the far more stringent PMA process. It is undisputed that the device at issue here received PMA, making *Riegel*, not *Lohr*, the applicable authority. The other pre-*Riegel* decisions must be read in light of the Supreme Court’s *subsequent* holding and plaintiff’s interpretation of them is simp-

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. *In re Fidelis I*, 592 F. Supp. 2d at 1158; *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).").

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*, 613 F. Supp. 2d at 282; *see also Parker*, 584 F. Supp. 2d at 1301-02; *Bausch*, 2008 WL 5157940, at \*4. In other words, a plaintiff must *link* the breach of a federal requirement (that is the same as a state law duty) to his alleged and legally cognizable injuries.

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ly no longer good law.

Finally, plaintiffs rely on a federal regulation purporting to interpret § 360k(a), 21 C.F.R. § 808.1 (PB26), but the *Riegel* court concluded that § 808.1 is ambiguous, arguably inconsistent with the statute, and "can add nothing to [the preemption] analysis but confusion." 128 S. Ct. at 1010-11.

Finally, 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 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 III, *infra*.

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

**A. Failure to warn**

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.<sup>6</sup> Here, as Judge Kyle explained

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<sup>6</sup> *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*, 22 Misc. 3d at 962-64; *Kemp v. Pfizer, Inc.*, 835 F. Supp. 1015, 1021 (E.D. Mich. 1993); *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; *see generally* cases cited at pages 15-16 n.4, *supra*.

in the federal MDL for Fidelis leads, “[p]laintiffs 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.” *In re Fidelis I*, 592 F. Supp. 2d at 1159. Thus, plaintiffs’ failure-to-warn claims would “impose requirements ‘different from or in addition to’ those approved by the FDA.” *Id.*; *see also In re Fidelis State Court Litig.*, 2009 WL 3417867, at \*12-\*13.

Plaintiffs’ own description of their failure-to-warn claims confirms that fact. They contend that, under FDA regulations, Medtronic “could have” given an additional but unspecified warning, that the FDA regulations “permit” label changes in certain limited circumstances, and that a manufacturer “may” add to or strengthen the label in certain situations. PB32-34. 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.

Indeed, the “requirements” that plaintiffs purport to reference in their complaint (PB32 (citing RA73-75)), have nothing to do with providing additional warnings to the public, but relate to PMA submissions and subsequent reporting obligations *to the FDA*. 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*. 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)* (last updated Jan. 7, 2010) (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, caused or contributed to the reportable event”); *see also* 21 C.F.R. § 803.16. 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 III, *infra*.

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. *See, e.g., In re Fidelis I*, 592 F. Supp. 2d at 1160 (“[w]here a federal requirement permits a course of conduct and the state makes it obligatory ... [the claim] is preempted” because it imposes a different or additional requirement) (internal quotation marks omitted); *see also, e.g., In re Fidelis State Court Litig.*, 2009 WL 3417867, at \*13; *McMullen*, 421 F.3d at 489-90 (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[], 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.”).<sup>7</sup>

Plaintiffs suggest that *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), should influence the outcome here because it “analyzed an almost identical statute” and found that manufacturers had a duty to amend warnings under federal law. PB33-34. That description fundamentally misrepresents *Wyeth*, which did *not* conclude that manufacturers have a *duty* to make additional warnings, but only that FDA regulations applicable to drug manufacturers *permit* additional warnings. The holding in *Wyeth*, which allowed a failure-to-warn claim against a drug manufacturer, was based on the fact that there is no express-preemption provision for drugs. *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 360k(a)—the statute that applies here but did not apply in *Wyeth*—state-law claims are preempted if they impose a requirement that *differs*

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<sup>7</sup> Indeed, 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.

*from or adds to* federal requirements. Thus, *Riegel* governs this case, and *Wyeth* is irrelevant here—it does not spare plaintiffs’ failure-to-warn claims from preemption under Section 360k(a). *See, e.g., In re Fidelis II*, 2009 WL 1361313, at \*3 n.1.

## **B. Design defect**

Plaintiffs contest Judge Nicolai’s observation that the design-defect claim would “require a jury to find that the older design of the Sprint Fidelis Leads was unsafe.” PB35. Yet they describe their design-defect claim as requiring a finding that the leads were “unreasonably dangerous for [their] intended use.” *Id.* The decisive point is that the FDA specifically approved the design for the leads and any argument that the leads should have been designed differently, or were “unreasonably dangerous” as designed, necessarily seeks to impose different or additional requirements. Judge Nicolai plainly was correct to agree with every other court to consider this type of claim and hold that design-defect claims are preempted by the MDA. *See, e.g., Riegel*, 128 S. Ct. at 1005-06 (“the MDA pre-empt[s] ... claims of ... negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of the [device]”); *In re Fidelis I*, 592 F. Supp. 2d at 1157-63 (similar); *In re Fidelis State Court Litig.*, 2009 WL 3417867, at 13 (“Plaintiffs ignore the fact that the FDA specifically approved the design and proposed manufacturing processes when it gave the Leads their PMA.”); *see generally* cases cited at pages 15-16 n.4, *supra*.

As shown below (see Part IV, *infra*), plaintiffs are mistaken when they suggest (at PB35) that the FDA recall classification had an effect on preemption. And, as we next discuss in more detail, they also are mistaken to imply that Medtronic “violat[ed] federal law” by continuing to sell the original version of the Fidelis lead after it received approval to manufacture a modified version. PB35 (citing RA63). In any event, these allegations are simply irrelevant here because Norma Mitaro’s lead was implanted in 2005 (PB3), two years before the approval of the modified version and the recall, both of which occurred in 2007 (RA63).<sup>8</sup>

### **C. Negligence**

Plaintiffs contend that their negligence claims avoid preemption because they allege that, after Medtronic received approval to modify the design of the leads, it “should have ceased use of [its original model] and only sold the FDA-approved alternative design.” PB36. 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.” PB36-37. But plaintiffs have again 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 re-

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<sup>8</sup> Moreover, plaintiffs do not allege that Norma Mitaro’s lead malfunctioned in any way related to the modification of the lead in 2007.

quirements. Plaintiffs identify no existing federal source for the requirements that they seek to impose on Medtronic through this negligence claim.

In fact, such a requirement would be 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 (in the absence of an FDA decision to withdraw approval of the prior iteration). Indeed, plaintiffs acknowledge that the FDA approved the Fidelis leads via a PMA-Supplement to the original Transvene Lead PMA. *See* PB6-8. 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 not only the Transvene lead but also the Quattro model that plaintiffs now cite as the standard by which the Fidelis leads should be judged). 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”).

Similarly, plaintiffs have not identified any federal requirement that manufacturers “seek necessary modifications” to a device at any particular time. PB37. Again, there is no such regulation. Furthermore, to the extent that plaintiffs are suggesting that Medtronic misrepresented information in a PMA-Supplement application or failed to follow through on reporting obligations to the FDA (PB37), that claim is impliedly preempted under *Buckman*. See Part III, *infra*.

Once again, the MDL court considered and rejected these very arguments, observing that “Plaintiffs have nowhere identified a federal requirement mandating a manufacturer to stop selling a device when an ‘improved’ version thereof is granted PMA” and “have similarly failed to identify any federal requirement to support their assertion that ‘[u]pon receiving notice of the defect, Medtronic had a duty to take reasonable steps to improve the safety of the Sprint Fidelis leads.’” *In re Fidelis I*, 592 F. Supp. 2d at 1162. The court concluded that “Plaintiffs have not pointed to any federal requirements ‘parallel’ to those they seek to foist onto Medtronic in their design-defect claims,” and that as a result the claims were preempted. *Id.* at 1163. So too here, as the court below properly held.

In any event, as noted above (at 26), plaintiffs cannot claim injury from continuing sales of the original leads in 2007 because Norma Mitaro’s lead was im-

planted in 2005, years before the subsequent modification of the leads was approved.

**D. Negligence per se**

Negligence per se claims are barred by 21 U.S.C. § 337(a), which specifies that all actions to enforce the FDCA “shall be by and in the name of the United States.” “[T]he doctrine of per se liability does not create an independent basis of tort liability but rather establishes, by reference to a statutory scheme, the standard of care appropriate to the underlying tort.” *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d 781, 790 (3d Cir. 1999); *see also Elliott v. City of New York*, 95 N.Y.2d 730, 734 (2001). By definition, then, any “per se” claim does not invoke a pre-existing state-law obligation, but merely assigns a state-law moniker to enforcement of a federal regulation. Courts consistently have seen through such transparent efforts to plead around § 337(a). *See, e.g., In re Fidelis I*, 592 F. Supp. 2d at 1163; *In re Fidelis State Court Litig.*, 2009 WL 3417867, at \*20 (“Where a statute expressly precludes a private right of action to enforce its provisions, litigants cannot avoid these limits by crafting negligence per se claims for violation of the statutory scheme.”); *Ilarraza*, 2009 WL 5245630, at \*3-\*6; *In re Orthopedic Bone Screw Prods. Liab. Litig.*, 193 F.3d at 790; *Mylan Labs., Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (describing effort to effectively enforce the FDCA through the Lanham Act as an “attempt, by ingenious pleading, to escape one prin-

principle of law by making it appear that another not truly appropriate rule is applicable”).

As discussed in more detail below (see Part III, *infra*), negligence-per-se claims also are precluded by the closely related implied-preemption doctrines at issue in *Buckman* because they impermissibly seek to interfere with the FDA’s exclusive authority to enforce its own regulations. *See* 531 U.S. at 352-53. As plaintiffs admit, *Buckman* preempts any claim for which “the existence of [a] federal enactment[] [is] a critical element.” PB43-44. Yet the existence of a federal enactment is, by definition, a “critical element” in a negligence-per-se claim. If it were not—*i.e.*, if the claim could be stated without reference to the regulation—then it would simply be a negligence claim. For this reason as well, Judge Nicolai correctly dismissed plaintiffs’ negligence-per-se claim.

Once again, plaintiffs fail to identify a single case adopting the position that they urge on this Court.

#### **E. Implied warranty**

Any claim that the Fidelis leads violated an implied warranty of merchantability or fitness for a particular purpose necessarily depends on a finding that the leads were unsafe or ineffective—*i.e.*, “not fit for the ordinary purposes for which [they were] used” (PB41 (internal quotation marks omitted))—and thus should have been designed, manufactured, labeled or sold differently from the manner ap-

proved by the FDA. *Riegel* is, again, on-point authority that such claims are preempted. See 128 S. Ct. at 1005-06 (“the MDA pre-empt[s] ... claims of ... breach of implied warranty”); see also, e.g., *id.* at 1002 (the MDA “bars common-law claims challenging the safety and effectiveness of a medical device given pre-market approval”); *In re Fidelis I*, 592 F. Supp. 2d at 1163-64; *In re Fidelis State Court Litig.*, 2009 WL 3417867, at 14; see generally cases cited at pages 15-16 n.4, *supra*.

Once again attempting to undo *Riegel* rather than respond to it, plaintiffs invoke 21 C.F.R. § 808.1(d)(1), which states that the MDA does not preempt claims based on laws “of general applicability” such as the UCC. PB41. But *Riegel* considered and rejected this very argument, finding that Section 808.1 is ambiguous, arguably inconsistent with the statute, and “can add nothing to our analysis but confusion.” 128 S. Ct. at 1011. Plaintiffs’ suggestion that *Riegel* ultimately “confirmed” that UCC warranty claims are excluded from preemption (PB42) is simply false. *Riegel* explicitly held that implied-warranty claims *are* preempted (128 S. Ct. at 1005-06) and rejected the distinction Plaintiffs attempt to resurrect under Section 808.1 (*id.* at 1010-11). See also *In re Fidelis I*, 592 F. Supp. 2d at 1163-64 (noting that “the *Riegel* plaintiffs made this same argument, and the Supreme Court rejected it”); *In re Fidelis State Court Litig.*, 2009 WL 3417867, at 14 (similar). Plaintiffs’ invocation of *Lohr* and another pre-*Riegel* decision as their only support

for this argument (PB41) is consistent with their futile effort to resist *Riegel*—but that is simply not the law that this Court must apply. *See* pages 19-20 n.5, *supra*.<sup>9</sup>

**F. Plaintiffs do not dispute the dismissal of other claims.**

Plaintiffs do not contest Judge Nicolai’s dismissal of their causes of action for negligent misrepresentation, intentional misrepresentation, fraud, constructive fraud, negligent infliction of emotional distress, unjust enrichment, violation of New York’s General Business Law, and their claim under the Medicare Secondary Payer Statute. *See* RA11-13.

**III. The Trial Court Correctly Applied *Buckman*.**

Plaintiffs’ brief, like their complaint, contains 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, e.g.*, PB11-23. These spurious allegations do not save plaintiffs’ claims from dismissal on preemption grounds. As Judge Nicolai correctly held, any claim that depends on the allegation that Medtronic violated FDA reporting or procedural requirements is barred by 21 U.S.C. § 337(a) and impliedly preempted by *Buckman*. *See* RA11-12.

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<sup>9</sup> Plaintiffs also make an extensive but ultimately irrelevant argument about “warranties [Medtronic] voluntarily made.” PB42-43. Implied warranties are, by definition, not “voluntarily made” but are implied by law. As noted, Judge Nicolai declined to dismiss plaintiffs’ express-warranty claim, although the court recognized the limitations on such a claim. RA12-13.

At the outset, it is important to note that, among the claims that plaintiffs seek to resuscitate in this appeal, only their negligence-per-se claim directly implicates this issue because Judge Nicolai found that all of the other claims were expressly preempted by Section 360k. *See* RA10-13. Nevertheless, the implied preemption doctrine in *Buckman* and the bar on private causes of action that seek to enforce the FDCA under Section 337 are an important element in the preemption equation.

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. 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.

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.<sup>10</sup> 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 violation (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.<sup>11</sup>

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<sup>10</sup> 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.”).

<sup>11</sup> This result does not leave a plaintiff who suspects fraud without recourse. As

For all of these reasons, courts have consistently agreed with Judge Nicolai (RA11-12) 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*, 638 F. Supp. 2d at 1231 (“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*, 2009 WL 2424559, at \*7-\*8; *Delaney v. Stryker Orthopaedics*, No. 08-03210, 2009 WL 564243, at \*4 (D.N.J. Mar. 5, 2009); *McCutchen v. Zimmer Holdings, Inc.*, 586 F.

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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.*

Supp. 2d 917, 922 (N.D. Ill. 2008); *Link*, 604 F. Supp. 2d at 1179; *Lake*, 22 misc. 3d at 962-64.

Once again, plaintiffs ignore the case law against them and fail to identify a single case supporting their position. *See* PB43-45.<sup>12</sup>

#### **IV. The Recall Classification Is Irrelevant.**

In a last-ditch effort to avoid preemption entirely, plaintiffs contend that, because the FDA designated Medtronic's voluntary withdrawal a recall, "there are no federal requirements [for the leads]." PB46. But, like Judge Nicolai (RA12), 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., In re Fidelis I*, 592 F. Supp. 2d at 1155-56; *Bausch*, 2008 WL 5157940, at \*3; *Kemp*, 835 F. Supp. at 1023; *In re Fidelis State Court Litig.*, 2009 WL 3417867, at 11; *Blanco*, 70 Cal. Rptr. 3d at 579-80; *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127, 132 (Tex. App. 2005), *cert. denied*, 128 S. Ct. 1441 (2008); *cf. Colombini*,

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<sup>12</sup> 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*, 552 U.S. 440 (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.

2009 WL 2170230, at \*3-\*4 (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 made and 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. *Cf. Talbott*, 63 F.3d at 28 (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).<sup>13</sup>

Plaintiffs attempt to avoid this controlling law by asserting that there are no federal requirements for an “adulterated” device. PB47. But, as Judge Kyle held in the Fidelis MDL, “it is the FDA’s task to determine whether medical devices are

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<sup>13</sup> The stock language that plaintiffs quote from a form letter sent to Medtronic regarding the Fidelis recall (*see* PB47) 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 11-12, *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 II, *supra*.

adulterated, and only the FDA may ‘take action with respect to adulterated products.’” *In re Fidelis I*, 592 F. Supp. 2d at 1162 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 authority 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. PB46-48. 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 III, *supra*.

**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 Nicolai found, "plaintiff, Norma Mitaro, was implanted with the ICD before the recall such that, at the time they were implanted, the premarket approval for the Sprint Fidelis leads was in place." RA12; *see also In re Fidelis I*, 592 F. Supp. 2d at 1156 ("Plaintiffs' argument ignores that PMA for the Sprint Fidelis leads was in place *at the time the leads were implanted*" which "is what matters"); *Kemp*, 835 F. Supp. at 1023 (preemption applied despite recall because, "when the [device] was implanted ..., [it] had received pre-market approval"); *In re Fidelis State Court Litig.*, 2009 WL 3417867, at 11 (similar); *Blanco*, 70 Cal. Rptr. 3d at 580-81 (similar). In other words, because plaintiffs contend that the lead Norma Mitaro 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. *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 defect, is defective in design, or is defective because of inadequate instructions or warnings.”) (emphasis added).

Plaintiffs dispute Judge Nicolai’s conclusion by, once again, conflating the general constitutional doctrine of conflict preemption with the statutory express preemption at issue here. PB47-48. As noted above (at 18-19 & n.5), the MDA’s express-preemption clause preempts any state-law requirement that would *add to* or *differ from* federal requirements and a “conflict” between the requirements is not required.

### **CONCLUSION**

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

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Respectfully submitted.

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## **CERTIFICATE OF COMPLIANCE**

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