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STATE OF
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2009 OCT 20 AM 11:/3FOURTH JUDICIAL DISTRICT ov

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HERN CO. DISTRICT

IN RE MEDTRONIC SPRINT FIDE**LCOU**RT ASAHIS**TRATOR**
LEAD PRODUCTS LIABILITY STATE COURT
LITIGATION,

ORDER GRANTING

DEFENDANTS' This document relates to:

MOTION TO DISMISS

REPRESENTATIVE CASES

*27-C*V-07-22446 *27-C*V-08-04900 *27-C*V-08-11803
27-*C*V-08-21114 27-CV-08-24251 *27-C*V-08-25493
27-CV-08-27586 *27-CV*-09-12958 *27-CV*-09-15891
27-CV-09-19604

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The above-entitled matter came on for hearing before the undersigned Judge of the

District Court pursuant to Defendants' Motion to Dismiss Representative Cases on September 4,

2009. Attorneys Daniel Gustafson and Michael Johnson argued on behalf of Plaintiffs.

Attorneys Kenneth Geller and Daniel Ring argued on behalf of Defendants. Other appearances

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were noted for the record. The Court having heard and read the arguments of counsel, and based

upon the files, records, and proceedings herein, makes
the following:

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Defendants' Motion to Dismiss Representative Cases is granted.

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All of Plaintiffs' claims against all Defendants raised in the Representative Cases' are dismissed with prejudice.

Pursuant to stipulation by the parties, the Representative Cases are *27*-CV-*07*-22446, *27*-CV-08-04900, *27-CV* 08-11803, 27-CV-08-21114, 27-CV-08-24251.27-CV-08-28493*, 2*7-CV-08-27586, 27-CV-09-12958, 27-*C*V-09 15891, and 27-*C*V-09-19604.

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Proceedings in all cases companioned with the Representative Cases (the "Companioned Cases:') remain stayed and shall be placed into dormant status upon any appeal of this Order.

The Scheduling Conference currently scheduled for Monday, October 26, 2009 at

9:00 a.m. is cancelled.

The attached Memorandum is incorporated within this Order as if fully set forth herein.

THERE BEING NO JUST REASON FOR DELAY, LET JUDGMENT BE ENTERED ACCORDINGLY

BY THE COURT:

Dated:
10/20/09

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Denise D. Reilly
Judge of District Court

MEMORANDUM

1.
Factual Background and Allegations

A.
The Representative Cases

Currently before this Court are more than 600 separate cases raising claims against

Defendants Medtronic, Inc., Medtronic Puerto Rico, Inc., and Medtronic Puerto Rico Operations

Co. *(*collectively "Medtronic") related to the use of certain electronic leads (the “Leads")

manufactured by Medtronic that were used in implantable cardiac defibrillators (“ICDs") from

2004 through October 2007. Plaintiff Shirley Bebeau filed the first case in this Court alleging

claims against Medtronic related to injuries arising from her use of the Leads. Other Plaintiffs

began their own actions against Medtronic and filed additional Complaints alleging claims

related to the Leads with the Court in late 2007. Medtronic moved to stay proceedings in all of

these related actions pending a decision from the Joint Panel on Multi-District Litigation

("JPML") on whether to consolidate all federal-court proceedings related to the Leads into a

single Multi-District Litigation ("MDL") action. On December 21, 2007, the Court issued an

Order staying proceedings in the state-court actions pending a ruling from the JPML. On

January 14, 2008, the Court issued an Order companioning all of the Sprint Fidelis Leads cases

filed with this Court with proceedings in the first-filed case brought by Bebeau (the

"Companioned Cases"). Proceedings in the Companioned Cases were stayed during the

pendency of the motion to dismiss the MDL proceedings. From the outset of proceedings in the

2 This recitation of the factual background is taken solely from Plaintiffs' allegations as set forth

in their Complaints. For ease of reference, the Court generally refers only to the Second Amended Complaint filed in *Bebeau.* However, the allegations of the *Bebeau* Complaint are substantively identical to the Complaints filed in all the Representative Cases.

3 Proceedings in this Court were further delayed during the election contest in Ramsey County relating to the November 4, 2008 general election for United States Senator due to the undersigned's participation on the judicial panel overseeing the contest.

[3]
Companioned Cases, Medtronic informed the Court that it intended to move to dismiss the

claims brought by the Plaintiffs in the Companioned Cases.

On May 26, 2009, the Court held a scheduling conference in the Companioned Cases.

That same day the Court issued a Scheduling Order setting forth the procedure and timelines that

would govern Medtronic's motion to dismiss. The Court granted Plaintiffs leave to amend their

previously filed pleadings in advance of the motion. In order to streamline proceedings, the

Court directed the parties to work together and select representative cases pleading all the claims

Medtronic believed were subject to dismissal (the “Representative Cases”) from among all of the

Companioned Cases. (Scheduling Order of May 26, 2009 at 9 2.) As of June 4, 2009, there

were 225 Companioned Cases filed with the Court. From among these, the parties selected the

following Representative Cases:

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• *Bebeau* v. *Medtronic, Inc., et al.,* Court File No. *27*-CV-*07-22*446 *(“Bebeau”)*

• *Bell v. Medtronic, Inc., et al.,* Court File No. 27-CV-08-04900 *(“Bell")*

• *Brue v. Medtronic, Inc., et al.,* Court File No. *27*-CV-08-11803 *(“Brue")*

Manning v. Medtronic, Inc., et al., Court File No. 27-CV-08-21114 (“*Manning*”*)*

Morrison, et al. v. Medtronic, Inc., et al., Court File No. 27-CV-08-24251 (“M*orrison*")

Eschere, et al. v. Medtronic, Inc., et al., Court File No. *27*-CV-08-25493 *("Eschete")*

Joest v. Medtronic, Inc., et al., Court File No. *27*-CV-08-27586 *(“Joest"*)

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• *Florence, et al. v. Medtronic, Inc., et al.,* Court File No*. 27*-CV-09-12958 (*“Florenc*e")

• *Diamond v. Medtronic, Inc., et al.,* Court File No. 27-CV-09-15891 *(“Diamond")*

• *B*owie v*. Medtronic, Inc., et al.,* Court File No. 27-CV-09-19604 ("*B*owie")

In the Representative Cases, Plaintiffs raise the following types of claims against

Medtronic: (1) strict-liability failure to warn; (2) strict liability manufacturing defect; (3)

negligence； (4) negligence per se; (5) breach of implied warranty; (6) breach of express

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warranty: (7) fraud and misrepresentation; (8) violation of consumer-protection statutes of

Minnesota, Georgia, Indiana, Kentucky, South Carolina, and Texas;* (9) negligent infliction of

emotional distress; (10) intentional infliction of emotional distress; (11) unjust enrichment; (12)

medical monitoring; (13) loss of consortium; and (14) violation of the Medicare Secondary Payer

Act. Medtronic has moved to dismiss all of these claims.

B.

The Sprint Fidelis Leads

At the most general level, Plaintiffs' claims against Medtronic arise from their allegations

that they were damaged by defects in the Leads. The Leads were designed and manufactured by

Medtronic for use in ICDs, which are used to treat abnormal heart rhythms by sending an electric

pulse into the heart via an insulated wire or "lead." *(Bebeau 2*d Am. Compl. 99 11-12.)

Electrodes that sense the heart's rhythm are built into the lead wires and positioned in the heart,

where they can monitor the heartbeat. *(Id.* 12.) At the time they were developed, the Leads

were some of the smallest-diameter leads used in ICDs. *(Cf. id.* (24.) A smaller diameter

makes a lead easier to implant because it is more easily threaded through the vessels and into the

heart. *(Bell* Compl. 1 14.) In addition, smaller leads are less likely to obstruct blood flow or

distort the tricuspid valve*. (Id.*) Because an ICD's leads are the conduit for the electricity used

to shock a heart back into normal rhythm, if there is a failure of a lead, the ICD will not function

properly*. (Bebeau 2*d Am. Compl. 13.) Fractured leads can cause the ICD to shock the heart

when no shock is needed or fail to shock the heart when a shock is needed to prevent fibrillation.

*(Bell C*ompl.
1 47*.)*

4 Plaintiffs in the Representative Cases are citizens of Minnesota, West Virginia, California, Oregon, Kentucky,
Tennessee, Louisiana, Mississippi, Arkansas, Indiana, Georgia, South Carolina, and Texas. *(Bebeau* 2d Am. Compl. 12*; Bell C*ompl. 1 1; *Brue* Am. Compl. 9 1; *Manning* Compl. 1 6; *Morrison* Am. Compl. 13; *Eschete Compl.* 112, 4, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24*; Joest* Am. Compl. 1 2*; Florence* 1st Am. Compl. 1 2*; Diamond C*ompl. 1 2; *Bowie A*m. Compl. 1 2.)

C. The Pre-Market **Approval Process for Medical Devices** În 1976, Congress passed the Medical Device Amendinents (“MDA”) to the Food, Drug

and Cosmetic Act (“FDCA”). The MDA classified medical devices into three separate

categories. *See* 21 U.S.C. $ 360c. Devices for a use in supporting or sustaining human life or

for a use which is of substantial importance in preventing impairment of human health," or that

*present[] a potential unreasonable risk of illness or injury" are Class III devices under this

framework. *Id. § 3*60c(a)(1)(C)(ii). Under the MDA, no Class III device may be sold or

distributed absent specific approval by the FDA. *Id.* $ 360e(a). The Leads are Class III medical

devices. *(Bebeau 2*d Am. Compl. 1 14.)

> Under the premarket approval ("PMA") process applicable to most Class III medical

devices, a medical device manufacturer must submit a detailed application to the FDA seeking

the agency's approval for a device before it may be sold or distributed. The PMA application

must contain:

> (A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
>
> (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;
>
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

5 Certain medical devices that were already sold and distributed at the time of the passage of the MDA were grandfathered in and exempted from PMA review. S*ee Riegel v. Medtronic, Inc.*, 128 S.Ct. 999, 1004 (2008) (explaining the difference in the scope of the FDA's review of a medical device under the PMA process compared with the substantial equivalence process).

(E) such samples of such device and of components thereof as the Secretary may reasonably require . . .;

(F) specimens of the labeling proposed to be used for such device;

(G) the certification required under section 2820)(5)(B) of Title 42 [relating to clinical trials supported by Federal agencies); and

(H) such other information relevant to the subject matter of the application as the Secretary ... may require.

21 U.S.C. $ 360e(c). For purposes of $$ 360c, 360d and 360e of the FDCA, "the safety and effectiveness of a device" are evaluated by the FDA as follows:

*(*A) with respect to the persons for whose use the device is represented or intended,

(B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and

(C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

Id. $ 360c(a)(2).

The FDA cannot approve a medical device under the PMA process unless it determines

there has been a "showing of reasonable assurance that such device is safe under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. $ 360e(d)(2)(A). Similarly, there must be a "showing of reasonable assurance that the device is effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." *Id.* § 360e(d)(2)(B). The FDA must deny an application for premarket approval if it finds that "the methods used in, or the facilities or controls used for, the manufacture, processing, packing, or installation of such device do not conform to the (good manufacturing practice) requirements of [the FDCA)." *Id.* § 360e(d)(2)(C) (citing 21 U.S.C. S 360j(f)). In addition, premarket approval must be denied if the FDA finds that "based on a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular." *Id.* § 360e(d)(2)(D). Finally, approval may be denied if a device fails "to conform in all respects to a performance standard under section 360d of [the FDCA]." *Id.* 360e(d)(2)(E). In determining whether to approve or deny an application for premarket approval, the FDA:

> shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading. In determining whether or not such labeling is false or misleading, the Secretary shall fairly evaluate all material facts pertinent to the proposed labeling.

Id. $ 360e(d)(1)(A).

Once a device has received premarket approval, the device manufacturer cannot make

any change to the device that affects its safety or effectiveness without first submitting a

supplemental PMA application to the FDA. 21 & U.S.C. § 360e(d)(6)(A)(i). The FDA must

approve a PMA Supplement "for an incremental change to the design of a device that affects

safety or effectiveness,"
if:

(I) nonclinical data demonstrate that the design modification creates the intended additional capacity, function, or performance of the device; and

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(II) clinical data from the approved application and any supplement to the approved application provide a reasonable assurance of safety and effectiveness for the changed device.

Id. § 360e(d)(6)(b)(i)(1)-(II). In reviewing a PMA Supplement, the FDA may require a

manufacturer to supply additional clinical data to evaluate the design modification of the device

to provide a reasonable assurance of safety and effectiveness." *Id. §* 360e(d) (6)(b)(ii). A

manufacturer may only implement the changes proposed under a PMA Supplement after it

receives approval by the FDA. 21 C.F.R. $ 814.39(a). However, a manufacturer need not

submit a supplemental application for "a modification in a manufacturing procedure or method

of manufacturing" so long as it submits a written notice to the FDA describing the change in

detail, summarizing the information supporting the change, and stating that the change has been

made under any good manufacturing practice requirements mandated by the Act. *Id.* S

360e(d)(6)(A)(i).

> Manufacturers of devices that have received premarket approval are subject to post

approval reporting obligations. The FDCA's implementing regulations specifically require

device manufacturers to submit reports to the FDA notifying the agency of any adverse events

relating to an approved
device:

> (a) If you are a manufacturer, you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information, from any source, that reasonably suggests that a device that you market:
>
> > (1) May have caused or contributed to a death or serious injury; or
>
> (2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.

21 C.F.R. $ 803.50(a); s*ee al*so 21 U.S.C. § 360i (vesting the FDA with authority to prescribe

regulations imposing post-approval reporting obligations upon device manufacturers). In

addition, manufacturers have an affirmative obligation to submit periodic reports to the FDA,

which must summarize published and unpublished reports from clinical investigations or

laboratory studies involving an approved device. 21 C.F.R. 814.84. This ensures that the FDA

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is kept abreast of developments relating to an

approved device.

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Medtronic Receives Premarket Approval from the FDA for the Leads

Before the Leads were used in any ICDs that were implanted in any patients, they were

submitted to the FDA for review and consideration through the PMA process. *(Bebeau 2*d Am.

Compl. 99 20-21.) The Leads were approved by the FDA as part of a PMA Supplement to an

earlier PMA for another ICD lead system. *(Id.* 1 27.) The original precursor to the Sprint Fidelis

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Leads was Medtronic's Transvene Leads System, which was approved by the FDA in December 1993 upon a PMA application submitted in April 1992. *(Id.* 97 17-18.) After the initial PMA for

the Transvene Leads was approved, Medtronic continued to refine the design of their ICD leads

and submitted more than 28 PMA Supplements to the FDA for approval of new lead products.

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(Id. 1 19.) It was through a PMA Supplement that the FDA granted approval to the Sprint

Quattro Leads, the immediate predecessor to the Leads. *(Bell C*ompl. 9 16.) Medtronic sought

FDA approval of the Leads through two PMA Supplements (the 29th and 30th Supplements to the

initial PMA application for the Transvene Leads system). *(Bebeau* 2d Am. Compl. 19 20-21.) In

late 2004, the FDA granted approval allowing the sale and distribution of four

types of Sprint

Fidelis Leads, Models 6930, 3931, 6948 and 6949. *(Id.* 122, 27.)

On June 8, 2004, prior to granting approval to the Leads, the FDA sent pre-approval

letters to Medtronic, indicating that the agency's approval of the Leads would be forthcoming

and informing Medtronic that "[failure to comply with the conditions of approval" would

invalidate the approval and that distribution of a device that violated the conditions of approval

was

was a violation of the FDCA. *(Bebeau* 2d Am. Compl. 1 27.) Paralleling the FDCA's

implementing regulations, the Conditions of Approval precluded Medtronic from "making any

changes affecting the safety, effectiveness, or manufacture" of the Sprint Fidelis Leads without

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submitting a PMA Supplement and required "prompt reporting and submission of adverse

reactions, device malfunctions, problems or defects." *(Id.* 1 28.) In addition, the Conditions of

Approval reiterated Medtronic's post-approval reporting obligations imposed under the

regulations.

(Id.)

Questions Arise About the Performance of the Leads

In early 2007, physicians at the Minneapolis Heart Institute encountered patients who

were experiencing electrical shocks from their ICDs. *(Bebeau* 2d Am. Compl. 1 61.) After

investigation, the physicians concluded that these shocks were a result of broken lead wires in the ICDs and began comparing the performance of the Leads with the earlier Sprint Quattro leads. *(Id.* 1967-69*, 7*2.) These physicians published a study in spring 2007, wherein they concluded that the Sprint Fidelis Leads were ten times more likely to fail than the Quattro leads.

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(Id. 1 69.) In March 2007, in response to physician-submitted concerns regarding the safety of the Sprint Fidelis Leads, the FDA Office of Compliance contacted Medtronic to discuss their concerns with the higher failure rate of the Sprint Fidelis Leads. *(Id.* 9 84.) On March 21, 2007, Medtronic issued a "Dear Doctor" letter informing the doctors that had implanted Sprint Fidelis Leads that Medtronic had received reports of a higher than expected fracture rate for the Sprint Fidelis Leads. *(Id.*) The letter suggested that the failure rate was due to poor implantation. *(Id.* 185 .)

In April 2007, the FDA Office of Device Evaluation issued its Annual Report Review for the Leads which noted that Medtronic had proposed certain changes to the Leads but had not explicitly stated that the changes were made in response to any failures of the device in the field. *(Bebeau 2*d Am. Compl. 1 86.) On May 15, 2007, Medtronic submitted a PMA Supplement for

"[a]pproval for design and manufacturing changes to improve the DF-1 leg strength and handling characteristics" of the Leads. *(Id.* 1 87.) In August 2007, Medtronic submitted another PMA

Supplement seeking FDA approval for changes to the connector-sleeve component of the Leads.

(Id. 1
88.)

Medtronic continued to receive reports of Lead fractures, so on October 15, 2007 it

initiated a voluntary suspension of distribution of the devices from the market. *(Bebeau* 2d Am. Compl. 1992-93.) Medtronic directed physicians to stop implanting ICDs containing the Leads

and to return all non-implanted Leads to Medtronic. *(Id.* 1 93.) The FDA considered

Medtronic's voluntary action withdrawing the Leads from the marketplace to constitute a recall

of the Leads and classified it as a Class I recall of a device under the FDC*A. (Id.* 9 94.)

On October 18, 2007, the FDA commenced an Establishment Inspection of Medtronic's

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manufacturing plants. *(Bebeau 2*d Am. Compl. 4 100.) As part of this inspection, the inspectors

reviewed the actions undertaken by Medtronic relating to adverse events that were potentially

related to the Leads. *(Id*. 1 101.) The FDA inspectors concluded that "the corrective and

preventive action procedures addressing the investigation of the cause of the nonconformities

related to product, processes, and the quality system were not implemented" as required by the

FDCA's implementing regulations. *(Id.)* The FDA inspectors also questioned whether

Medtronic's interim reporting of adverse events involving the Leads to the FDA was sufficient.

(Id.
104.)

After the withdrawal of the Leads from the market, Medtronic advised all patients with

Leads in their ICDs to contact their physicians regarding programming their ICDs to be more

sensitive to Lead fractures. *(Bebeau* 2d Am. Compl. 9 121.) Medtronic did not recommend

explantation of all ICDs containing the Leads because Medtronic's Independent Physician

Quality Panel believed it was "inappropriate to prophylactically replace [the Leads] except in

unusual individual patient circumstances." *(Id.* 1 124.) The failure rate of the Leads continues to

increase. *(Id.* 1
135.)

By way of the Companioned Cases, Plaintiffs seek damages and injunctive relief from the

Court claiming that they have been damaged by their use of the Leads.

As of March 2009, Medtronic "has identified thirteen patient deaths in which [Lead) fractures may have been a possible or likely contributing factor." *(Bebeau* 2d Am. Compl. 1137.) This is out of 257,000 Leads that were implanted. *(Id.* | 133.)

II.

Procedural Posture

A.

Proceedings Before the MDL Court

After the recall of the Leads, numerous plaintiffs brought claims against Medtronic in

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federal court alleging that they had suffered injuries from the Leads. In February 2008, the

JPML referred all of the federal-court actions raising products-liability claims against Medtronic

relating to the Sprint Fidelis Leads to an MDL proceeding venued in the United States District

Court for the District of Minnesota (the "MDL Court"). *In re Medtronic, Inc. Sprint Fidelis*

*Leads Prods. Liab. Litig. 5*36 F. Supp. 2d 1375 (J.P.M.L. 2008). In June 2008, the MDL

Plaintiffs siled a Master Consolidated Complaint alleging 21 claims against Medtronic in the

MDL proceedings. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig., 5*92 F. Supp.

2d 1147, 1154 (D. Minn. 2009) (hereinafter *" In re Sprint Fidelis Leads I').* Litigation before the

MDL Court continued throughout 2008, although discovery in that court remained stayed

pending decision on Medtronic's motion to dismiss all claims.

The allegations and claims raised by the MDL Plaintiffs in their Master Consolidated

Complaint mirror those made by the Plaintiffs in the Representative Cases. The MDL Plaintiffs

alleged that Medtronic failed to adequately test the Leads prior to seeking FDA approval, that the

choice of direct-resistance spot welding for manufacturing the Leads was improper because it

was prone to damaging the Leads, that Medtronic failed to adequately disclose the risks of this

welding technique, that Medtronic failed to take steps to ensure that the Leads were not damaged

The 21 claims alleged against Medtronic in the Master Consolidated Complaint were: (1) strict liability failure to warn; (2) strict-liability manufacturing defect; (3) negligence; (4) negligence per se; (5) breach of implied warranty; (6) breach of express warranty; (7) negligent misrepresentation; (8) intentional misrepresentation; (9) fraud; (10) constructive fraud; (11) violation of the Minnesota False Statements in Advertising Act; (12) violation of the Minnesota Deceptive Trade Practices Act; (13) violation of the Minnesota prevention of Consumer Fraud Act; (140 violation of the Minnesota Senior Citizen and Handicapped Person Consumer Fraud Act; (15) negligent infliction of emotional distress; (16) loss of consortium; (17) wrongful death; (18) survival action; (19) medical monitoring; (20) unjust enrichment; and (21) Medicare Secondary Payer Act. *In re Sprint Fidelis Leads 1,* 592 F. Supp. 2d at 1154, n. 9. Similar claims have been alleged in the Representative Cases.

during production, and that Medtronic failed to take corrective action to prevent Lead failures.

*Compare In re Sprint Fidelis Leads I, 5*92 F. Supp. 2d at 1153 *with (Bebeau* 2d Am. Compl. 19 43-44, 52.) The MDL Plaintiffs also alleged that Medtronic failed 10 timely file adverse event

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reports after being confronted with information regarding the increased failure rates of the Leads.

*In re Sprinu Fidelis Leads 1, 5*92 F. Supp. 2d at 1153; *cf. (Bebeau* 2d Am. Compl. 99 138-43,

146-49.) In essence, like the claims in the Representative Cases, the MDL Plaintiffs' claims

were predicated upon assertions that the Leads were defective and that Medtronic misrepresented

the risks associated with the Leads to them, to their physicians and to the FDA.

On January 5, 2009, the MDL Court granted Medtronic's motion to dismiss in full. *In re*

*Sprint Fidelis Leads I, 5*92 F. Supp. 2d at 1166. The MDL Court dismissed all of the claims

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against Medtronic with prejudice on the grounds that they were all preempted by the FDCA. *Id.*

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After the dismissal of their claims, the MDL Plaintiffs moved the MDL Court for leave to file an Amended Master Consolidated Complaint. On May 12, 2009, the MDL Court issued an Order

denying this motion to amend on the grounds that the proposed amendment was untimely and

that the proposed claims were futile because, like the dismissed claims, the amended claims were

preempted under federal law. *In re Medtronic, Inc. Sprint Fidelis Leads Prods. Liab. Litig.,*

MDL No. 08-1905, 2009 WL 1361313, at * 2 (D. Minn. May 12, 2009) (hereinafter *"In re Sprint*

Fidelis Leads Ir)) ("[A]ll of the claims in the Proposed Revised Amended MCC (including the

newly asserted ones) are preempted for the reasons stated in the January 5, 2009 Order."). In

rejecting the proposed amendments, the MDL Court explained "that the flaws endemic to the

[previously dismissed] MCC are equally endemic to the Proposed Revised Amended MCC

because the very premise underlying Plaintiffs' claims is faulty." *Id.* The allegations of the

Complaints in the Representative Cases repeat nearly verbatim those of the proposed Amended

Master Consolidated Complaint deemed futile by the MDL Court. *(Compare Bebeau* 2d Am.

Compl. w*ith* Stull

Aff. Ex. A.)

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Proceedings Before this Court

As noted above, proceedings in the Companioned Cases were stayed during the pendency

of Medtronic's motion to dismiss in the MDL Court. After the lifting of the stay, the focus of the

parties and the Court was streamlining the procedure for Medtronic to bring a motion to dismiss

claiins in the Companioned Cases. (See Scheduling Order, May 26, 2009.) To this end, the

Court issued a Scheduling Order setting forth specific briefing deadlines for Medtronic's motion.

The Order also gave leave to Plaintiffs to amend their pleadings, but directed them to file any

amended complaints with the Court on or before July 3, 2009. *(Id.* at 15.)

After the issuance of the Scheduling Order, Plaintiffs objected to any continuing stay of discovery and pleading obligations during the pendency of any motion to dismiss. On June 19, 2009, the Court heard Plaintiffs' motion opposing any continuing stay of the litigation. On June 22, 2009, the Court denied Plaintiffs' motion and continued to stay responsive-pleading obligations and discovery in all of the Companioned Cases pending a ruling from the Court on the instant motion to dismiss. (Order on Pls.' Mot. Opp'g Any Stay of Litig., June 22, 2009.)

The Court rejected Plaintiffs' argument that discovery was needed to present a factual record to this Court prior to ruling on any motion to dismiss. The Court noted that its ruling upon any motion to dismiss would "be based solely upon the legal sufficiency of the allegations in Plaintiffs' pleadings and not on any factual record outside those pleadings." *(Id.* at 4.)

Pursuant to the Scheduling Order, Medtronic served and filed its motion papers on July 21, 2009. The Representative Plaintiffs filed their opposition brief with the Court on August 7, 2009. Plaintiffs in the *Eschete* action filed a supplemental memorandum in opposition to

Medtronic's motion on August 14, 2009. Medtronic filed its

reply brief with the Court on
August 26, 2009. The Court heard argument on the motion to dismiss on September 4, 2009.

III.
Standard of Review

A pleading that fails to state a claim on which relief can be granted must be dismissed.
Minn. R. Civ. P. 12.02(e). In reviewing a motion to dismiss, the Court must accept the facts as
pleaded as true and the complainant is entitled to have the benefit of all favorable and reasonable
inferences. *Bodah v. Lakeville Motor Express, Inc.*, 663 N.W.2d 550, 553 (Minn. 2003). The
critical inquiry is whether the pleading states a legally cognizable claim; as the Supreme Court
long ago held:

A claim is sufficient against a motion to dismiss based on Rule 12.02(5) if it is possible on any evidence which might be produced, consistent with the pleader's theory, to grant the relief demanded. To state it another way, under this rule a pleading will be dismissed only if it appears to a certainty that no facts, which could be introduced consistent with the pleading, exist which would support granting the relief demanded.

N. States Power Co. v. Franklin, 122 N.W.2d 26, 29 (Minn. 1963). For purposes of review
under 12.02(e), "it is immaterial whether or not the pleader can prove the facts alleged."
Martens v. Minn. Mining & Mfg. Co., 616 N.W.2d 732, 739 (Minn. 2000). However, if a claim

In reviewing a motion under Minnesota Rule of Civil Procedure 12.02(e), the Court may only consider the allegations set forth in the pleading. If the Court considers matters outside of the complaint, the motion is converted into one for summary judgment. Minn. R. Civ. P. 12.02. The Court's review of the instant motion is limited to the allegations set forth in the Complaints filed in the Representative Cases. Insofar as either party has cited to materials not specifically referenced in the Complaints, the Court has not considered such materials in rendering its decision. (*Cf.* Pls.' Mem. in Opp. at

11 (citing publicly available FDA report from March 2009 that was not cited in any of the pleadings filed in the Representative Cases). In its Scheduling Order, the Court gave Plaintiffs ample time to amend their pleadings in advance of Medtronic's motion to dismiss. Insofar as Plaintiffs failed to reference specific documents in their amended complaints, they cannot cure their pleading defects by referencing such documents in their opposition papers. The Court refuses to consider such documents in reviewing the instant motion; Plaintiffs had the clear opportunity to incorporate allegations relating to these documents when they filed their amended pleadings with the Court in the summer of 2009.

9 The Supreme Court has not adopted the revised motion-to-dismiss standard adopted by the United States Supreme Court for review of motions to dismiss under Rule 12(b)(6) of the Federal Rules of Civil Procedure. S*ee Bell Atl. Corp. v. Twombly,* 550 U.S. 544 (2007). The Supreme Court has mentioned *Twombl*y in passing in two opinions; the first identified the inapplicability of *Twombly* to a price-fixing dispute and the second acknowledged that *Twombly r*ecognized that a Court is not bound by legal conclusions masquerading as factual allegations when

is not legally sufficient it must be dismissed. *Elzie v. Comm'r of Pub. Safety,* 298 N.W.2d 29, 32 (Minn. 1980).

IV.

The Representative Plaintiffs' Claims Are Preempted Under Federal Law

As in the MDL Court, Medtronic moves to dismiss the bulk of Plaintiffs' claims pursuant to two intertwined theories of preemption. First, Medtronic argues that any claims that would require a determination that the Leads should have been designed, manufactured, tested, marketed or labeled differently" from the manner approved by the FDA as part of the PMA process are expressly preempted by 21 U.S.C. § 360k(a), the MDA's preemption provision. See *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008). Second,

Medtronic argues that insofar as Plaintiffs" claims rest on allegations that FDA approval of the Leads through the PMA process

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was obtained or retained by allegedly improper means (e.g., through Medtronic's alleged

inadequate reporting of adverse events), such claims are disguised claims seeking to enforce the

FDCA and its implementing regulations which cannot be brought by private litigants because

there is no private right of action to enforce the FDCA. *Buckman Co. v. Plaintiffs 'Legal*

Comm'ee, 531 U.S. 341 (2001).

Plaintiffs make two basic arguments in opposition to Medtronic's preemption arguments.

First, Plaintiffs argue that their claims are not preempted because the recall of the Leads

reviewing a motion to dismiss. *See Lori*x v. *Crompton Corp.,* 736 N.W.2d 619, 631 n.3 (Minn. 2007*); Herbert v. City of Fifty Lakes,* 744 N.W.2d 226, 235 (Minn. 2008). Neither case convinces this Court that the Supreme Court has forsaken the *Northern States Po*wer standard applied by Minnesota courts for nearly fifty years. However, the Court notes that a panel of the Minnesota Court of Appeals recently opined that *Twombly* does indeed apply to cases in Minnesota. S*ee Bahr v. Capella Univ.,* 765 N.W.2d 428, 436-37 (Minn. Ct. App. 2009) ("The court demands that the complaint state enough factual matter' or 'factual enhancement' to suggest, short of 'probability,' 'plausible grounds' for a claim - a pleading with enough heft' to show entitlement.") (quoting *Twombly,* 550 U.S. at 556-57). Nonetheless, the Court does not believe *Bahr*'s adoption of *Twombly* mandates rejection of the *Northern States Powe*r standard because the Supreme Court has granted review o*f Bahr. See Bahr v. Capella Univ.*, No. A08-1367, Order, Aug. 11, 2009 (granting Petition for Review). Absent express adoption of the *Twombly* standard by the Supreme Court, this Court must continue to apply the *Northern States Power* test when reviewing motions to dismiss. S*ee Lake Superior Center Auth. v. Hammel, Green* & *Abrahamson, Inc.,* 715 N.W.2d 458, 483 (Minn. Ct. App. 2006) (recognizing that the Court of Appeals “has no authority to overrule decisions of the Supreme Court").

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cancelled their PMA approval and, thus, their state-law claims do not interfere with the FDA's
regulatory scheme. Second, Plaintiffs argue that their claims are not subject to preeniption
because they are parallel common-law claims that are not preempted under the MDA.
As explained in greater detail below, after reviewing all of the pleadings and the
applicable law, the Court concludes that Plaintiffs' claims against Medtronic must be dismissed
as preempted under federal law."

A.
Under *Riegel,* 21 U.S.C. § 360k Preempts Differing or Additional State-Law Requirements Applicable to Medical Devices Approved by the FDA Pursuant to the Premarket Approval Process of the Medical Device Amendments to the Federal Food, Drug and Cosmetic Act

Medtronic argues that all of Plaintiffs' claims are preempted under 21 U.S.C. § 360k
pursuant to the United States Supreme Court's decision in *Riegel.* 128 S.Ct. 999. The *Riegel*
Court analyzed the MDA's preemption provision, which precludes the States from imposing any
requirements upon FDA-approved medical devices as follows:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter

21 U.S.C. $ 360k(a).

10 Because the preemption principles at issue arise under the Supremacy Clause of the United States Constitution, they arise under federal law so the Court is bound to follow the decisions of the United States Supreme Court. *Nicol* v. *Tanner,* 256 N.W.2*d* 796, 800 (Minn, 1976)*; see also, Dahl v. R.J. Reynolds Tobacco, Co.,* 742 N.W.2d 186, 191 (Minn. 2007) ("The preemption doctrine stems from the Supremacy Clause of the United States Constitution, which provides that the laws of the United States "shall be the supreme law of the land . . . anything in the Constitution or laws of any state to the contrary notwithstanding.") (quoting U.S. Const. art. VI, cl. 2.). The United States Supreme Court has jurisdiction to review state-court determinations of preemption under the FDCA. S*ee, e.g., Wyeth v. Levin*e, 129 S.Ct. 1187 (2009) (reviewing decision of the Vermont Supreme Court interpreting the scope of preemption under the FDCA).

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As interpreted by the United States Supreme Court in *Riegel,* § 360k(a) preempts the bulk of state tort-law clains relating to medical devices that have been approved by the FDA pursuant to the PMA process. 128 S.Ct. at 1008 ("Absent other indication, reference to a State's 'requirements includes its common-law duties."). In deciding whether a specific claim is preempted, the Court must first ascertain "whether the Federal Government has established requirements applicable to" the specific device at issue. *Id.* at 1006. The Court must then determine whether the claim arises from state-law requirements that are "different from, or in addition to" the federal requirements. *Id.* Preemption is not limited to requirements that "relate[] to the safety or effectiveness of [a] device," but specifically applies to state-law requirements that "relate[] . . . to any other matter included in a requirement applicable to the device" under the Act. 21 U.S.C. § 360k(a) (emphasis added).

The *Riegel* Court concluded that "[p]remarket approval ... imposes

‘requirements' under
the MDA." 128 S.Ct. at 1007. FDA approval of a premarket application shows the FDA has
reviewed a device's testing, design specifications, intended use, manufacturing method,
performance standard, and labeling, and decided the device is safe and effective.” *Martello v.*
Ciba Vision Corp., 42 F.3d 1167, 1169 (8th Cir. 1994) (citing 21 U.S.C. $$ 360e(c)(1),
360c(a)(2)). Thus, the design, manufacturing, labeling, and marketing standards applicable to a device set forth in a PMA application (or PMA Supplement) that has been approved by the FDA constitute federal “requirements" for purposes of preemption under $ 360k(a*). Riegel*, 128 S.Ct.
es
at 1007. The *Riegel C*ourt noted that after the FDA approves a device under the PMA process, it
"requires a device that has received premarket approval to be made with almost no deviations
from the specifications in its approval application,” so such specifications constitute
requirements under the FDCA*. Id.* Because the Leads were approved by the FDA pursuant to
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the PMA process, they were subject to federal requirements, so claims alleging violation of
additional or contrary state-law requirements are preempted as a matter of law under $ 360k."

Plaintiffs seek to avoid preemption under $ 360k by directing the Court to the United

States Supreme Court's decision in M*edtronic, Inc. v. Lohr,* 518 U.S. 470 (1996), and arguing that the preemptive scope of the MDA is strictly limited. Plaintiffs quote the decision of a plurality of the *Lohr* Court and the dissent in *Riegel* in support of their argument. (See Pls.' Mem. in Opp. at 24 (quoting *Lohr,* 518 U.S. at 491*, Riegel,* 128 S.Ct. at 1015 n.4 (Ginsburg, J. dissenting)).) This argument plainly ignores the clear holding of *Riegel* that common-law claims related to medical devices approved under the PMA process are explicitly preempted under $ 360k*. Riegel,* 128 S.Ct. at 1008-09. Indeed, the *Riegel* Court's conclusion was the same as that of a majority of the justices in *Lohr. See id.* at 1007 (recognizing that five of the justices in *Lohr* "concluded that common-law causes of action for negligence and strict liability do impose *requirement[s]' and would be preempted by federal requirements specific to a medical device") (quoting 518 U.S. at 503-05, 512).

Plaintiffs next seek to avoid preemption under $ 360k by pointing to the FDA'S implementing regulations, which purport to limit the scope of such preemption by providing that preemption occurs only “when the (FDA) has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act. . . ." 21 C.F.R. § 808.1(d). Under $ 808.1(d), state requirements of general applicability to a medical

"Plaintiffs characterize the review of the PMA Supplement process as “abbreviated" and "less than rigorous," and argue that the preemptive effect of the FDA's approval of

the Leads under that process should be lessened. (Pls.' Mem. at 4; see *also Bebeau* 2d Am. Compl. $ 22.) However, the *Riegel* Court did not distinguish between the initial PMA process and the PMA Supplement process when it concluded that FDA approval of a device pursuant to a PMA application (or PMA Supplement) imposes federal requirements on a device for purposes of preemption. Indeed, the device at issue in *Riegel* was approved by the FDA pursuant to the PMA Supplement process. *See Riegel, 1*28 S.Ct. at 1005. Accordingly, the Court's conclusion that the Leads are subject to federal requirements that preempt different or additional state-law requirements is not affected by the fact that the Leads were approved by the FDA pursuant to the PMA Supplement process rather than pursuant to an original PMA application.

device are not preempted under $ 360k. S*ee id.* (“Section (360k(a)] does not preempt state or
local requirements of general applicability where the purpose of the requirement relates .. to
other products in addition to devices (e.g., requirements such as general electrical codes, and the
Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the
requirements are not limited to devices.') However, the *Riegel C*ourt expressly rejected the
argument that state common-law claims for negligence, strict liability, and breach of implied
warranty could be preserved by this regulation. 128 S.Ct. at 1011; *see also Covert* v. *Stryker*
Corp., ---- F. Supp. 2d. ----, 2009 WL 2424559, at *5-*6 (M.D.N.C. Aug. 5, 2009) (recognizing
that the *Riegel* Court “significantly limit[ed] the effect of"> $ 808.1(d)(1). Section 808.1(d)(1)
does not save Plaintiffs' claims from preemption
under $ 360k.

Finally, Plaintiffs argue that the subsequent recall of the Leads invalidated their PMA

and, thus, their claims are not subject to preemption under $ 360k."2 Plaintiffs argue that by classifying Medtronic's withdrawal of the Sprint Fidelis Leads from the marketplace as a recall, the FDA found that the Sprint Fidelis Leads were defective and in violation of federal law. (Pls.' Mem. in Opp. at 28.) Under Plaintiffs' theory, the FDA's approval of the Leads was thereby "cancelled," so the Leads are not subject to any federal requirements with which state-law claims can conflict, and, thus, there is no longer any preemption of their claims. *(Id.* at 30.) Plaintiffs cite no cases in support of this novel theory. Indeed, the MDL Plaintiffs raised the same argument in the MDL proceedings, and it was specifically rejected by the MDL Court, which noted that (1) there is a specific regulatory proceeding that governs the withdrawal of PMA from an approved device, which was never invoked by the FDA to withdraw the PMA for the Leads,

12 Plaintiffs also seek to avoid preemption under $ 360k by arguing that their state-law claims fit within the parallel common-law claim exception recognized by *Riegel.* 128 S.Ct. at 1011. As explained in greater detail below, under 21 U.S.C. $ 337(a) Plaintiffs are impliedly preempted from raising the claims they characterize as falling within the parallel-claim exception. See § IV.B *infra.*

and (2) even if a recall invalidated the PMA, it was undisputed that the Leads had FDA approval at the time they were implanted, so claims that they were defective at that time would necessarily remain preempted. *In re Sprint Fidelis Leads I, 5*92 F. Supp. 2d at 1155-56. Courts throughout the country have reached the same conclusion. S*ee Kemp v. Pfizer, Inc.,* 835 F. Supp. 1015,

1023 (E.D. Mich. 1993) (“The fact that can approved medical device) was later withdrawn from
the market, even if the FDA had mandated the withdrawal, does not change the fact that the
MDA preempted state law requirements concerning its safety, effectiveness, and otherwise.");
see
see also Blunco v. Baxter Healihcare Corp., 158 Cal. App.4th 1039， 1056 (2008) (“The fact the
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FDA implemented a Class I recall of the Valve does not alter our conclusion (that the plaintiff's
claims are preempted]."); *Baker v. St. Jude Med., S.C., Inc., 178* S.W.3d 127, 134 n. 5 (Tex. Civ.
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App. 2005) (“We likewise disagree with appellants' assertion that preemption, if applicable,
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evaporates if the FDA later determines that the PMA approval was wrongly granted."). Likewise, this Court also rejects Plaintiffs' argument that the recall of the Leads constitutes a de
facto revocation or withdrawal of the FDA's approval. *Cf.* 21 U.S.C. § 360e(e) (setting forth
framework for the FDA to withdraw approval from a previously approved device and requiring
notice and an opportunity to be heard before approval may be withdrawn). This same reasoning
precludes Plaintiffs argument that the FDA's approval was invalidated pursuant to the Conditions of Approval. '3 Plaintiffs' claims remain subject to preemption under $ 360k.

Having determined that the Leads were subject to federal requirements

imposed under the
PMA process, the Court must now examine the substance of Plaintiffs' claims to determine
whether they seek to impose additional or contrary state-law requirements on the Leads and are

13 As Medtronic notes, the statutes and regulations governing the FDA specifically require express action and hearings by the FDA in order to withdraw or suspend a device's PMA. *See* 21 U.S.C. $$ 360(e)(1), (3); 21 C.F.R. $$ 814.46, .47.

thus preempted under *Riegel.* In granting approval 10 Medtronic to market the Leads, the FDA

necessarily passed on the sufficiency of the design, manufacturing process and labeling as

proposed by Medtronic. S*ee Martello,* 42 F.3d at 1169; s*ee also Worthy v. Collagen Corp., 967*

S.W.2d 360, 369 (Tex. 1998) ("To obtain premarketing approval, the design, manufacture,

distribution, and use of a device are all subject to thorough scrutiny by a panel of experts."). To

determine that the design, manufacturing and labeling of the Leads was deficient under state law

would necessarily impose contrary requirements upon a federally-approved device.

Similarly, the FDA's decision to grant PMA to the Leads was made after the agency "weigh[ed]

any probable benefit to health from the use of the device against any probable risk of injury or

illness for such use."" *Riegel,* 128 S.Ct. at 1004 (quoting 21 U.S.C. § 360c(a)(2)(C)). A state

law claim that would permit a jury to substitute its judgment for that of the FDA and conclude

that the health benefits of the Leads were outweighed by their risks would necessarily impose

additional or contrary requirements upon an FDA-approved medical device, and is thus

preempted under *Riegel. Cf. Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1099 (6th

Cir. 1997) ("Thus, because under the federal requirement the FDA has determined that the

benefits of the device outweigh the risks and, under the state requirement, a jury in a state court

action could conclude that the risks outweigh the benefits, the state requirement is different from

the federal requirement."). Accordingly, a jury may not second-guess the FDA's determination

that the Leads were safe and effective pursuant to the PMA and could be marketed in accordance

with the terms of the agency's approval. *Gomez v. St. Jude Med. Daig Div., Inc.*, 442 F.3d 919,

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930 (5th Cir. 2006) ("To permit a jury to second-guess the Angio-Seal design by applying the

Louisiana statutory standard for unreasonably dangerous design would risk interference with the

federally-approved design standards and criteria."); *see also Blunt* v. *Medtronic, Inc., 7*38 N.W.2d 143, 152 (Wis. Ct. App. 2007) (recognizing that a jury finding of liability on a design

defect claim "would result in a jury finding that the FDA's approval of the device was

erroneous" and "would usurp the power Congress gave to the FDA").

Applying the foregoing principles to Plaintiffs' claims compels this Court to conclude

that all claims raised in the Representative Cases that allege defects in the Leads' design,

manufacturing, testing, labeling and warnings are preempted as a matter of law.

1.

Plaintiffs' Claims Predicated Upon Allegedly Inadequate Warnings or Instructions Are Preempted Under $ 360k

A predicate for Plaintiffs' claims for relief under strict-liability and negligence!theories

is that Medtronic failed “to add or strengthen the warning regarding adverse events occurring

with Sprint Fidelis Leads” and failed to warn of the “increased frequency and severity of adverse

events.":15 (*See, e.g., Bebeau 2*d Am. Compl. 11159, 170, 187, 189, 208, 210, 220, 222, 242,

250.) Plaintiffs point to Medtronic's alleged failure to add to or strengthen the instructions for

safe use” of the Leads after receiving reports of adverse events related to their use*. (Id.* 19 159,

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187, 224.) In addition, Plaintiffs allege insufficiencies in Medtronic's warnings as a predicate

for their claims for intentional misrepresentation. *(Id.* 19 *272, 275, 277.)* Medtronic argues that

such claims are expressly preempted under $ 360k because they would impose requirements

14 Plaintiffs' negligence claims are largely reiterations of their failure-to-wam and defective-manufacturing claims, so the Court does not address them separately. All of Plaintiffs' negligence claims are plainly preempted under *Riegel,* which specifically held that "the MDA preempt[s] claims of . . . negligence in the design, testing, inspection, distribution, labeling, marketing, and sale of [a device approved for sale by the FDA under the PMA process]." *Riegel, 1*28 S.Ct. at 1005-06. This conclusion applies equally to Plaintiffs' claims for pre- and post-recall negligence.

1 Such allegations form the predicate for Plaintiffs' claims for strict-liability failure to warn and instruct and under a variety of negligence-based claims. *(See Bebeau 2*d Am. Compl. Counts I-III, V-IX*; Manning* Compl. Counts I, III; *Morrison* Am. Compl. Counts I-III, V-IX*; Eschete* Ist Supp. & Am. Compl. Counts I-III, V-I*X; Joest* Am. Compl. Counts I-III, V-I*X; Florence* Ist Am. Compl. Counts I-III, V-I*X; Diamond* Compl. Counts I-III; V-IX; *Bowie* Am, Compl. Counts I-III, V-IX.)

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upon the Leads labeling and instructions different from those imposed by the FDA pursuant to

the PMA process.

> As part of the PMA process, the FDA evaluates the safety and effectiveness of a device

under the conditions of use set forth on the proposed labeling. 21 U.S.C. $ 360c(a)(2)(B). In

addition, before granting approval to a device, the FDA determines that the labeling proposed for

the device is neither false nor misleading. 21 U.S.C. § 360e(d)(1)(A). In order to ensure that

manufacturers adhere to the specifications approved by the FDA through the PMA process, the

MD*A* specifically forbids a manufacturer from making any changes to a device's labeling that

would affect the safety or effectiveness of a device without FDA approval. 21 U.S.C. $

360e(d)(O)(
A)(i).

By way of the PMA process, the FDA specifically approved of Medtronic's warnings and

instructions for the Leads. For a jury to determine that these FDA-approved warnings and

instructions were deficient in some way under state law would result in imposing requirements

different to those imposed by the MDA, a result that is impermissible under *Riegel*. 128 S.Ct. at

1011 (“Surely ... the MDA would pre-empt a jury determination that the FDA-approved

labeling for [a medical device approved under the PMA process] violated a state common-law

requirement for additional warnings."); *see also In re Sprint Fidelis Leads I,* 592 F. Supp. 2d at

1159 (dismissing the MDL Plaintiffs' failure-to-warn claim as preempted under *Riegel* because it

was predicated upon the theory that Medtronic was "required to provide warnings above and

beyond those on the [Leads'] product label," even though the label had been specifically

approved by the FDA as part of the PMA process*); Mitaro v. Medtronic, Inc.*, No. 3642/08, 2009

WL 1272398, at *3 (N. Y. Sup. Ct. Apr. 9, 2009) (dismissing claim against Medtronic for failure to warn and instruct regarding the Sprint Fidelis Leads as

preempted under *Riegel)*. The

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adequacy of Medtronic's warning has already been passed on by the FDA and, under *Riegel, a*

jury may not second-guess this determination. *Cf.* CIV JIG. 75.25 (directing a jury considering a

failure-to-warn claim under either a negligence or strict-liability theory to balance the benefit and

burdens associated with providing warnings against the likelihood of harm arising from use of

the product). As a matter of law, Plaintiffs' failure-to-warn claims are preempted under $ 360k.

Plaintiffs point to 21 C.F.R. $ 814.39(d)(2) in support of their argument that Medtronic

had a duty to supplement the Leads' warnings after learning of adverse events. (*See, e.g.,*

*Bebeau 2*d. Am. Compl. 1 75.) Section 814.39 does not save Plaintiffs' claims from preemption

because it merely allows a device manufacturer to “add or strengthen a contraindication,

warning, precaution, or information about an adverse reaction” or “add or strengthen an

instruction that is intended to enhance the safe use of a device.” 21 C.F.R. $ 814.39(d)(2)(i), (ii).

However, **[b]ecause $ 814.39 permits, but does not require, a manufacturer to provide interim

supplemental warnings pending approval by the FDA, a common-law

duty to provide such a

warning imposes an additional obligation" and is therefore preempted by $ 360k. M*cMullen v*.

Medtronic, Inc., 421 F.3d 482, 489 (7th Cir. 2005); *see also In re Sprint Fidelis Leads II, 2*009

WL 1361313, at *2 ("[W]here a federal requirement permits a course of conduct and the claim

alleged would make it obligatory, the claim is preempted."). Because Plaintiffs' claims for

failure to warn and instruct seek to impose additional obligations upon Medtronic beyond those

imposed by the FDA pursuant to the PMA process, they are preempted as a matter of law by $

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2. **Plaintiffs' Claims for Defective Manufacturing or Design**
Are Preempted Under $
360k

As in the MDL Court, Plaintiffs' manufacturing- and design-defect claims are

predicated upon the assertion that the welding technique chosen by Medtronic to anchor the

Leads into the ICDs resulted in an increased fracture rate. (S*ee, e.g., Bebeau 2*d Am. Compl. 11 43, 193, 207.); s*ee also In re Sprint Fidelis Leads I,* at 592 F. Supp. 2d at 1157. Plaintiffs allege a systemic flaw in the FDA-approved design of the Leads and the manufacturing process used to create them. (S*ee Bebeau* 2d. Am. Compl. 1949, 193, 207.) ! Plaintiffs ignore the fact that the FDA specifically approved the design and proposed manufacturing processes when it gave the Leads their PM*A*.

> In order to succeed on their defective-manufacturing claims, Plaintiffs would have t*o* prove to a jury that that the Leads were unreasonably dangerous for their intended use in the ICDs notwithstanding the FDA's approval of their design and manufacture. S*ee, e.g., Bilotta* v. *Kelley Co.*, 346 N.W.2d 616,623 n. 3 (Minn. 1984) ("In order to recover under the theory of strict liability, the plaintiff must establish (1) that the defendant's product was in a defective condition unreasonably dangerous for its intended use, (2) that the defect existed when the product left the defendant's control, and (3) that the defect was the proximate cause of the injury sustained."). Plaintiffs allege that the Leads were unreasonably dangerous for their intended use

“because the foreseeable risks of malfunction and failure outweigh the benefits" associated with

their use. *(Bebeau 2*d Am. Compl. 1 192.) However, the *Riegel* Court specifically held that $

16 *(See Bebeau* 2d. Am. Compl. Counts IV-VI, VIII*; Bell C*ompl. Counts I, III*; Brue* Am. Compl. Counts I, III; *Manning* Compl. Counts II-III; *Morrison A*m. Compl. Counts IV-VI, VIII; *Eschete* 1st Supp. & Am. Compl. Counts IV-VI, VIII, XX*V; Joest* Am. Compl. Counts IV-VI, VIII; *Florence* 1st. Am, Compl. Counts IV-VI, VIII*; Diamond* Compl. Counts IV-VI, VIII*; Bowie* Am. Compl. Count IV-VI, VIII.)

"? (See also Bell Compl. 1945, 47 (alleging that the Leads were uniformly defective*); Brue* Am. Compl. 99 45, 47 (same).)

360k necessarily precludes a jury from substituting its own judgment that the risks associated

with an FDA-approved device outweigh its benefits, noting that the MDA vests the FDA with

the sole authority to determine whether a proposed device is safe and effective. *Riegel,* 128 S.Ct.

at 1008. Unlike a jury, the FDA has to consider the benefits provided by a device to the universe

of patients; "[a] jury, on the other hand, 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.”

Id. As a matter of law, a jury cannot supplant the FDA's determination that a device's design

and manufacturing specifications are reasonably safe and effective. *Riegel,* 128 S.Ct. at 1007*;*

see also In re Sprint Fidelis Leads 11, 2009 WL 361313, at *2 (holding that the

MDL Plaintiffs'

identical defective-design claims were futile and subject to preemption).

Plaintiffs' manufacturing- and design-defect claims, whether founded on negligence or

strict-liability principles, are preempted.

3. Plaintiffs' Claims for Breach of Implied Warranty Are Preempted Under $ 360k

Plaintiffs seek to impose liability upon Medtronic for breaching the implied warranty that

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the Leads were merchantable and fit and safe for ordinary use." *(Bebeau* 2d Am. Compl. 9

254.)'. For a jury to find for Plaintiffs on such claims it would necessarily have to supplant the

FDA's decision that the Leads were safe and effective with a determination that the Leads were

not safe and fit for ordinary use. Such a result is specifically barred under *Riegel. See* 128 S.Ct.

at 1006, 1011 (affirming dismissal of a similar claim for breach of implied warranty as

preempted as a matter of law under $ 360k); s*ee also In re Sprint Fidelis Leads 1,* 592 F. Supp.

2d at 1164.

18 (See also Bell Compl. Count II; *Brue* Am. Compl. Count II; *Manning* Compl. Count V; M*orrison* Am. Compl. Count X; *Eschete* 1st Supp. & Am. Compl. Count X*; Joest* Am. Compl. Count X*; Florence* 1st Am. Compl. Count *X; Diamond C*ompl. Count X*; Bowie A*m. Compl. Count X.)

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Plaintiffs argue that their breach-of-implied warranty claims are preserved from

preemption under 21 C.F.R. $ 808.1(d)(1), which purports to exempt warranty claims from

preemption pursuant to § 360k. Citing pre-*Riegel* cases, Plaintiffs ignore the fact that the *Riegel*

Court both specifically questioned the effect of $ 808.1(d)(1) on the scope of § 360k preemption

and held that breach-of-implied-warranty claims were preempted by the MDA. *See Riegel,* 128

S.Ct. at 1006, 1010-11; s*ee also Rile*y v*. Cordis Corp.*, 625 F. Supp. 2d 769, 789 (D. Minn. 2009)

("Riegel explicitly rejected this argument, explaining that 8 808.1(d)(1) 'add(s) nothing to our

analysis but confusion?") (quoting *Riegel,* 128 S.Ct. at 1011). After *Riegel,* courts throughout

the country have held that claims for breach of implied warranties are preempted under $ 360k.

S*ee, e.g., Williams v. Cyberonics, Inc.,* --- F.Supp.2d ----, 2009 WL 2914414, at *6 (E.D. Pa.

Sept. 10, 2009*); Horowitz* v*. Stryker Corp.,* 613 F. Supp.2d 271, 284-85 (E.D.N.Y. 2009)

(holding that claims for breach of implied warranty of merchantability and implied warranty of

fitness fall“squarely within the MDA's preemption provision”)*; Parker* v*. Stryker Corp.*, 584 F.

Supp. 2d 1298, 1303 (D. Colo. 2008) (same). Given this settled law, the Court holds that

Plaintiffs" breach of implied warranty claims are preempted under $ 360k.

4. Plaintiffs' Claims for Breach of Express Warranty Are Preempted Under $ 360k

Plaintiffs plead two distinct express-warranty claims." First, Plaintiffs allege that

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Medtronic expressly warranted that the Leads were “safe, effective, fit and proper for their

intended use." *(Bebeau 2*d An. Compl. 1 259.) Second, Plaintiffs allege claims pursuant to

Medtronic's written Implantable High Voltage Lead Limited Warranty*. (Id.* 1 260.) In its

written warranty, Medtronic does not warrant that the Leads are safe and effective. *(Id.)*

*1*9 (S*ee Bebeau 2*d Am. Compl. Count XI; *Bell* Compl. Count VII*; Brue* Am. Compl. Count VII*; Manning* Compl. Count VI; *Morrison* Am. Compl. Count XI*; Eschete* Ist Supp. & Am. Compl. Count IX; *Joest* Compl. Count XI; *Florence* Ist Am. Compl. Count XI*; Diamond* Compl., Count XI; *Bowi*e Am. Compl. Count XI.)

Plaintiffs correctly note that the *Riegel c*ourt did not address whether claims for

breach of
express warranty are necessarily preempted under $ 360k. *Riegel*, 128 S.Ct. at 1006 n.2. However, other courts, including the MDL Court, have concluded that breach of express
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warranty claims predicated upon allegations, like those made by Plaintiffs, that a device is not
safe and effective are indeed preempted under § 360k. S*ee Miller v. DePuy Spine, Inc.,* --- F.
Supp. 2d. ----, 2009 WL 1767555, at *3 (D. Nev. May 1, 2009) (“Where, as here, an essential
element of a plaintiff's claim of breach of express or implied 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 its requirement that the device be made as approved. Such a warranty claim
is directly preempted by *Riegel."); In re Sprint Fidelis Lead*s *I, 5*92 F.Supp.2d at 1164 (“A jury
finding in Plaintiffs' favor on [their express-warranty] claims, therefore, would be required to
conclude that the [Leads) were unsafe. As the safety and effectiveness of the leads are matters
solely for the FDA, and because the FDA determined that the [L]eads were safe and effective
when granting PMA, these claims are preempted."). Here, the predicate for Medtronic's liability
for Plaintiffs' express-warranty claims is that Medtronic's “warranties and representations were
false in that the [Leads] were not safe and were unfit for the uses for which they were intended.”
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(Bebeau Compl. 1 261.) Such a claim is clearly preempted under $ 360k. S*ee Parker,* 584 F.

Supp. 2d at 1303 (“Plaintiff's express warranty claim would contradict the FDA's determination

that the representations made on the label were adequate and appropriate and, thus, impose

requirements different from or in addition to the federal requirements. Therefore, that claim is

preempted by section 360k."); *see also Covert, 2*009 WL 2424559, at *16 (“Given the ‘unusual breadth of the “relating to' language used in § 360k(a), it would seem that [breach-of-express

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warranty] claims are subject to express preemption under that statute ....') (quotation omitted).

As a matter of law, Plaintiffs' breach-of-express-warranty claims are preempted under $ 360k.

5. Pl**aintiffs' Claims for Fraud, Misrepresentation, and Deceit**

Are Preempted Under $ 360k

Plaintiffs plead a variety of claims predicated upon assertions that Medtronic

misrepresented, either negligently or intentionally, the safety and effectiveness of the Leads. 20

(S*ee, e.g., Bebeau* 2d Am. Compl. 99 2*67, 271-72, 277,* 283, 292, 304, 312, 315, 320(a)-(d), 325

27, 332, 338.) In order for Plaintiffs to recover on these fraud- and misrepresentation-based

claims, a jury would have to determine that the Leads were not safe and effective thereby

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supplanting the FDA s determination to the contrary. S*ee, e.g.*,

CIVJIG 57.10 (liability for fraudulent misrepresentation requires a finding of false representation of material fact; CIVJIG 57.20 (liability for negligent misrepresentation requires a finding of dissemination of false information); CIVJIG 57.40 (liability for consumer fraud would require a finding of dissemination of false information or deceptive practices). A jury may not retroactively question the soundness of the FDA's determination that an approved device is safe and effective without violating the principles laid down in *Riegel. In re Sprint Fidelis Leads I, 592* F. Supp. 2d at 1165 (concluding that the MDL Plaintiffs' fraud and misrepresentation claims were derivative of their other claims and preempted under § 360k); see *also Riley*, 625 F. Supp. 2d at 786 (holding that fraud and misrepresentation clains were preempted under *Riegel); Scott v. Pfizer, Inc.,* 249 F.R.D. 248, 255 (E.D. Tex. 2008) (same). This conclusion equally holds true for Plaintiffs' claims under various consumer-protection statutes, which are predicated upon alleged misrepresentations or deceit. See *Baker* v. *St. Jude Med., S.C., Inc., 1*78 S.W.3d 127, 137 (Tex. *20 (*See *Bebeau* 2d. Am. Compl. Counts XII-XIX*; Bell C*ompl. Counts VI, VIII; *Brue* Am. Compl. Count VI, VIII; *Manning* Counts VII-XIV*; Morrison* Am. Compl. Counts XII-XVIII, XXI-XXII; *Eschete* 1st Supp. & Am. Compl. Counts XII-XX*; Joest C*ompl. Counts XII-XI*X; Florenc*e 1st Am. Compl. Counts XII-XX*; Diamond* Compl. Counts XII-X*X; Bo*wie Am. Compl. Counts XII-XIX.)

Ct. App. 2005) ("[C]laims for ... DTPA violations are preempted because they would require a finding that the Silzone valve was unsafe, a direct contradiction to the PMA approval and PMA

supplemental approval granted by the FDA."); s*ee also Kemp,* 835 F. Supp. at 1021 (recognizing that claims arising under state consumer-protection statutes are preempted by $ 360k). As a matter of law, Plaintiffs' misrepresentation- and deceit-based claims are preempted by $ 360k.

6. Plaintiffs' Derivative Claims Are Preempted Under $ 360k

Finally, the Court holds that all of Plaintiffs' claims that are derivative of their preempted claims are also subject to preemption. ?' (*See, e.g., Bebeau 2*d Am. Compl. 11 332 (predicating negligent-infliction-of-emotional distress claim on allegations of negligent manufacturing and marketing of the Leads as safe and effective); 338 (predicating unjust-enrichment claim upon allegations of misrepresentations of the quality, nature and fitness of the Leads)*; Bell Co*mpl. 1 83 (predicating intentional-infliction-of-emotional-distress claim on misrepresentations regarding the safety and effectiveness of the Leads).) Accordingly, the Court holds that Plaintiffs' claims for loss of consortium, intentional infliction of emotional distress, negligent infliction of emotional distress, medical monitoring, unjust enrichment, or under the Medicare as Second Payer Act are preempted as a matter of law. *See Riegel,* 128 S.Ct. at 1006 (affirming dismissal of loss-of-consortium claim on preemption grounds because "it was derivative of the pre-empted claims); *In re Sprint Fidelis Leads 1,* 592 F. Supp. 2d at 1165 (dismissing claims for loss of consortium, unjust enrichment, negligent infliction of emotional distress, and violations of consumer-protection statutes as preempted derivative claims); *Kemp v. Medtronic, Inc.,* 231

F.3d

216, 237 (6th Cir. 2000) (same); *O'Neal v. SmithKline Beecham Corp.,* No. Civ. S-06-1063

21 (See Bebeau 2d Am. Compl. Counts XX-XXI*; Bell* Compl. Counts IV-V, IX-X*; Brue* Am. Compl. Counts IV-V, IX*; Manning* Compl. XV-XVII*; Morrison* Am. Compl. Counts XIX-XX, XXIII-XXIV*; Eschete* Ist Supp. & *A*m. Compl. Counts XXI-XXIV*; Joest* Am. Compl. Counts XX-XXII*; Florence* I st Am. Compl. Counts XXI-XXIV; *Diamond* Compl. Counts XXI-XXIII; *Bowie* Am. Compl. Counts XX-XXI.)

FDC/DAD, 2008 WL 1721891, at *5 (E.D. Cal. Apr. 10, 2008) (concluding, inter alia, that negligent-infliction-of-emotional-distress claim was a preempted derivative claim); *In re Sulzer Hip Prosthesis* & *Knee Prosthesis Liab. Litig.*, 455 F. Supp. 2d 709*,* 720 n.13 (N.D. Ohio 2006)

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(recognizing that claim for medical monitoring is simply a request for injunctive relief and is

preempted if the underlying substantive claims are preempted). Plaintiffs' derivative-claims are

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preempted under $ 360k.

B.

Plaintiffs' Claims Do Not Avoid Preemption Because They Do Not Fit Within the Narrow **Parallel-State-Law Claim Exception to $ 360k Preemption and Are Preempted by 21 U.S.C. $ 337(a)**

"State requirements are pre-empted under the MDA only to the extent that they are

'different from, or in addition to the requirements imposed by federal law." *Riegel,* 128 S.Ct. at

1011 (quoting 21 U.S.C. § 360k(a)(1)). Accordingly, “8 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements.” *Id. (*quoting *Lohr,* 518 U.S. at 495). “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.” *Riley*, 625 F. Supp. 2d at 776. Plaintiffs argue that all of their claims are parallel common-law claims so are not subject to preemption under $ 360k. Medtronic counters Plaintiffs parallel-claim argument with another preemption-based argument focused on the preemptive effect of 21 U.S.C. § 337(a), which provides that all actions to enforce the FDCA “shall be by and in the name of the United States.” 21 U.S.C. § *337*(a). Medtronic argues that Plaintiffs' purportedly parallel claims seek to do nothing more than enforce the FDCA and its implementing regulations, and, thus, Plaintiffs lack standing to bring such claims, which are impliedly preempted by $ 337(a). *See Buckman*, 531 U.S. at 349.

> The United States Supreme Court has recognized that “[t]he FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions.” *Buckman Co.*, 531 U.S. at 349. There is no

private right of action under $ 337(a). *Id.* The FDA has sole and exclusive authority to enforce the FDCA and its implementing regulations and claims predicated upon injuries alleged to have arisen from violation of those regulations are preempted. *See Flynn* v. *Am. Home Prods. Corp.,* *627* N.W.2d 342, 349 (Minn. Ct. App. 2001) ("[T]he existence of state-law claims against applicants for, and recipients of, FDA drug approval for alleged violation of FD*A* regulations conflicts with the FDA's authority to consistently police fraud within the agency's powers.").22 The FDA's exclusive authority extends to all actions "to enforce MDA premarket approvals." *See Clark v. Medtronic, Inc.,* 527 F. Supp. 2d 1090, 1095 (D. Minn. 2008). Insofar as Plaintiffs seek to predicate their "parallel" common-law claims upon alleged violations of the FDCA and its implementing regulations, such claims are preempted under *Buckman.*

In trying to save their claims from preemption under $ 360k, Plaintiffs repeatedly point to alleged violations by Medtronic of its reporting obligations to the FDA under the PMA and the Conditions of Approval and argue that their state-law claims merely parallel these obligations. (S*ee, e.g., Bebeau* 2d Am. Compl. 99 160, 188, 198, 205-06, 212-17, 226, 230-31, 233-35, 239, 243, 248, 251, 280, 288, 295, 316, 329, 333.) However, it is nonsensical to speak of a state-law claim for failure to follow the conditions of the PMA in the absence

of the federal regulatory

structure that provides for that PMA ... under the logic of *Buckman,* any such state-law claim

would be preempted.*" Riley: 6*25 F.Supp.2d at 789-90; s*ee also Lake* v*. Kardjian, 87*4 N.Y.S.3d

22 Insofar as Plaintiffs' fraud or misrepresentation claims are predicated upon alleged misrepresentations or omissions made by Medtronic to the FDA, such claims are necessarily preempted by *Flynn* and *Buckman. (Cf. Bebeau 2d* Am. Compl. 11267*; 277, 280, 285, 295*, 316, 322, 329.)

*7*51, 755 (N. Y. Sup. Ct. 2008) (holding that the failure to comply with the MDA's reporting

requirements does not constitute a parallel claim that would escape preemption under *Riegel).*

The MDL Plaintiffs made similar arguments in the MDL proceedings where they were rejected

by the MDL Court, which noted that "what Plaintiffs are really alleging is that Medtronic

violated the FDCA by failing to inform the FDA in a timely fashion of adverse lead events" and held that such claims were necessarily preempted under *Buckman. In re Sprint Fidelis Leads 1,*

592 F. Supp. 2d at 1160-61; *(cf. Bebeau* 2d Am. Compl. 1 29 ("Medtronic failed to comply with

the (FDCA) and the regulations in its filing for and response to inquiries made by the FDA as

part of the PMA Supplement process."). Plaintiffs have presented no basis for this Court to

deviate from that conclusion in these proceedings. Any claims predicated upon alleged

violations by Medtronic to submit reports required by the FDA are not parallel claims that avoid

preemption under *Riegel* and *Buckman.*

Applying these principles, the Court concludes that none of Plaintiffs' claims are parallel common-law claims that avoid preemption under both § 360k and 337(a).

1. Plaintiffs' Claims Predicated Upon Medtronic's Alleged Failure to Warn Are Not Parallel Claims and Are Preempted Under $ 337(a)

Absent a federal requirement, there can be no parallel claim that avoids preemption. *Cf.* *Riegel*, 128 S.Ct. at 1011 (recognizing the parallel-claim exception arises for state-law requirements mirroring federal requirements). Plaintiffs have not identified a federal requirement mandating Medtronic to make changes to the Leads' warnings upon which they could bootstrap a parallel failure-to-warn claim. Instead, Plaintiffs merely cite to 21 C.F.R. S 814.39(d), which, as explained in greater detail above,[23] simply permits a device manufacturer to make changes to approved labeling without receiving pre-approval from the FDA. "As other courts have explained, a failure-to-warn claim cannot parallel $ 814.39(d) because § 814.39(d) merely permits a device manufacturer to make a temporary change to a label whereas a successful failure-to-warn claim would require such a change." *Riley,* 625

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23 See supra S IV.A.2.

F.Supp.2d at 783
(emphasis original); s*ee also In re Sprint Fidelis Leads 1, 5*92 F. Supp. 2d at 1160 (holding that a
claim under $ 814.39 is not a parallel claim because § 814.39's language is permissive and not
mandatory and, thus, a common-law duty mandating supplemental warnings is an impermissible
state-law requirement preempted by $ 360k). Plaintiffs' failure-to-warn claims do not fit within
the parallel-claim exception recognized b*y Riegel* and remain
preempted.

Insofar as Plaintiffs' failure-to-warn claims are predicated upon alleged violations of the
Leads' Conditions of Approval or applicable federal regulations or upon Medtronic's alleged
failure to advise the FDA about the dangerous nature of the Leads, such claims are preempted
under *Buckman.* See *Webster v. Pacesetter, Inc.,* 259 F. Supp. 2d 27, 39 (D.D.C. 2003) (holding
that claims that "if defendant had adhered to MD*A* requirements regarding record-keeping,
adverse incident reporting, investigation, monitoring and complaint file maintenance, the
(medical device would have been recalled or placed on alert notice and plaintiff would not have
been injured" as "precisely the type of claim barred by the Supreme Court" in *Buckman).* As
Medtronic notes, for a jury to pass on the sufficiency of a medical-device manufacturer's
disclosures to the FDA would impermissibly usurp the agency's exclusive authority to enforce
the provisions of the FDCA and its implementing regulations. (See Defs.' Mem. at 22.*)*
Applying *Buckman*, the MDL Court already rejected Plaintiffs'

argument that Medtronic's

preemption defense is defeated because the failure to increase warnings was in violation of the

Sprint Fidelis Leads' Conditions of Approval. *In re Sprint Fidelis Leads 1, 5*92 F. Supp. 2d at

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1160-61. This Court agrees that such allegations are nothing more than allegations that Medtronic violated the FDCA by failing to inform the FDA in a timely fashion of adverse lead

events." *Id.* at 1160; (*cf. Beheau 2*d Am. Compl. 19 160, 188 (predicating failure-to-warn claims

upon allegations that "Medtronic failed to advise the FDA what it knew about the dangerous

nature of the Sprint Fidelis Leads").) However, a claim predicated upon such allegations fails as

a matter of law because there is no private right of action to enforce the FDCA. 21 U.S.C. §

3*37*(a*); Buckman,* 531 U.S. at 349 n.4 ("[T]he FDCA leaves no doubt that it is the Federal

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Government rather than private litigants (which is) authorized to file suit for noncompliance with

the medical device provisions" in the FDCA."). Plaintiffs' failure-to-warn claims are not parallel

common-law claims preserved from preemption

under *Riegel.*

Plaintiffs' Claims Predicated Upon Alleged Design and Manufacturing Defects Are Not Parallel Claims and Are Preempted Under $ 337(a)

Plaintiffs seek to avoid the preemptive effect of $ 360k by arguing that their

manufacturing-defect claims are simply parallel common-law claims preserved by *Riegel.*

Plaintiffs rest this argument upon their allegations that the "Leads did not conform with

applicable specifications, including the FDA's requirements." (Pls.' Mem. in Opp. at 37; *see*

*also Bebeau 2*d Am. Compl. 1142-52.) More specifically, Plaintiffs allege that the welding

techniques Medtronic used in manufacturing the Leads and that the company's quality assurance

protocols were inadequate and in violation of the FDA's Current Good Manufacturing Practices

("CGMPs") and Quality System Regulations ("QSRs"). *(Id*. 19 113-20; 197; 205-07.) Plaintiffs

argue that their defective manufacturing claims do nothing more than parallel these federal

requirements, and are, thus, preserved from preemption under *Riegel.*

As a matter of law, Plaintiffs' defective-manufacturing claims are not saved by their

assertions that these claims are predicated on violations of the CGMPs and QSR requirements.

The regulatory framework imposed by the CGMPs and QSRs "leave[s] it up to the manufacturer

to institute a quality control system specific to the medical device it

produces to ensure that such device is safe and effective.” *Horowitz,* 613 F. Supp. 2d at 279*; see also* Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, 61 Fed. Reg. 52,602, 52.603 (Oct. 7, 1996) (explaining the CGMPs and the QSR framework and repeatedly highlighting the fact that the system is “flexible” and provides manufacturers with substantial discretion). The FDA guidelines set forth in the CGMPs and QSRs “are simply too generic, standing alone, to serve as the basis for Plaintiffs' manufacturing defect claims.” *In re Sprint Fidelis Leads 1, 5*92 F. Supp. 2d at 1158. Given the flexibility inherent in this system, Plaintiffs cannot show that Medtronic's chosen welding techniques violated the CGMPs and QSRs; such claims are not parallel claims because they are not predicated upon a violation of a federal requirement. 24 *id*; *see also United States v. Utah Med. Prods., Inc.*, 404 F. Supp. 2d 1315, 1324 (D. Utah 2005) (refusing to sanction medical-device manufacturer for alleged violations of the CGMPs and QSRs and noting, because of the inherent flexibility of the regulatory scheme, "[t]he fact that the road chosen by sa device manufacturer] may be different

in degree than that thought to be appropriate by a regulator does not mean that it is wrong, or in violation of the regulations"); *United States v. Laerdal Mfg. Corp.*, 853 F. Supp. 1219, 1227 (D. Or. 1994) ("[T]he GMP regulations do not prescribe each particular step required of [a manufacturer) in order for it to comply with these regulations."). Furthermore, the issue of compliance with the CGMPs is a matter properly left to determination by the FDA" rather than by a court or jury. See *United States* v. W. Serum Co., 498 F. Supp. 863, 867 (D. Ariz. 1980);

24 The inherent flexibility of the CGMPS and QSRs also dooms Plaintiffs' claims that alleged violations of this regulatory scheme can form the basis of a valid claim for negligence per se because no mandatory statutory or regulatory duty was breached by Medtronic. See *In re Sprint Fidelis Leads 1,* 592 F. Supp. 2d at 1163.

see also Nat'l Ass 'n of Pharm. Mfrs. v. Food & Drug Admin., 497 F. Supp. 412, 416 (S.D.N.Y. 1980) ("[W]e believe that a binding definition of good manufacturing practices is just the sort of regulatory area best left to the expertise of the FDA.").

Plaintiffs next try to preserve their defective-design claims by arguing that Medtronic was negligent in continuing to sell the Leads as initially approved by the FDA, after Medtronic

received approval from the agency in the summer of 2007 for what Plaintiffs claim was a safer

alternative design for the Leads. (Pls. Mem. in Opp. at 39 (citing *Bebeau* 2d Am. Compl. 1

89).) Plaintiffs argue that such a claim is a parallel claim preserved from preemption because it

is "wholly consistent with the FDA's approval of Medtronic's altered design for the Leads."

(*Id.*) However, this argument ignores the fact that this claim is wholly inconsistent with the

FDA's approval of the earlier design as safe and effective. S*ee, e.*g., 21 U.S.C. $$

360e(d)(2)(A), (B). Plaintiffs cite no case, statute, or regulation supporting the proposition that

approval of a subsequent design for a device mandates removal of previously approved devices

from the market. *Cf.* 21 U.S.C. $ 360e(e) (setting forth requirements for withdrawal of approval

from a previously approved device).

Plaintiffs also allege what they term “parallel claims” against Medtronic for failing to

submit PMA supplements for every change made by Medtronic to the manufacturing processes

for the Leads. (S*ee, e.g., Bebeau* 2d Am. Compl. 1930-41 (claiming that Medtronic violated its

duty to submit PMA Supplements when it made changes to the Leads' manufacturing

processes).) Plaintiffs fail to cite any law to support their position that Medtronic was required

to file a PMA Supplement modifying the Leads once it became aware of increases in the

incidence of adverse effects.25 (See Pls.Mem. in Opp. at 39.*); cf. In re Sprint Fidelis Leads 1,*

2 As Medtronic notes, the FDA did question Medtronic's failure to submit a PMA supplement related to post-cure time and temperature for insulation in the Leads after they were withdrawn from the market. *(Bebeau* 2d Am.

592 F. Supp. 2d at 1162 (noting that the MDL Plaintiffs had failed to support this exact same

assertion in response to Medtronic's motion to dismiss all claims in the MDL proceedings).

Indeed, the regulations governing the PMA process specifically permit manufacturers to make

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certain changes to manufacturing processes without submitting PMA Supplements. *See* 21

C.F.R. $ 814.39(b) (recognizing that a medical-device manufacturer may make a change to

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manufacturing processes "without submitting a PMA supplement if the change does not affect

the device's safety or effectiveness and the change is reported to FDA in postapproval periodic

reports"). Furtherinore, claims predicated upon the alleged failure to submit PMA Supplements

to the FDA do not seek to enforce any common-law duty but instead seek nothing more than to

enforce the FDCA's implementing regulations, a duty which is left

solely to the FDA under 21

U.S.C. § 337(a). *In re Sprint Fidelis Leads 1, 5*92 F. Supp. 2d at 1162.26 Private litigants, like

Plaintiffs, lack standing to bring such claims. *See Delaney*, 2009 WL 564243, at * 4 (D.N.J.

Mar. 5, 2009) (“[A]ny changes not submitted to FDA for PMA review would constitute a

violation of the MDA or rather the FDCA, which the Supreme Court has made clear does not

constitute a private right of action."').

Compl. 1 40.) However, this does not cure the defects in Plaintiffs' pleadings; Plaintiffs have not pleaded any connection with this alleged violation of a federal requirements and their alleged injuries. *Cf. Covert,* 2009 WL 2424559, at * 14 (dismissing purported parallel claims when the pleading failed to allege "whether or how the alleged (regulatory] violations related[d] to (plaintiffs] alleged injuries")*; Rollins v*. S*t. Jude Med.,* 583 F. Supp. 2d 790, 803 (W.D. La. 2008) (dismissing claim for failure to include information in FDA reports where there was no “allegation as to how this alleged failure, standing alone, caused (the complained-of] injuries"). Similarly, Plaintiffs have not alleged any connection between their allegations regarding problems with the sterilization system at Medtronic's Villalba facility and their claimed injuries. *(Cf. Bebeau 2*d Am. Compl. 1945-52.)

26 in their memorandum in opposition to Medtronic's motion, Plaintiffs set forth a litany of alleged failures of Medtronic to comply with the regulatory requirements imposed on it under the FDCA. *(See* Pls.' Mem. in Opp. at 6-7 (alleging violation of the Conditions of Approval by failing to submit PMA Supplements for subsequent changes to the design or manufacture of the Leads); at 11-12 (detailing alleged failures by Medtronic related to their post approval reporting to the FDA). Insofar as Plaintiffs argue that such violations form the basis of their "parallel” common-law claims, such argument necessarily fails because enforcement of regulatory violations as alleged lies solely with the FDA under 21 U.S.C. § 337(a*). See Kemp v. Medtronic, Inc.,* 231 F.3d at 236 ("States are not granted any authority to enforce compliance with the specific federal requirements established by the PMA process.").

Finally, Plaintiffs argue that their defective-manufacturing claims are

parallel claims

preserved under *Riegel* because they allege that the Leads are defective in that they were

adulterated under 21 U.S.C. $ 351(f). (Pls. Mem. in Opp. at 33; *see also Bebeau 2*d Am.

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Compl. 1 245.) However, "[Plaintiffs) . . . cannot escape preemption by reference to provisions

of the FDCA that govern the sale of adulterated and misbranded devices because there is no

private right of action under the FDCA." *Parker*., 584 F. Supp. 2d at 1301 (citing 21 U.S.C. §

[n 2]

337); Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir. 1994) ("[O]nly the government

has a right to take action with respect to adulterated products."). "To recognize an exception to

the usual scope of federal preemption concerning Class III devices for products purported to be

adulterated would, in effect, be to create a private right of action under the MDA," a result which

is specifically barred by *Buckman. See Talbott v. C. R. Bard, Inc.,* 865. F. Supp. 37, 50 (D. Mass.

1994).

Plaintiffs' defective-manufacturing and defective-design claims are not parallel common

law claims that avoid preemption under $ 360k.

3.

Plaintiffs' Alleged Negligence Per Se Claims Are Not Parallel

e Claims Are Not Parallel Claims and Are Preempted Under $

337(a)

Plaintiffs argue that their negligence per se claims are parallel common-law claims that survive preemption.?? As Medtronic notes, this argument ignores the fact that negligence per se claims predicated upon alleged violations of the FDCA or its implementing regulations are

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nothing more than an attempt to take an impermissible end-run around *Buckman*'s limitations on standing. S*ee, e.g., Mitaro,* 2009 WL *127*2398, at * 4 (holding that negligence per se claim is "preempted under 21 USC § 337(a) which provides that all proceedings to enforce or to restrain violations of the FDCA are in the domain solely of the federal government'); *see also Cupek v.*

27 *(See Bebeau* 2d Am. Compl. Counts VIII-IX*; Manning* Compl. Count I*V; Morrison* Compl. Counts VIII-IX; *Eschete* Ist Supp. & Am. Compl. Counts VIII-IX*; Joest* Am. Compl. Counts VIII-IX; *Florence* 1st Am. Compl. Counts VIII-IX; Diamond Compl. Counts VIII-IX; Bowie Am. Compl. Counts VIII-IX.)

Medtronic, Inc., 405 F.3d 421, 424 (6th Cir. 2005) (affirming denial of leave to amend to replead negligence per se claim predicated upon violation of Conditions of Approval on grounds of futility because such a claim is a disguised fraud-on-the-FDA claim preempted under *Buckman)*;

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In re Sprint Fidelis Leads 1, 592 F. Supp. 2d at 1163 (recognizing that the MDL Plaintiffs' claims for negligence per se predicated upon claimed violations of

the FDCA's prohibition on

selling misbranded or adulterated medical devices were preempted under 21 U.S.C. $ 337(a) and

Buckman). Where a statute expressly precludes a private right of action to enforce its provisions,

litigants cannot avoid these limits by crafting negligence per se claims for violation of the statutory scheme. S*ee Alumbaugh v. Union Pac. R. Co.,* 322 F.3d 520, 524 (8th Cir. 2003) (“For

a negligence *per s*e claim to succeed, it must be shown that the legislature intended to create a

private right of action in favor of the class of persons to which the plaintiff belongs for violation

of the statute."); s*ee also Meyer v. Lindala, 67*5 N.W.2d 635, 641 (Minn. Ct. App. 2004)

(holding that where statute does not create a private cause of action violation of that statute could

not be evidence of negligence per se). As recognized by the MDL Court, "[t]he negligence per

se doctrine ... is not a magic transforming formula that automatically creates a private right of

action for the civil enforcement, in tort law, of every statute."*" In re Sprint Fidelis Leads 1, 5*92

F. Supp. 2d at 1163 (quoting *Talley v. Danek Med., Inc.,* 179 F.3d 154, 158 (4th Cir.1999)). As a

matter of law, Plaintiffs negligence per se claims are preempted under

21 U.S.C. § 337(a).28

28 Plaintiffs' negligence per se claims fail for the separate and independent reason that the regulatory provisions upon which they are predicated do not define an applicable standard of care owed to the public but instead impose administrative requirements upon medical-device manufacturers. S*ee Talley,* 179 F.3d at 159 ("Where a statutory provision does not define a standard of care but merely imposes an administrative requirement, such as the requirement to obtain a license or to file a report to support a regulatory scheme, violation of such requirement will not support a negligence per se claim."); s*ee also King v. Danek Med., Inc., 37* S.W.3d 429, 453-60 (Tenn. Ct. App. 2000) (same).

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V.

Conclusion

Because the Court concludes that all of Plaintiffs' claims are preempted under federal

law,29 Medtronic's Motion to Dismiss Representative Cases is granted. All claims raised in the

Representative Cases are dismissed with prejudice.50

29 Medtronic moved to dismiss certain claims in the Representative Cases on grounds unique to the individual Plaintiffs in each case. Because the Court's ruling on the issue of preemption is dispositive of Plaintiffs' claims, the Court does not pass on the merits of Medtronic's non-preemption-based arguments.

30 The Court's dismissal is with prejudice. Prior to hearing this motion, Plaintiffs in the Companioned Cases were given time to serve and file any amended Complaints in the Companioned Cases. In addition, Plaintiffs' counsel in the Companioned Cases were involved in the proceedings before the MDL Court and, thus, had nearly 2 years to craft their pleadings. Accordingly, the Court believes that dismissal with prejudice of these claims is appropriate.