

Nos. A09-2263, A09-2270, A09-2278, A09-2280, A09-2283,
A09-2284, A09-2285, A09-2292, A09-2298

IN THE MINNESOTA COURT OF APPEALS

IN RE MEDTRONIC, INC. SPRINT FIDELIS LEAD
PRODUCTS LIABILITY STATE COURT LITIGATION

SCOTT A. JOEST, ROBERT T. BELL, MARY MANNING, ROBERT MORRISON, ET AL.,
SHIRLEY BEBEAU, CARL ESCHETE, ET AL., DENNIS C. DIAMOND, DONALD FLO-
RENCE, ET AL., LINDA BRUE, *Plaintiffs–Appellants*,

v.

MEDTRONIC, INC., ET AL., *Defendants–Appellees*.

On Appeal From The District Court of Minnesota,
Fourth Judicial District, Hennepin County

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TABLE OF CONTENTS

	Page
TABLE OF AUTHORITIES	iii
ISSUES PRESENTED.....	1
STATEMENT OF FACTS	3
A. Statutory And Regulatory Background.....	3
1. The rigorous Premarket Approval process for Class III devices.....	5
2. Ongoing post-approval reporting for approved devices	8
3. Enforcement of FDA requirements for approved devices.....	8
B. The Fidelis Leads	9
SUMMARY OF THE ARGUMENT	12
STANDARD OF REVIEW	15
ARGUMENT	15
I. The MDA’s Express-Preemption Clause Preempts State-Law Causes Of Action Such As Those Pleaded By Plaintiffs.....	15
II. Plaintiffs’ Claims Do Not Fall Into The Exception To Preemption For Parallel Claims.....	22
A. Manufacturing defect	25
B. Express warranty	31
C. Misrepresentation and consumer protection	35
III. The Recall Classification Is Irrelevant.	37
A. Recall does not invalidate Premarket Approval.....	38
B. Plaintiffs’ claims would be preempted even if recall did invalidate Premarket Approval.....	42
IV. The District Court Correctly Applied <i>Buckman</i>	44
A. <i>Buckman</i> and Section 337(a) bar claims for which the regulatory scheme is an essential element.	45
B. <i>Buckman</i> and Section 337(a) bar plaintiffs’ claims based on alleged violations of reporting and other obligations Medtronic owed to the FDA.	49

TABLE OF CONTENTS
(continued)

	Page
CONCLUSION	51
CERTIFICATE OF COMPLIANCE WITH RULE 132.01(3)(a)(1).....	53

TABLE OF AUTHORITIES

	Page(s)
CASES	
<i>Adkins v. Cytac Corp.</i> , 2008 WL 2680474 (W.D. Va. July 3, 2008)	21, 30
<i>Anthony v. Stryker Corp.</i> , 2010 WL 1387790 (N.D. Ohio Mar. 31, 2010).....	18, 22, 26, 29
<i>Bagumyan v. Medtronic, Inc.</i> , No. BC 385151, slip op. (Cal. Sup. Ct. May 29, 2009).....	20, 26
<i>Baker v. St. Jude Med., S.C., Inc.</i> , 178 S.W.3d 127 (Tex. App. 2005).....	38
<i>Banner v. Cyberonics, Inc.</i> , 2010 WL 455286 (D.N.J. Feb. 4, 2010)	19
<i>Bates v. Dow Agrosiences LLC</i> , 544 U.S. 431 (2005).....	2, 17, 23
<i>Bausch v. Stryker Corp.</i> , 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008).....	21, 24, 30, 38
<i>Bell Atlantic Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	11
<i>Bencomo v. Guidant Corp.</i> , 2009 WL 1951821 (E.D. La. June 30, 2009)	20, 33
<i>Blanco v. Baxter Healthcare Corp.</i> , 70 Cal. Rptr. 3d 566 (Cal. Ct. App. 2008).....	21, 38, 42
<i>Blunt v. Medtronic, Inc.</i> , 760 N.W.2d 396 (Wis. 2009)	20
<i>Buckman Co. v. Plaintiffs’ Legal Comm.</i> , 531 U.S. 341 (2001).....	<i>passim</i>
<i>Clark v. Medtronic, Inc.</i> , 572 F. Supp. 2d 1090 (D. Minn. 2008).....	21
<i>Colombini v. Westchester County Health Care Corp.</i> , 2009 WL 2170230 (N.Y. Sup. Ct. July 6, 2009).....	20, 23, 38
<i>Covert v. Stryker Corp.</i> , 2009 WL 2424559 (M.D.N.C. Aug. 5, 2009)	19, 22, 29, 49
<i>Cupek v. Medtronic, Inc.</i> , 405 F.3d 421 (6th Cir. 2005)	16

TABLE OF AUTHORITIES
(continued)

	Page(s)
<i>Despain v. Bradburn</i> , 282 S.W.3d 814 (Ark. 2008).....	21
<i>DM Research, Inc. v. Coll. of Am. Pathologists</i> , 170 F.3d 53 (1st Cir. 1999).....	30
<i>Dorsey v. Allergan, Inc.</i> , 2009 WL 703290 (M.D. Tenn. Mar. 11, 2009).....	20
<i>Elzie v. Comm’r of Pub. Safety</i> , 298 N.W.2d 29 (Minn. 1980).....	15
<i>Funk v. Stryker Corp.</i> , 673 F. Supp. 2d 522 (S.D. Tex. 2009).....	19, 22, 29, 36
<i>Heisner v. Genzyme Corp.</i> , 2010 WL 894054 (N.D. Ill. Mar. 8, 2010).....	18, 29
<i>Hofts v. Howmedica Osteonics Corp.</i> , 597 F. Supp. 2d 830 (S.D. Ind. 2009).....	21, 22, 28, 35
<i>Horowitz v. Stryker Corp.</i> , 613 F. Supp. 2d 271 (E.D.N.Y. 2009).....	<i>passim</i>
<i>Huber v. Howmedical Osteonics Corp.</i> , 2009 WL 2998160 (D.N.J. Mar. 10, 2009)	33
<i>Hughes v. Boston Scientific Corp.</i> , 669 F. Supp. 2d 701 (S.D. Miss. 2009)	19, 40, 49, 50
<i>Ilarraza v. Medtronic, Inc.</i> , 2009 WL 5245630 (E.D.N.Y. Dec. 28, 2009).....	19, 22, 26, 29
<i>Kemp v. Medtronic, Inc.</i> , 231 F.3d 216 (6th Cir. 2000)	8
<i>Kemp v. Pfizer, Inc.</i> , 835 F. Supp. 1015 (E.D. Mich. 1993).....	38, 42
<i>Lake v. Kardjian</i> , 874 N.Y.S.2d 751 (N.Y. Sup. Ct. 2008).....	21, 33, 49
<i>Lemelle v. Stryker Orthopaedics</i> , 2010 WL 996523 (W.D. La. Mar. 15, 2010).....	18, 22, 29
<i>Link v. Zimmer Holdings, Inc.</i> , 604 F. Supp. 2d 1174 (N.D. Ill. 2008).....	21, 49
<i>Mahoney & Hagberg v. Newgard</i> , 729 N.W.2d 302 (Minn. 2007).....	15

TABLE OF AUTHORITIES
(continued)

	Page(s)
<i>McCutchen v. Zimmer Holdings, Inc.</i> , 586 F. Supp. 2d 917 (N.D. Ill. 2008).....	49
<i>McGuan v. Endovascular Techs., Inc.</i> , 2010 WL 445602 (Cal. Ct. App. Feb. 9, 2010)	19, 36, 49
<i>McQuiston v. Boston Scientific Corp.</i> , 2009 WL 4016120 (W.D. La. Nov. 19, 2009).....	19, 36
<i>Medtronic, Inc. v. Lohr</i> , 518 U.S. 470 (1996)	7, 23
<i>In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.</i> , 592 F. Supp. 2d 1147 (D. Minn. 2009).....	passim
<i>In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.</i> , 2009 WL 294353 (D. Minn. Feb. 5, 2009).....	30
<i>In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.</i> , 2009 WL 1361313 (D. Minn. May 12, 2009)	2, 20, 22
<i>Michael v. Shiley, Inc.</i> , 46 F.3d 1316 (3d Cir. 1995).....	33
<i>Micro Motion, Inc. v. Kane Steel Co.</i> , 894 F.2d 1318 (Fed. Cir. 1990)	31
<i>Miller v. DePuy Spine, Inc.</i> , 638 F. Supp. 2d 1226 (D. Nev. 2009).....	20, 32, 48
<i>Mitaro v. Medtronic, Inc.</i> , 886 N.Y.S.2d 71, 2009 WL 1272398 (N.Y. Sup. Ct. 2009)	28, 38, 49
<i>Moore v. Sulzer Orthopedics, Inc.</i> , 337 F. Supp. 2d 1002 (N.D. Ohio 2004)	37
<i>Mullin v. Guidant Corp.</i> , 970 A.2d 733 (Conn. App. Ct. 2009).....	20
<i>Parker v. Stryker Corp.</i> , 584 F. Supp. 2d 1298 (D. Colo. 2008).....	21, 24, 30, 32
<i>Patton v. Newmar Corp.</i> , 538 N.W.2d 116 (Minn. 1995)	43
<i>Prudhel v. Endologix, Inc.</i> , 2009 WL 2045559 (E.D. Cal. July 9, 2009).....	28

TABLE OF AUTHORITIES
(continued)

	Page(s)
<i>Purcel v. Advanced Bionics Corp.</i> , 2008 WL 3874713 (N.D. Tex. Aug. 13, 2008)	27
<i>Radke v. County of Freeborn</i> , 676 N.W.2d 295 (Minn. Ct. App. 2004), <i>rev'd on other grounds</i> , 694 N.W.2d 788 (Minn. 2005)	30
<i>Rankin v. Boston Scientific Corp.</i> , 2010 WL 672135 (E.D. Ky. Feb. 19, 2010)	18
<i>Riegel v. Medtronic, Inc.</i> , 451 F.3d 104 (2d Cir. 2006).....	6, 7
<i>Riegel v. Medtronic, Inc.</i> , 552 U.S. 312 (2008).....	<i>passim</i>
<i>Riley v. Cordis Corp.</i> , 625 F. Supp. 2d 769 (D. Minn. 2009)	<i>passim</i>
<i>Risavich v. Medtronic, Inc.</i> , No. 08-14183, slip op. (N.Y. Sup. Ct. Feb. 1, 2010).....	19
<i>Risavich v. Medtronic, Inc.</i> , No. 08-14183	19
<i>Rollins v. St. Jude Medical</i> , 583 F. Supp. 2d 790 (W.D. La. 2008)	28
<i>Steele v. Depuy Orthopaedics, Inc.</i> , 295 F. Supp. 2d 439 (D.N.J. 2003)	38
<i>Talbott v. C.R. Bard, Inc.</i> , 63 F.3d 25 (1st Cir. 1995)	<i>passim</i>
<i>Thiele v. Stich</i> , 425 N.W.2d 580 (Minn. 1988).....	28, 34
<i>Williams v. Allergan USA, Inc.</i> , 2009 WL 3294873 (D. Ariz. Oct. 14, 2009).....	19
<i>Williams v. Cyberonics, Inc.</i> , 654 F. Supp. 2d 301 (E.D. Pa. 2009)	19
<i>Wolicki-Gables v. Arrow Int'l, Inc.</i> , 641 F. Supp. 2d 1270 (M.D. Fla. 2009).....	16, 19, 26
 STATUTES, REGULATIONS, AND RULES	
18 U.S.C. § 1001 (1994 & Supp. IV 1998)	9

TABLE OF AUTHORITIES
(continued)

	Page(s)
21 U.S.C. 360h(e)	41
21 U.S.C. § 301	3
21 U.S.C. § 332	9
21 U.S.C. § 333	9
21 U.S.C. § 333(a)	9
21 U.S.C. 333(f)(1)(A)	9
21 U.S.C. § 334	9
21 U.S.C. § 337(a)	<i>passim</i>
21 U.S.C. § 360	<i>passim</i>
21 U.S.C. § 360c	3, 5
21 U.S.C. § 360c(a)(1)(A)(i)	5
21 U.S.C. § 360c(a)(1)(B)	5
21 U.S.C. § 360c(a)(1)(C)	6
21 U.S.C. § 360c(a)(1)(C)(ii)	12
21 U.S.C. § 360c(a)(2)(B)	7
21 U.S.C. § 360c(a)(2)(C)	6
21 U.S.C. § 360e(c)	6
21 U.S.C. § 360e(c)(1)(G)	6
21 U.S.C. § 360e(d)	7
21 U.S.C. 360e(d)(1)(A)	6
21 U.S.C. § 360e(d)(6)(A)(i)	7

TABLE OF AUTHORITIES
(continued)

	Page(s)
21 U.S.C. § 360e(e).....	3, 38
21 U.S.C. § 360e(e)(1).....	38
21 U.S.C. § 360e(e)(2).....	39
21 U.S.C. § 360e(g)(1)(A).....	39
21 U.S.C. § 360h(e)	3, 38
21 U.S.C. § 360k.....	<i>passim</i>
21 U.S.C. § 360k(a)	<i>passim</i>
21 U.S.C. § 360k(a)(2).....	15
21 U.S.C. § 510(k)	45
Medical Device User Fee and Modernization Act of 2002, PUB. L. No. 107-250, 116 Stat. 1589, title I, § 101(1) (Oct. 26, 2002).....	46
PUB. L. No. 94-295, 90 Stat. 539 (1976).....	3, 4
21 C.F.R. § 7.3(g)	41
21 C.F.R. § 7.40	38
21 C.F.R. § 7.40(a).....	38
21 C.F.R. § 7.41	10
21 C.F.R. § 7.41(a).....	38
21 C.F.R. § 7.46(a).....	38
21 C.F.R. § 7.59	38
21 C.F.R. § 10.30.....	9, 48
21 C.F.R. § 10.45	39

TABLE OF AUTHORITIES
(continued)

	Page(s)
21 C.F.R. § 16.62	39
21 C.F.R. § 16.80	39
21 C.F.R. § 16.95(b)(2).....	39
21 C.F.R. § 16.120	39
21 C.F.R. § 803.50	8
21 C.F.R. § 803.50(a).....	8
21 C.F.R. § 808.1(d)	17
21 C.F.R. § 808.1(d)(1).....	36
21 C.F.R. § 810.10	38
21 C.F.R. § 810.18	38
21 C.F.R. § 814.39	7, 8
21 C.F.R. § 814.44	6, 7
21 C.F.R. § 814.44(a).....	6
21 C.F.R. § 814.44(e).....	7
21 C.F.R. § 814.46	38, 46
21 C.F.R. § 814.46(c).....	39
21 C.F.R. § 814.84	8
21 C.F.R. § 814.84(b)(2).....	8
Minn. R. Civ. P. 12.02(e).....	15

TABLE OF AUTHORITIES
(continued)

	Page(s)
OTHER AUTHORITIES	
Brief for United States as <i>Amicus Curiae</i> , <i>Buckman Co. v. Plaintiffs’ Legal Comm.</i> , 531 U.S. 341 (2001), No. 98-1768, 2000 WL 1364441 (Sept. 13, 2000)	9
Brief for United States as <i>Amicus Curiae</i> , <i>Warner-Lambert Co. v. Kent</i> , 128 S. Ct. 1168 (2008), No. 06-1498, 2007 WL 4218889 (Nov. 28, 2007).....	9
FDA, <i>Fraud, Untrue Statements of Material Facts, Bribery, and Illegal Gratuities; Final Policy</i> , 56 Fed. Reg. 46,191, 46,193 (Sept. 10, 1991).....	47
FDA, <i>Medical Device Quality Systems Manual: A Small Entity Compliance Guide</i> (1st ed. 1996) (HHS Pub. FDA 97-4179) (FDA, QS Manual), available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/default.htm	26
FDA, <i>Medtronic Recalls Sprint Fidelis Cardiac Leads: Questions and Answers for Consumers</i> , available at http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm103022.htm (last updated July 10, 2009).....	11
FDA, <i>Statement on Medtronic’s Voluntary Market Suspension of Their Sprint Fidelis Defibrillator Leads</i> , available at http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2007/ucm109007.htm (Oct. 15, 2007))	10
H.R. REP. NO. 94-853 (1976)	4
RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998)	43
S. REP. NO. 94-33 (1975), <i>reprinted in</i> 1976 U.S.C.C.A.N. 1070.....	4

ISSUES PRESENTED

This appeal does *not* present the far-reaching question plaintiffs suggest: Whether federal law “preempts *all possible* state law remedies” for alleged defects in a Class III medical device that has received Premarket Approval (PMA) from the Food and Drug Administration (FDA). Appellants’ Brief (AB) 1 (emphasis added). Instead, it involves only the much more limited question whether federal law preempts the claims actually pleaded in the nine representative complaints that were dismissed by the Honorable Denise Reilly.

As Judge Reilly recognized, Medtronic’s motion to dismiss is controlled by 21 U.S.C. § 360k(a) and the express-preemption principles that were announced by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008). These principles subsequently have been confirmed and applied in over 30 lower-court opinions across the country. Included among this consistent pattern of post-*Riegel* decisions dismissing claims similar to those here is that of the Honorable Richard Kyle of the United States District Court for the District of Minnesota in the federal multi-district litigation (MDL) for Medtronic’s Sprint Fidelis leads (Fidelis leads)—the device at issue in this litigation as well. There, Judge Kyle held that claims substantially identical to those here are preempted by federal law. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig. (In re Fidelis I)*, 592 F. Supp. 2d 1147 (D. Minn. 2009) (dismissing all claims in the master consolidated

complaint for the federal MDL involving the same device that is at issue in this litigation); *see also In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig. (In re Fidelis II)*, 2009 WL 1361313, at *2 (D. Minn. May 12, 2009) (denying request to amend complaint because, *inter alia*, all claims remained preempted).

Given *Riegel*, Judge Reilly plainly was correct to hold that none of the claims pleaded in the representative complaints here (which were based on the original and amended master consolidated complaints in the MDL) fall into the limited category of “parallel” claims that the *Riegel* Court identified as surviving preemption.

The issues actually presented by this appeal are:

1. Whether, as Judge Reilly held (JA588-97), all of plaintiffs’ claims are expressly preempted by federal law because they would impose requirements on a Class III medical device approved by the FDA via the PMA process that differ from or add to existing federal requirements.

Riegel v. Medtronic, Inc., 552 U.S. 312 (2008)

21 U.S.C. § 360k(a)

2. Whether, as Judge Reilly held (JA597-606), plaintiffs have failed to plead manufacturing-defect, express-warranty, misrepresentation, and consumer-protection claims that fall into the 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., 552 U.S. 312 (2008)

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

21 U.S.C. § 360k(a)

3. Whether, as Judge Reilly held (JA585-86), a Class I recall under 21 U.S.C. § 360h(e) has no effect on the FDA's PMA for a device because, *inter alia*, an entirely separate statutory and regulatory procedure under 21 U.S.C. § 360e(e) governs withdrawal of PMA.

Riegel v. Medtronic, Inc., 552 U.S. 312 (2008)

21 U.S.C. § 360e(e)

21 U.S.C. § 360h(e)

4. Whether, as Judge Reilly held (JA597-606), 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)

STATEMENT OF THE CASE AND THE 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), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1071; *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.*, 552 U.S. at 315 (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 in particular 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.*)—into the MDA. That provision specifies 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* JA582-84.

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. 552 U.S. at 326-27. 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 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* JA570-74. 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*, 552 U.S. at 312 (2008).

The FDA closely 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*, 552 U.S. at 318 (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 319 (citing 21 C.F.R. § 814.44(e)).

The Supreme Court has observed that obtaining “[p]remarket approval is a ‘rigorous’ process.” *Id.* at 317 (quoting *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996)). “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 318 (quoting 21 U.S.C. § 360e(d)).

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 319 (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*, 552 U.S. at 319 (citing 21 C.F.R. § 814.39(c)); *see also Kemp v. Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000). *See generally* JA572-73. Medtronic’s Fidelis leads received the FDA’s Premarket Approval after being subjected to this rigorous and exacting process. *See* pages 9-10, *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*, 552 U.S. at 319 (citing 21 C.F.R. §§ 803.50(a), 814.84(b)(2)). *See generally* JA573.

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

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.” JA569. The Fidelis leads are defibrillator leads designed and manufactured by Medtronic. The FDA approved the Fidelis leads through PMA-

Supplements to Medtronic’s original 1993 PMA for the Transvene Lead System. JA573-74. 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.” *In re Fidelis I*, 592 F. Supp. 2d at 1153 n.7. As plaintiffs admit, the FDA granted Premarket Approval to the four Fidelis leads at issue in this litigation—Models 6930, 6931, 6948, and 6949—on June 8, 2004, following a six-month-long evaluation of Medtronic’s PMA-Supplement applications. AB3-4; *see also* JA573-74.

On October 15, 2007, Medtronic announced a voluntary withdrawal of the Fidelis leads. JA575-76. The FDA classified that action as a Class I recall, pursuant to 21 C.F.R. § 7.41. *Id.* 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*

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*.

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 Reilly (*see* JA580-81)—that plaintiffs' factual allegations, as opposed to bare conclusions, must be taken as true for purposes of a motion to dismiss.² That said, the representative complaints do not identify any FDA finding that even theoretically could provide a plausible basis for plaintiffs' allegations about fraud and concealment. More importantly, as Judge Reilly found (JA588-606), even with the benefit of the liberal standard on a motion to dismiss, none of the vague and conclusory allegations in the complaints brings any of plaintiffs' state-law claims into the limited class of claims that can avoid preemption following *Riegel*. *See* Parts I, II, *infra*.

² Although Medtronic believes that the Minnesota Supreme Court eventually will adopt the pleading standard announced in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007)—and indeed Minnesota courts frequently follow federal decisions in interpreting Minnesota state rules that are identical to the parallel federal rules—there was no confusion on the correct standard below. Plaintiffs concede that Judge Reilly adopted the correct standard under current Minnesota law. AB11-12 n.8. And, as shown below, their contention that Judge Reilly nevertheless misconstrued their allegations reflects, not errors on Judge Reilly's part, but plaintiffs' adoption of new arguments on appeal.

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. 552 U.S. at 325. *Riegel* further observed that juries are ill-equipped to perform this cost-benefit analysis because, *inter alia*, they “see[] only the cost[s]” of a device—that is, its potential to cause harm—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 the cost-benefit analyses for such devices 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 321-28.

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 federal requirements.” JA583 (quoting 21 U.S.C. § 360k(a)).

As Judge Reilly recognized (JA586-88), the dispositive (and only real) issue in this case is whether plaintiffs’ claims fall into the window left open by *Riegel* for “parallel” claims that are the same as—*i.e.*, that do not differ from or add to—existing federal requirements. Plaintiffs argue that three categories of their claims—manufacturing defect, express warranty, and misrepresentation—constitute parallel claims, conceding that the remainder do not. AB19-31. But plaintiffs rely upon arguments that were expressly rejected in *Riegel*, and almost completely ignore the growing body of case law interpreting the parallel-claim exception, which has consistently rejected purported parallel claims like those pleaded here. *See* pages 18-21, *infra*. Plaintiffs’ cursory attempts to show that their claims escape preemption on this ground 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* Parts I, II, *infra*.

Courts also consistently have rejected plaintiffs’ alternative contention that the MDA’s express-preemption clause does not apply to a device that has been recalled. Indeed, plaintiffs do not identify a single case accepting it. Given the clear statutory and regulatory distinction between an FDA recall classification and a withdrawal of PMA, the uniform rejection of plaintiffs’ argument is not surprising. In any event, because plaintiffs do not dispute that their devices were marketed and sold prior to the recall and at a time when they were subject to valid PMAs, this argument is simply irrelevant. Plaintiffs’ assertion that litigation imposes “requirements” only with respect to future conduct is mistaken both legally and factually. *See Part III, infra.*

Plaintiffs similarly miss the mark when criticizing Judge Reilly’s interpretation of *Buckman*. 21 U.S.C. § 337(a) vests in the federal government the exclusive authority to enforce the FDCA and its implementing regulations. As Judge Reilly 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 Section 337(a). Other courts consistently have agreed with that interpretation. To the extent that a state-law claim cannot be stated without reference to the federal regulatory scheme, it necessarily is nothing more than a (perhaps circuitous) effort to enforce that scheme and thus is barred under *Buckman* and Section 337(a). *See Part IV, infra.*

STANDARD OF REVIEW

This Court reviews *de novo* the decision to grant a motion to dismiss under Minn. R. Civ. P. 12.02(e). *Mahoney & Hagberg v. Newgard*, 729 N.W.2d 302, 306 (Minn. 2007). If a claim is not legally sufficient, it must be dismissed. *Elzie v. Comm’r of Pub. Safety*, 298 N.W.2d 29, 32 (Minn. 1980).

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*, 552 U.S. at 321; *see also* JA583. 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*, 552 U.S. at 322), 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*, 552 U.S. at 322

("[p]remarket approval ... imposes [federal] 'requirements'" as that term is used in § 360k(a)); *see also* JA583.³

Plaintiffs criticize the approval process for Fidelis leads and insinuate that the FDA did not conduct a "rigorous" review of the leads. *See* AB4-7. 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) ("[N]othing 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.⁴

³ Because the device in *Riegel* was approved through the PMA-Supplement process, the Court's holding applies equally to requirements imposed by an original or a supplemental approval (as in this case). *Riegel*, 552 U.S. at 319-20; *see also, e.g., Cupek v. Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Wolicki-Gables v. Arrow Int'l, Inc.*, 641 F. Supp. 2d 1270, 1284 (M.D. Fla. 2009).

⁴ Plaintiffs belabor the supposed necessity for a "specific" federal requirement applicable to a device, yet they ultimately concede, as they must, that the PMA process imposes "specific" requirements. AB14-15 & n.13. In general, plaintiffs'

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). 552 U.S. at 313 (internal quotation marks omitted); *see also* JA584-85. 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*, 552 U.S. at 328.

Plaintiffs suggest that not all common-law causes of action create state “requirements” as that term is used in Section 360k, relying on language from a pre-*Riegel* Supreme Court opinion, *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), and one of the FDA’s implementing regulations, 21 C.F.R. § 808.1(d). AB15-16. But *Riegel* explicitly held that state duties imposed through litigation *do* create “requirements” under Section 360k. 552 U.S. at 323-27. That holding controls the interpretation of the MDA (and arguably overrules the language plaintiffs quote from *Bates*, which was interpreting a different but similarly worded statute). And *Riegel* explicitly held that the regulation plaintiffs cite was inconsistent with the statute, could not be coherently explained even by the FDA, and “can add noth-

brief misleadingly portrays the interpretation of Section 360k as if it were a matter of first impression to be decided according to the canons of statutory interpretation (AB12-16), when *Riegel* has established a mandatory and straightforward test to be applied in cases, such as this, where a device has received PMA.

ing to [the] analysis [of § 360k] but confusion.” 552 U.S. at 329. This Court now is bound by *Riegel*’s categorical statement that “reference to a State’s ‘requirements’ includes its common-law duties” (*id.* at 324), regardless of plaintiffs’ citation of outdated and discarded authority.

In sum, *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)). Subsequent case law has confirmed the broad scope of that preemption doctrine. 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 1152 (citations omitted). Other than the order presently on appeal, those cases include:

- *Anthony v. Stryker Corp.*, 2010 WL 1387790 (N.D. Ohio Mar. 31, 2010) (MDA preempted claim for manufacturing defect);
- *Lemelle v. Stryker Orthopaedics*, 2010 WL 996523 (W.D. La. Mar. 15, 2010) (MDA preempted claims for products liability, which was conceded by the plaintiff, and implied warranty);
- *Heisner v. Genzyme Corp.*, 2010 WL 894054 (N.D. Ill. Mar. 8, 2010) (MDA preempted claims for strict liability, negligence, and failure to warn);
- *Rankin v. Boston Scientific Corp.*, 2010 WL 672135 (E.D. Ky. Feb. 19, 2010) (MDA preempted claims for negligent design and manufacture);

- *McGuan v. Endovascular Techs., Inc.*, 2010 WL 445602 (Cal. Ct. App. Feb. 9, 2010) (MDA preempted claims for failure to warn, strict liability, negligence, express warranty, implied warranty, fraud, and statutory fraud);
- *Banner v. Cyberonics, Inc.*, 2010 WL 455286 (D.N.J. Feb. 4, 2010) (MDA preempted claim for strict liability);
- *Risavich v. Medtronic, Inc.*, No. 08-14183, slip op. (N.Y. Sup. Ct. Feb. 1, 2010) (MDA preempted claims for negligence, products liability, and breach of warranty);
- *Ilarraza v. Medtronic, Inc.*, 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.*, 673 F. Supp. 2d 522 (S.D. Tex. 2009) (MDA preempted claims for design defect, manufacturing defect, failure to warn, and statutory fraud);
- *McQuiston v. Boston Scientific Corp.*, 2009 WL 4016120 (W.D. La. Nov. 19, 2009) (MDA preempted claims for design defect, manufacturing defect, failure to warn, express warranty, implied warranty, and fraud);
- *Hughes v. Boston Scientific Corp.*, 669 F. Supp. 2d 701 (S.D. Miss. 2009) (MDA preempted claims for negligence, strict liability, implied warranty, failure to warn, and negligence per se);
- *Williams v. Allergan USA, Inc.*, 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.*, 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*, 641 F. Supp. 2d 1270 (MDA preempted claims for design defect, negligence, 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);
- *Bencomo v. Guidant Corp.*, 2009 WL 1951821 (E.D. La. June 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);
- *In re Fidelis I*, 592 F. Supp. 2d 1147 (MDA preempted all claims in consolidated complaint in federal MDL); and *In re Fidelis II*, 2009 WL 1361313, at *2 (denying request to amend complaint in federal MDL because all claims remained preempted);
- *Mullin v. Guidant Corp.*, 970 A.2d 733, 735 (Conn. App. Ct. 2009) (MDA preempted claims for breach of implied and express warranties, “failure to evaluate the safety of the [device], and subjecting [the plaintiff] to unreasonable danger”);
- *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);
- *Bagumyan v. Medtronic, Inc.*, No. BC 385151, slip op. (Cal. Sup. Ct. May 29, 2009) (MDA preempted claims for manufacturing defect, failure to warn, and implied warranty);
- *Dorsey v. Allergan, Inc.*, 2009 WL 703290 (M.D. Tenn. Mar. 11, 2009) (MDA preempted strict liability claim);
- *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271 (E.D.N.Y. 2009) (MDA preempted claims for negligence, defective design, manufacturing defect, failure to warn, express warranty, and implied warranty);
- *Blunt v. Medtronic, Inc.*, 760 N.W.2d 396 (Wis. 2009) (MDA preempted claims for strict liability and negligence);

- *Bausch v. Stryker Corp.*, 2008 WL 5157940 (N.D. Ill. Dec. 9, 2008) (MDA preempted claims for strict liability and negligence);
- *Despain v. Bradburn*, 282 S.W.3d 814 (Ark. 2008) (MDA preempted claims for strict 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);
- *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);
- *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, manufacturing defect, and design defect);
- *Clark v. Medtronic, Inc.*, 572 F. Supp. 2d 1090 (D. Minn. 2008) (MDA preempted claims for negligence and failure to warn);
- *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).

As shown below, there is nothing to distinguish plaintiffs' claims from those that consistently have been found to be preempted by Section 360k(a) in these post-*Riegel* decisions.⁵

⁵ Almost alone against this tide of authority, plaintiffs repeatedly rely on the decision of the Southern District of Indiana in *Hofts v. Howmedica Osteonics Corp.*, 597 F. Supp. 2d 830 (S.D. Ind. 2009). *Hofts* is one of only a few post-*Riegel* medical-device-preemption decisions affirmatively cited in plaintiffs' brief and is the only one that receives a *passim* designation in their table of authorities. See

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

Federal law and the PMA for the Fidelis leads imposed (and continue to impose) federal requirements that control the design, manufacture, testing, marketing, labeling, and post-market surveillance of the devices. Accordingly, the only real question 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. *See Riegel*, 552 U.S. at 330. Recognizing this, plaintiffs suggest that three categories of their claims fall into the established but limited exception to preemption for state-law causes of action that are parallel to alleged violations of federal regulations. As Judge Reilly correctly found (JA597-606), however, plaintiffs' vague assertions in the representative complaints about violations of various federal requirements are inadequate to show that any of their state-law causes of action properly constitute 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

ABiii. Yet *Hofts* has been explicitly rejected by at least five courts as fundamentally inconsistent with *Riegel*. *See Anthony*, 2010 WL 1387790, at *5; *Ilarraza*, 2009 WL 5245630, at *7; *In re Fidelis II*, 2009 WL 1361313, at *3 ; *Covert*, 2009 WL 2424559, at *5, *12-*13; *Horowitz*, 613 F. Supp. 2d at 284-85; *see also Lemelle*, 2010 WL 996523, at *5-*6 (implicitly rejecting *Hofts*); *Funk*, 673 F. Supp. 2d at 528-29 (same).

Bates, analyzing similar language in another statute, a requirement under state law must be “*genuinely* equivalent” to a requirement under federal law to survive preemption as a “parallel” claim. 544 U.S. at 454; *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 a state-law claim that does not meet the MDA’s “different from, or in addition to” standard for preemption. True parallel claims are not expressly preempted because “they do not *add to* or *differ from* federal requirements.” *In re Fidelis I*, 592 F. Supp. 2d at 1152.

Once a manufacturer establishes that the preemption doctrines in *Riegel* apply to a device because it was approved through the PMA process, the burden necessarily shifts to the plaintiff 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” or add to 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).”); *Colombini*, 2009 WL 2170230, at *4

(where PMA required manufacturer to address certain issues but the plaintiffs “cite[d] to no document from the FDA which specifically mandates” plaintiffs’ preferred solution, plaintiffs “have not demonstrated that they have any parallel claims that are not subject to preemption”).⁶

Moreover, “to proceed with [a purported parallel] 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 *4.⁷ 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. Otherwise, the plaintiff has not identified a true parallel claim.

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 Reilly held, each of plaintiffs’ state-law claims, as alleged, would impose

⁶ 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.

⁷ 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 IV, *infra*.

requirements on the leads that either differ from or add to the existing requirements under federal law.

A. Manufacturing defect

Plaintiffs contend that their manufacturing-defect claims escape preemption because the representative complaints allege that (i) “the PMA [for Fidelis leads] requires Medtronic not just to spot-weld the components of the leads, but to spot-weld them properly,” and (ii) “the cables in [plaintiffs] leads were not properly welded to the other components.” AB19-20. No one disputes that it is possible to plead a non-preempted manufacturing-defect claim (*see, e.g.*, page 27 n.9, *infra*), but this is not one.

1. Plaintiffs did not actually plead that the “proper welding” requirement was part of the PMA for the leads. The passages they cite (AB19-20 & n.18) say nothing about the PMA, and their opposition to Medtronic’s motion to dismiss the manufacturing-defect claims focused, not on the PMA, but on an alleged (but non-existent) requirement for “proper welding” under the FDA’s Good Manufacturing Practices / Quality System Regulation (GMP/QSR). *See, e.g.*, Respondents’ Appendix (RA)18-21, 47-48; JA601-03.

Plaintiffs do not dispute Judge Reilly’s holding—consistent with numerous other courts—that the GMP/QSR are too vague to provide the basis for a parallel

claim.⁸ JA601-03. But plaintiffs’ new argument, attempting to relocate the “proper welding” requirement in the PMA for the leads, would fare no better even had it been properly pleaded. The problem with a hopelessly vague requirement such as

⁸ Indeed, tying themselves in knots, plaintiffs now contend that the GMP/QSR are so vague that they do not even constitute “requirements.” AB20 n.21. Their suggestion that this “cuts against preemption” (*id.*) makes no sense—the Fidelis leads are subject to federal requirements for purposes of Section 360k because they were approved through the PMA process, not because they are subject to the GMP/QSR.

The vagueness of the GMP/QSR does, however, mean—as Judge Reilly held—that they “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.” JA602 (quoting *In re Fidelis I*, 592 F. Supp. 2d at 1158 (quoting FDA, *Medical Device Quality Systems Manual: A Small Entity Compliance Guide*, at 1-2 (1st ed. 1996) (HHS Pub. FDA 97-4179) (FDA, *QS Manual*))); *see also* FDA *QS Manual*, at 1-2 (“In most cases, *it is left to the manufacturer to determine the best methods to obtain quality objectives.*”) (emphasis added). Moreover, 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.” *Id.* 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. For example, the plaintiffs in the federal *Fidelis* MDL “allege[d] that Medtronic’s welding techniques were ‘defective,’ but they [did] not plead[] 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).” *In re Fidelis I*, 592 F. Supp. 2d at 1158. Accordingly, “holding Medtronic liable for such a welding ‘defect’ would impose requirements ‘different from, or in addition to’ those under federal law.” *Id.* The intentionally flexible federal regulations simply do not impose the same requirements that plaintiffs seek to impose under state law. *See also, e.g., Anthony*, 2010 WL 1387790, at *2-*3; *Bagumyan*, No. BC 385151, slip op. at 9 (holding manufacturing-defect claims based on the GMP/QSR preempted in another case involving Fidelis leads); *Ilarraza*, 2009 WL 5245630, at *4-*7 (similar); *Wolicki-Gables*, 641 F. Supp. 2d at 1288 (similar); *Horowitz*, 613 F. Supp. 2d at 284 (similar).

“spot weld ... properly” is that plaintiffs’ (as yet unspecified) theory about the specific welding procedures Medtronic should have used (*i.e.*, whatever plaintiffs think would have been “proper” welding) necessarily would impose requirements on the manufacturing process for the leads that do not exist under the PMA, even if the PMA used the words “spot weld ... properly.” A manufacturing-defect claim based on this supposed requirement would involve nothing but plaintiffs imposing their own idiosyncratic interpretation—which was nowhere alleged in their complaints—of the preferred manufacturing process for the Fidelis leads. And, should such a claim be allowed to proceed, the jurors would add another layer of uncertainty when imposing their own interpretation on an almost completely unbounded term like “proper welding”—either giving meaning to the term that conflicts with (*i.e.*, is “different from”) existing federal requirements or adopting a level of specificity that is not found in (*i.e.*, is “in addition to”) existing federal requirements. That was precisely the problem with plaintiffs’ now-abandoned GMP/QSR argument—here too, the proposed claim, by its very nature, would impose *additional or different* requirements on the leads and thus is preempted.⁹

⁹ Nor do the cases that plaintiffs cite (AB21-22) help their cause. In *Purcel v. Advanced Bionics Corp.*, 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 (N.D. Tex. Aug. 13, 2008). That unique situation has no relevance to plaintiffs’ attempt to impose their own preferred, but unspecified,

2. Plaintiffs also complain that Judge Reilly should have put the burden on Medtronic to prove that each of the claims in the representative complaints was “different from or in addition to” the federal requirements for the Fidelis leads. AB21. They did not make this argument below, however, so it has been forfeited. *See, e.g., Thiele v. Stich*, 425 N.W.2d 580, 582 (Minn. 1988) (“A reviewing court must generally consider only those issues that the record shows were presented and

manufacturing process on the Fidelis leads.

Similarly, *Rollins v. St. Jude Medical*, 583 F. Supp. 2d 790 (W.D. La. 2008), involved a plaintiff who alleged that the PMA for the device required it to be packaged in a clearly specified way (in a specific orientation with a .035-inch guide wire) but it was negligently packaged in a different way (in a different orientation with a .038-inch guide wire), leading to her injuries. As Judge Kyle noted in the federal MDL, that is an example of the type of claim that might be sufficient to avoid preemption (*In re Fidelis I*, 592 F. Supp. 2d at 1158-59), but it bears no relationship to plaintiffs’ contention that the leads were not welded “properly.”

The other opinions that plaintiffs cite, Medtronic submits, were wrongly decided, but in any event shed no light on the arguments made by plaintiffs here. As noted above (21 n.5), *Hofts* has been rejected by five to seven other courts. *Prudhel v. Endologix, Inc.*, 2009 WL 2045559 (E.D. Cal. July 9, 2009) found that the manufacturing-defect claim was not preempted but did not consider whether the GMP/QSR are too vague to state a parallel claim (an issue that plaintiffs here appear to concede on appeal). And *Mitaro v. Medtronic, Inc.*, 886 N.Y.S.2d 71 (table), 2009 WL 1272398 (N.Y. Sup. Ct. 2009), is a cursory New York state court opinion that also did not consider whether the GMP/QSR are sufficiently definite and specific to form the basis of a parallel claim, but simply found the plaintiffs’ bare allegation of a deviation from federal requirements to be sufficient to state a potential parallel claim under New York law.

Finally, plaintiffs misrepresent Judge Kyle’s decision in the federal MDL. Judge Kyle first held that manufacturing-defect claims like those made here were expressly preempted, before *also* holding that they were inadequately pleaded. *In re Fidelis I*, 592 F. Supp. 2d at 1157-58.

considered by the trial court in deciding the matter before it. ... Nor may a party obtain review by raising the same general issue litigated below but under a different theory.”) (internal quotation marks omitted).

In any event, Medtronic met its affirmative burden on a motion to dismiss by establishing that the Fidelis leads received PMA and showing that, according to the allegations in the complaint, plaintiffs’ state-law claims would impose requirements that differed from or added to the federal requirements for the leads. *See* JA610-11. It would make no sense to require Medtronic to prove the negative for each of plaintiffs’ claims (*i.e.*, that among all federal requirements for Fidelis leads, there is none that is identical to plaintiffs’ state-law claim, however it might be articulated). Once Medtronic established that Section 360k applied to the claim *as pleaded*, it became plaintiffs’ burden to establish a parallel-claim exception within the allegations of their complaints. Moreover, the implication of plaintiffs’ argument is that questions of preemption with respect to medical devices can never be resolved through a motion to dismiss, but must proceed through discovery to summary judgment. On the contrary, courts regularly grant motions to dismiss on the basis of federal preemption under Section 360k. *See, e.g., Anthony*, 2010 WL 1387790; *Lemelle*, 2010 WL 996523; *Heisner*, 2010 WL 894054; *Illaraza*, 2009 WL 5245630; *Funk*, 673 F. Supp. 2d 522; *Covert*, 2009 WL 2424559; *Riley*, 625 F. Supp. 2d 769; *In re Fidelis I*, 592 F. Supp. 2d 1147; *Horowitz*, 613 F. Supp. 2d

271; *Bausch*, 2008 WL 5157940; *Parker*, 584 F. Supp. 2d 1298; *Adkins*, 2008 WL 2680474; *Talbott v. C.R. Bard, Inc.*, 63 F.3d 25 (1st Cir. 1995).

3. Plaintiffs finally complain that Judge Reilly committed “a miscarriage of justice” by refusing to order disclosure of “unredacted copies of PMA 920015 [for the original Transvene lead] and its supplements [of which, there currently are 58].”¹⁰ AB21. Not so.

The district court has “broad discretion to fashion protective orders and to order discovery only on specified terms and conditions,” including orders “staying the production of discovery until [a] motion to dismiss [has been] heard.” *Radke v. County of Freeborn*, 676 N.W.2d 295, 300 (Minn. Ct. App. 2004), *rev’d on other grounds*, 694 N.W.2d 788 (Minn. 2005).

Courts across the country consistently state 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) (first emphasis added); *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.*, 2009 WL 294353, at *2 (D. Minn. Feb. 5, 2009) (it is not the role of courts or discovery to

¹⁰ Contrary to this professed outrage, plaintiffs appear to have had access to the PMAs for the Fidelis leads (*see, e.g.*, JA7-8 (providing details of “the supplemental PMAs S029 and S030,” the PMAs for Fidelis leads, and representing that those specific details are based on “information known to Plaintiff”)).

help people ““find out if [they have] any basis for a claim,”” but only to help them gather information once they have pleaded a viable claim) (quoting *Micro Motion, Inc. v. Kane Steel Co.*, 894 F.2d 1318, 1327 (Fed. Cir. 1990)); *see generally* JA609-13 (discussing fact that proposed discovery was not necessary to decide legal issue of preemption and would be unduly burdensome for court and parties if plaintiff has not pleaded a viable cause of action).

In the medical-device context in particular, 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 rule that would give every device recipient license to impose substantial discovery costs on the device manufacturer without first stating a viable claim.

It thus was well within Judge Reilly’s considerable discretion to rule on Medtronic’s motion to dismiss on the basis of federal preemption before authorizing potentially burdensome and costly discovery.

B. Express warranty

Plaintiffs contend that their express-warranty claims escape preemption (AB24-28), but they ignore the central fact in this inquiry: The only express-warranty claims that plaintiffs alleged below challenge the safety or effectiveness of the Fidelis leads. *See* JA593; *see also, e.g.*, JA286-87 (“Defendants expressly

warranted to Plaintiff ... that the Sprint Fidelis Leads were safe, effective, fit and proper for their intended use” but “[t]hese warranties and representations were false in that the Sprint Fidelis Leads were not safe and were unfit for the uses for which they were intended.”). As Judge Reilly correctly held, “breach of express warranty claims predicated upon allegations, like those made by Plaintiffs, that a device is not safe and effective are ... preempted under § 360k.” JA594; *see also Riegel*, 552 U.S. at 315 (“the pre-emption clause enacted in the Medical Device Amendments of 1976, 21 U.S.C. § 360k, bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration”).

Plaintiffs portray this as an unsettled area of law by focusing on distinctions between FDA-mandated labels and voluntary statements, but those distinctions are irrelevant here. AB24-28. Every court to explicitly consider the issue since *Riegel* has concluded 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*, 638 F. Supp. 2d at 1230; *see also, e.g., In re Fidelis I*, 592 F. Supp. 2d at 1164; *Parker*, 584 F. Supp. 2d at

1303; *Lake*, 874 N.Y.S.2d at 754; *Bencomo*, 2009 WL 1951821, at *5; *see generally Riegel*, 552 U.S. at 326-27.¹¹

Plaintiffs' express-warranty claims are problematic for another reason. Despite the summary contentions quoted above, none of the representative complaints alleged an actual statement in which Medtronic warranted that the Fidelis leads were safe and effective. Indeed, the text of Medtronic's express limited warranty for the Fidelis leads, which was incorporated into many of the complaints (*e.g.*, JA286-87), completely undermines those express-warranty claims because it does *not* include a warranty that the lead is safe and effective. Instead, it (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 id.* Plaintiffs have nev-

¹¹ Plaintiffs' reliance on pre-*Riegel* cases and cases decided under regulatory regimes that do not have an express-preemption clause analogous to Section 360k (AB24-28) is misplaced. For example, the primary case plaintiffs rely upon in defense of their express-warranty, misrepresentation, and consumer-protection claims is the pre-*Riegel* decision, *Michael v. Shiley, Inc.*, 46 F.3d 1316 (3d Cir. 1995). *See* AB27-31. Notably, since *Riegel* the U.S. District Court for the District of New Jersey has certified an interlocutory appeal to the Third Circuit, asking the court of appeals to address "[w]hether ... *Riegel* ... requires that *Shiley* ... be overruled" (*Huber v. Howmedical Osteonics Corp.*, 2009 WL 2998160, at *3 (D.N.J. Mar. 10, 2009)), although that appeal was voluntarily dismissed by the parties after briefing was complete (Order, No. 09-2590 (3d Cir. Dec. 3, 2009)). Those post-*Riegel* decisions plaintiffs do cite do not consider whether the warranty alleged might impermissibly require a finding that the device at issue was not safe or effective. To the extent that they could be construed as allowing such a claim, they would be 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]." 552 U.S. at 315.

er alleged that Medtronic violated *that* limited warranty and have never identified any other statements that allegedly gave rise to a warranty of safety and fitness.

Plaintiffs try to muddy the waters by suggesting that the district court failed to consider certain other alleged statements by Medtronic as part of its express-warranty analysis. AB23-24 & n.25. But those statements were not part of the express-warranty claims pleaded in plaintiffs' complaints (*see, e.g.*, JA286-88), and were not brought to Judge Reilly's attention in plaintiffs' opposition to Medtronic's motion to dismiss the express-warranty claims (RA52-53). Accordingly, plaintiffs have forfeited any reliance on those statements to support an express-warranty claim. *Thiele*, 425 N.W.2d at 582 ("A reviewing court must generally consider only those issues that the record shows were presented and considered by the trial court in deciding the matter before it. ... Nor may a party obtain review by raising the same general issue litigated below but under a different theory.") (internal quotation marks omitted).

In any event, plaintiffs had good reason not to invoke those statements below. Indeed, it is not clear what plaintiffs believe Medtronic was warranting in these alleged statements. For example, a statement that the Fidelis leads are "state of the art" (AB 24 n.25) is hopelessly vague (*see* [www.merriam-webster.com/dictionary/state of the art](http://www.merriam-webster.com/dictionary/state%20of%20the%20art) ("the level of development ... reached at any particular time usually as a result of modern methods")), as is a statement that they are

“based on” the designs of prior models. AB24 n.25. Moreover, on any reasonable interpretation of those statements, Fidelis leads indisputably were, at the time, “state of the art” devices “based on” earlier model leads. *See* AB3-4 (describing the evolution of Medtronic’s leads, culminating in the Fidelis model). Finally, even if plaintiffs had raised these statements below and provided a plausible explanation of what allegedly was being warranted by these statements and how that warranty was breached, plaintiffs are simply wrong when they suggest that preemption would not apply to warranties based on these statements because they relate only to “the quality of the Sprint Fidelis leads versus other leads.” AB23. To the extent these statements can be interpreted as making a cognizable comparison between Fidelis leads and other leads, it would be a comparison *about safety and effectiveness*. Thus, the same preemption analysis would apply to express-warranty claims based on these statements as applied to the express-warranty claims that plaintiffs actually made below.

C. Misrepresentation and consumer protection

The flaw in plaintiffs’ attempt to salvage their misrepresentation and consumer-protection claims is evident from the dates of the cases they cite. *See* AB30. Indeed, the only decision plaintiffs identify addressing federal preemption of misrepresentation claims after *Riegel* is the much-maligned *Hofts* opinion. *See* page 21 n.5, *supra*. Other than *Hofts*, post-*Riegel* cases consistently have found that mi-

misrepresentation, fraud, and statutory fraud (*i.e.*, consumer protection) claims are preempted by Section 360k. *See, e.g., McGuan*, 2010 WL 445602, at *4-*8 (MDA preempted fraud and statutory-fraud claims); *Funk*, 673 F. Supp. 2d at 526-27 (MDA preempted statutory-fraud claims); *McQuiston*, 2009 WL 4016120, at **6 (MDA preempted fraud claims); *Riley*, 625 F. Supp. 2d at 773-86 (MDA preempted misrepresentation and fraud claims); *In re Fidelis I*, 592 F. Supp. 2d at 165 (MDA preempted misrepresentation, fraud, and statutory-fraud claims).¹²

This consistent pattern of post-*Riegel* decisions is not surprising. To prove that a statement regarding the safety and effectiveness of a device was false or misleading, a plaintiff necessarily would have to “challeng[e] the safety and effectiveness of a medical device given premarket approval by the [FDA].” *Riegel*, 552 U.S. at 315. Moreover, a finding that Medtronic should not have made a statement regarding the leads, or should have made a different statement, would effectively impose a requirement on the warnings or disclosures for the leads that is different from or in addition to the requirements imposed by the FDA. That is a stereotypical example of a claim that is preempted following *Riegel*.

¹² Once again, plaintiffs simply ignore *Riegel* and ask this Court to create an exemption from preemption for unfair-trade-practice claims based on 21 C.F.R. § 808.1(d)(1). *See* AB29-30). As noted above (at 17-18), *Riegel* expressly considered that regulation, found it fundamentally flawed, and rejected the very limitation that plaintiffs advocate. 552 U.S. at 326-30.

In sum, each of the three categories of 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. Because plaintiffs' claims do not fall into the exception to preemption under the MDA for true "parallel" claims, they were appropriately dismissed.¹³

III. The Recall Classification Is Irrelevant.

Plaintiffs concede that their remaining claims (*i.e.*, everything except manufacturing defect, express warranty, misrepresentation, and consumer protection) seek to impose different or additional requirements than exist under federal law, but nevertheless argue that those claims avoid preemption because the FDA designated Medtronic's voluntary withdrawal of the Fidelis leads as a recall. AB31. On the contrary, every court to consider this argument, like Judge Reilly (JA585-86), has held that a 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; *Moore v. Sulzer Orthopedics, Inc.*, 337 F. Supp. 2d 1002 (N.D. Ohio 2004);

¹³ Plaintiffs ask without elaboration that this Court reinstate their dependent claims (*e.g.*, loss of consortium) if it reverses the district court's preemption ruling regarding any of their primary claims. AB36. Given plaintiffs' limited briefing on this issue and the hypothetical nature of the inquiry, Medtronic suggests that, if the Court were to send any of plaintiffs' claims back to the district court for further proceedings, the Court allow Judge Reilly to address, in the first instance, whether any of plaintiffs' derivative claims should also be resuscitated. *Cf.* AB36.

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*, 886 N.Y.S.2d 71; *Blanco*, 70 Cal. Rptr. 3d at 579-80; *Bausch*, 2008 WL 5157940, at *1, *3; *Baker v. St. Jude Med., S.C., Inc.*, 178 S.W.3d 127 (Tex. App. 2005); *cf. Colombini*, 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.

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. §§ 10.45, 16.120 (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* JA585-86; *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).¹⁴

¹⁴ Plaintiffs are equally mistaken when they imply that PMA is automatically revoked whenever a manufacturer allegedly violates one of the standard “conditions of approval” for devices with PMA. AB35 n.37. 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. 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

Indeed, plaintiffs appear to concede this point, stating that they “do not argue that the Leads’ PMA approval was withdrawn or invalidated” by the recall and that Judge Reilly’s opinion “misunderst[ood] Appellants’ argument.” AB32. But plaintiffs’ opposition to Medtronic’s motion to dismiss argued that “[a]ny FDA premarket approval that [the leads] once had is no longer valid”; emphasized that “Plaintiffs ... allege a cancellation of the Lead’s PMA as a factual matter”; and concluded: “Simply put, the Fidelis Leads do not have FDA approval.” RA39-42; *see also* RA11 (“[a]s a result [of the recall], the FDA Premarket Approval is cancelled”). It is not surprising that plaintiffs abandon the misguided argument they made below, but their new strategy fares no better.

Plaintiffs now suggest that their claims escape preemption because, as a matter of law, the recall classification means that the Fidelis leads violated federal requirements. AB32-33. This contention fails for a number of reasons. First, there is conflicting authority on the general proposition underlying plaintiffs’ argument. The statutory authority for recalls requires a finding only that “there is a reasonable probability that a device intended for human use would cause serious, adverse

PMAs effectively undo the statutory and regulatory regime by which the FDA is bound. *Cf. Hughes*, 669 F. Supp. 2d at 710-12 (finding preemption despite allegations that the manufacturer violated reporting requirements in conditions for premarket approval). 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 IV, *infra*.

health consequences or death.” 21 U.S.C. 360h(e). It is only the less-authoritative implementing regulation which says that the FDA “considers [a recalled device] to be in violation of the laws it administers.” 21 C.F.R. § 7.3(g).

Second, even if the law were unambiguous, as a practical matter the FDA does not make a finding that a device violates the law before classifying a manufacturer’s voluntary action as a recall—and the FDA’s statements regarding the Fidelis recall in particular say nothing about the violation of a federal requirement, but focus exclusively on the fact that the leads had a slightly higher failure rate than other leads on the market (while observing that they continue to perform as expected in the majority of patients). *See* pages 10-11, *supra*.

Third, and most important, this entire issue is irrelevant. Even if the recall classification stood for the abstract proposition that the FDA believes that Fidelis leads violate “the laws [that the FDA] administers” (21 C.F.R. § 7.3(g)), that would not save plaintiffs’ claims from preemption because plaintiffs still would not have identified a federal requirement applicable to the leads that is the same as one of their state-law claims. For example, plaintiffs’ manufacturing-defect claim alleges that Medtronic should have used a different spot-welding process (AB19-20), but an abstract statement that the leads violate the law does not help plaintiffs show that there is a federal requirement that the leads be welded in the particular (unspecified) way that plaintiffs think they should have been welded.

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 22-25), 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. This they have not done (and cannot do).

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

Setting aside the legal or evidentiary impact of a recall classification to PMA status generally, the Fidelis recall is irrelevant to the preemption analysis in this case. As Judge Kyle found in the federal MDL, “Plaintiffs’ argument ignores that PMA for the Sprint Fidelis leads was in place *at the time the leads were implanted,*” which “is what matters.” *In re Fidelis I*, 592 F. Supp. 2d at 1156; *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. *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); *Patton v. Newmar Corp.*, 538 N.W.2d 116, 119 (Minn. 1995) (“to establish a *prima facie* case of liability, the plaintiffs must demonstrate that ... the defect existed *when the [product] left [the defendant’s] control*”) (emphasis added).

In a futile effort to avoid this well-established principle, plaintiffs contend that their state-law claims cannot impose “requirements” because that term applies only to the control of future conduct, and there is no ongoing conduct with a recalled device. AB33. That argument is inconsistent with the language of Section 360k(a), which makes no such distinction, and is contrary to the uniform case law on this issue. *See* pages 37-38, *supra*. In any event, such a rule would be patently overbroad and factually untenable. First, plaintiffs’ distinction would apply to any device that has been taken off the market for whatever reason. Indeed, on plaintiffs’ theory, the recall classification is irrelevant—simply stopping future sales would place a medical device outside the scope of preemption. Such an irrational rule finds no support in the statute or case law and would undermine the very purposes of the MDA’s express-preemption statute by injecting concerns over varying

state-court standards into a manufacturer's decision-making process. *See* pages 3-5, *supra*. More fundamentally, plaintiffs' theory that claims involving a recalled product do not affect ongoing conduct is factually mistaken. Recalled products can and do remain on or return to the market with approval from the FDA (sometimes but not always following agency approval of a corrective procedure). And, as in the case of Fidelis leads, recalled devices often remain in patients and are subject to continuing regulatory reporting obligations and oversight by the FDA. In other words, a state-law claim *can* affect future conduct even when a device has been recalled, and thus plaintiffs' proposed limitation fails on its own terms.

IV. The District Court Correctly Applied *Buckman*.

The representative complaints 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, e.g.*, JA10-12, 20-21, 34-37. These spurious allegations do not save plaintiffs' claims from dismissal on preemption grounds. As Judge Reilly 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* JA598-601, 605-06.

Plaintiffs concede that *Buckman* and Section 337(a) preclude claims based on “violations of federal statutory and regulatory requirements” (AB37), but they both misconstrue the scope of *Buckman* and Section 337(a) and misrepresent their own claims in an effort to avoid that result here.

A. *Buckman* and Section 337(a) bar claims for which the regulatory scheme is an essential element.

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 21 U.S.C. § 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*, 552 U.S. at 317-18.

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(1) (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 Reilly correctly concluded (JA601), 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).¹⁵

¹⁵ Indeed, a finding of fraud in connection with FDA submissions would not 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 manufac-

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.¹⁶ 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-

submitter 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 III), no such action has been taken, or even alleged, with respect to the Fidelis leads.

¹⁶ *See Riegel*, 552 U.S. at 325 (“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.”).

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.¹⁷

For all of these reasons, courts have consistently agreed with Judge Reilly 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

¹⁷ 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.*

information to the FDA would be preempted ... under the implied preemption principles stated in *Buckman*”); *Hughes*, 669 F. Supp. 2d at 711-12; *In re Fidelis I*, 592 F. Supp. 2d at 1161; *Covert*, 2009 WL 2424559, at *7-*8; *McCutchen v. Zimmer Holdings, Inc.*, 586 F. Supp. 2d 917, 922 (N.D. Ill. 2008); *Link*, 604 F. Supp. 2d at 1179; *McGuan*, 2010 WL 445602, at *6-*7; *Mitaro*, 2009 WL 1272398, at *4; *Lake*, 874 N.Y.S.2d at 754-55.

B. *Buckman* and Section 337(a) bar plaintiffs’ claims based on alleged violations of reporting and other obligations Medtronic owed to the FDA.

Although plaintiffs assert that Judge Reilly was “simply wrong” in holding that their claims based on violations of reporting requirements and similar obligations owed to the FDA are preempted under *Buckman* (AB36), plaintiffs once again ignore the case law against them and fail to identify a single case supporting their position. Each of the pre-*Riegel* decisions that they cite (AB37-38) involved failure-to-warn allegations (which, after *Riegel*, are expressly preempted), *not* allegations that the manufacturer failed to comply with reporting requirements owed to the FDA. And plaintiffs’ bald assertion that the causes of action they have alleged existed “long before the Medical Device Amendments were even enacted” (AB37) is obviously false. There is no pre-existing common-law duty to file an adverse event report with the FDA, to follow CAPA documentation procedures, or to file PMA-Supplement applications. Because the existence of the FDCA is a necessary

element in claims based on those allegations (*i.e.*, they cannot be stated without reference to the regulatory scheme), such claims necessarily would infringe upon the FDA’s authority to police its own regulations. Those claims are barred by Section 337(a) and impliedly preempted under *Buckman*.

Plaintiffs may be trying to argue that the basic common-law concepts of, for example, “negligence” predate the FDCA. But that obviously misses the point. As plaintiffs admit, “preemption analysis turns not on the particular legal label applied to a claim, but rather on the substance of the requirements imposed by state and federal law.” AB18; *see also Hughes*, 669 F. Supp. 2d at 712 (“The way the plaintiff characterizes her cause of action ... does not change the outcome. The plaintiff is alleging that BSC made misrepresentations to the FDA. State tort claims alleging misrepresentation to the FDA are preempted under *Buckman*.”). Indeed, *Buckman* itself involved a claim that sounded in “fraud,” yet because it was fraud in connection with an FDA-created requirement, the claim was impliedly preempted.

Given Sections 360k(a) and 337(a), as interpreted by the Supreme Court in *Riegel* and *Buckman*, respectively, Judge Reilly was plainly correct in holding that all of plaintiffs’ claims are preempted. 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 Sec-

tion 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). As Judge Reilly held, 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. And she correctly rejected plaintiffs' efforts to avoid that result by distorting the law surrounding recalls and implied preemption.

CONCLUSION

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

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CERTIFICATE OF COMPLIANCE WITH RULE 132.01(3)(a)(1)

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