UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
05-MDL-1726(JMR/AJB)

In Re: Medtronic, Inc., Implantable Defibrillators Litigation	)))	ORDER

The Medtronic, Inc., Implantable Defibrillator Multidistrict Litigation ("MDL") cases have been transferred to this Court by Order of the Judicial Panel on Multidistrict Litigation. The cases were transferred for consolidated pretrial proceedings pursuant to 28 U.S.C. § 1407. Prior to instituting a full discovery/pretrial schedule, defendant, Medtronic, Inc. ("Medtronic"), has asked the Court to consider its motion for summary judgment based on its claim that federal preemption bars plaintiffs' claims. The Court has done so. Medtronic's motion is denied.

I. Background[1]

Medtronic manufactures implantable cardioverter-defibrillators ("ICDs") and cardiac resynchronization therapy defibrillators ("CRT-Ds"). Each device contains a small computer, battery, and capacitor which stores electrical energy to be used to regulate cardiac function. These three-ounce devices are surgically implanted into a subcutaneous pocket. A properly functioning ICD

[1]When considering a motion for summary judgment, the Court views the facts most favorably to the plaintiffs, the nonmoving parties. See Ludwig v. Anderson, 54 F.3d 465, 470 (8th Cir. 1995).

or CRT-D offers potentially lifesaving treatment for patients susceptible to cardiac arrhythmia.

Medtronic's defibrillators are Class III medical devices. These devices are subject to the most intensive review by the Food and Drug Administration ("FDA"). Under the Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"), Class III medical devices are used for "supporting or sustaining human life" or are of "substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C)(ii)(I) (2002). Class III devices are subject to a rigorous premarket approval ("PMA") process before they may be put on the market. An applicant for PMA must demonstrate a "reasonable assurance" that the device is both "safe . . . [and] effective under the conditions of the use prescribed, recommended, or suggested in the proposed labeling thereof." 21 U.S.C. § 360e(d)(2)(A),(B)(2004).

Even after approval, medical device manufacturers must self-report adverse events through the FDA's medical device reporting ("MDR") system. 21 C.F.R. § 803, et. seq. (2005). These MDR regulations assist the FDA in protecting "the public health by helping to ensure that devices are . . . safe and effective for their intended use." Id. at § 803.1(a). The manufacturer must make an FDA report "no later than 30 calendar days" after it "become[s] aware of information, from any source, that reasonably suggests that a device [it] market[s] . . . has malfunctioned and

this device or a similar device that [it] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." Id. at § 803.50(a).

The FDA first reviewed the devices before the Court when it considered Medtronic's Model 7271 defibrillator, which received its approval on October 9, 1998. Following the initial approval, Medtronic has systematically modified, updated, or improved its defibrillators. On these occasions, Medtronic filed PMA Supplement applications. As modifications of previously issued PMAs, these later applications were somewhat less rigorous.

In November, 2000, Medtronic sought FDA approval for its updated Marquis 7274. A new battery, the Chi 4420L, constituted a major difference between the proposed Marquis 7274 and its predecessors. Medtronic's PMA Supplement application included detailed information and a description of the new battery. The PMA Supplement application described modifications of the previous battery design, a summary of the testing performed on the battery, battery modeling methodology, and projected the expected life of the new battery. On March 1, 2000, the Marquis Model 7274 received FDA approval.

Sometime in early 2003, during routine laboratory testing, Medtronic discovered a defect in the Chi 4420L battery which caused it to discharge prematurely. Medtronic's engineers continued to test the Chi 4420L battery between February and September of 2003.

Through these tests, Medtronic engineers identified and came to understand the shorting mechanism which led to its observed battery depletion anomaly. Medtronic did not notify the FDA or the medical community of this discovery, even though it had identified, and known for more than six months, a defect which could cause its defibrillators to lose their electrical charge in days instead of years.

Medtronic claims it opted against notifying the FDA, physicians, or patients during this period because it had not received any field reports of early battery depletion. Medtronic avers that, absent field reports of failure, it assumed the potential for depletion was limited to laboratory conditions. During this six-month period, Medtronic sold and shipped thousands of Marquis devices with potentially defective batteries to patients throughout the country.

Even in the absence of field reports of battery failure or premature discharge, Medtronic began to redesign its Chi 4420L battery to address the defect in the Spring of 2003. While this redesign was underway, Medtronic sought and obtained approval for three additional device models – the Maximo DR and VR ICDs and Insync II Protect – each containing the Chi 4420L battery. Each device’s PMA Supplement application failed to advise the FDA of the Chi 4420L's documented shorting problem, or that this anomaly could lead to premature depletion. Thus, these new devices received FDA

approval, and went into production and distribution with a battery Medtronic knew could short and discharge prematurely.

On October 6, 2003, Medtronic filed another PMA Supplement application with the FDA seeking approval to implement three design changes to the Chi 4420L battery. The application stated that the prior design had experienced internal shorts, which it asserted was a "known failure mode" in the devices. (Ex. O, p. 9.) Medtronic included the "known failure mode" language in its October, 2003, PMA Supplement application, despite earlier drafts of the submissions which described the defect as "a previously undetected failure mode," and described and diagramed details of the known problem. (Ex. F.) Medtronic claims it deleted references to the "previously undetected failure mode" from its FDA submissions, because if supplied, the information might "not [have made] sense to the [FDA] reviewer." (Ex. E, Keller Depo. 172:22.)

Based on the information Medtronic supplied, the FDA approved the new battery's PMA Supplement application on October 23, 2003. Even with this new approval in hand, Medtronic did not notify physicians or patients that its Marquis devices which contained the Chi 4420L battery posed a greater risk of battery depletion than its newly-designed and approved battery. It also continued to ship and sell ICDs and CRT-Ds containing the Chi 4420L batteries.

Somewhere between February and April, 2004, Medtronic began to receive field reports of premature battery depletion. Upon

receiving this information, Medtronic, for the first time, reported battery problems through the FDA's MDR system.

By December, 2004, more than one year and nine months after its own discovery of the problem, Medtronic received nine field returns of devices with premature battery depletion. Even with this field evidence in hand, it was not until February, 2005 -- two full years after its own discovery of the battery discharge anomaly -- that Medtronic first warned the public of the defective battery. At that time, it initiated a voluntary field action, and sent a "Dear Doctor" letter advising physicians that certain Marquis devices posed a risk of failure, and cautioned that "[o]nce a short occurs, [battery] depletion can take place within a few hours to a few days, after which there is a complete loss of device function." (Ex. H.) On March 16, 2005, the FDA initiated a regulatory enforcement action against Medtronic, ordering a total Class II recall of the 87,000 Marquis devices containing the Chi 4420L battery.

Plaintiffs seek damages for personal injuries resulting from their receipt of Marquis devices with a defective battery. Their Master Complaint asserts state law product liability claims sounding in negligence and strict liability. Other claims include negligence per se premised on the FDCA, breaches of express and implied warranties, misrepresentation by omission, violations of state Consumer Protection Statutes, and violations of Minnesota

false advertising and deceptive trade practices statutes. In addition, plaintiffs seek disgorgement of "unjust enrichment" related to payment for the devices, and the spouses of patients seek recovery for derivative loss of consortium claims.

In support of their opposition to Medtronic's motion, plaintiffs have offered the affidavit of Dr. Suzanne Parisian, a former FDA employee.[2] Dr. Parisian avers that Medtronic failed to inform the FDA of certain information essential to its continued approval of the Chi 4420L battery. She states that the information Medtronic supplied was not complete, and failed to advise the FDA of known defects and failures in its PMA and PMA supplement applications. In her view, Medtronic failed to take appropriate action to warn patients and the medical community about the dangers associated with the devices as part of the PMA Supplement process. She points to specific post-marketing requirements, which she claims imposed upon Medtronic certain obligations which were not fulfilled, particularly concerning timely performance of post-marketing studies, timely submission of reports, and altering devices without prior FDA approval. Assuming these facts to be

[2]Medtronic objects to consideration of this affidavit. Its objections are presently overruled. Dr. Parisian's education, training, and experience are sufficient. Her testimony is relevant and, for purposes of this motion, the Court accepts her affidavit. Fed. R. Evid. 702. The Court, of course, disregards her legal conclusions, but does credit her opinions concerning the factual matters upon which she opines.

true, as the Court must at this time, these allegations have legal consequences.

Medtronic now moves for summary judgment, claiming all of plaintiffs' state law claims are preempted by the MDA and FDA regulations promulgated pursuant to it. Medtronic argues that plaintiffs' claims challenge and conflict with the FDA's regulatory judgment, as well as the FDA's requirements for the devices' design, labeling, and manufacturing processes, thus triggering both the doctrines of express and implied preemption.

II. Analysis

A. Summary Judgment

Summary judgment may only be granted when there are no material facts in dispute and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986); Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 247-48 (1986). When material facts or questions of law remain in dispute, summary judgment must be denied.

B. Preemption

Federal preemption derives from the Supremacy Clause of the United States Constitution. The Constitution establishes the laws of the United States as "the supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. IV, cl. 2. In practice, this

means state laws conflicting with federal laws or regulations are preempted. Malone v. White Motor Corp., 435 U.S. 497, 504 (1978).

A court considering a preemption challenge "is not to pass judgment on the reasonableness of state policy," but instead "to decide if a state rule conflicts with or otherwise 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives' of the federal law." Livadas v. Bradshaw, 512 U.S. 107, 120 (1994) (citation omitted). Thus, the Court must "ascertain Congress' intent in enacting the federal statute at issue." Metro. Life Ins. Co. v. Massachusetts, 471 U.S. 724, 738 (1985).

Preemption "is compelled whether Congress' command is explicitly stated in the statute's language or implicitly contained in its structure and purpose." Id. at 738 (citations omitted). Express preemption is found when Congress declares a clear intent to preempt state law. Hillsborough County v. Automated Med. Labs., Inc., 471 U.S. 707, 712-713 (1985). But state law may be impliedly preempted, even in the absence of an express Congressional statement, "when a federal law completely occupies the field of regulation so that by implication there is no room for state regulation and the coexistence of federal and state regulation is not possible." Missouri Bd. of Exam'rs for Hearing Instrument Specialists v. Hearing Help Express, Inc., 447 F.3d 1033, 1035 (8th

Cir. 2006). Medtronic asks the Court to find both express and implied preemption here.

1. Express Preemption

The Medical Device Amendments to the FDCA provide that:

> 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 Act 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 Act.

21 U.S.C. § 360k(a). In interpreting § 360k, the Court is guided by the Supreme Court's decision in Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996) (plurality opinion), and the Eighth Circuit Court of Appeals' decision in Brooks v. Howmedica Inc., 273 F.3d 785 (2001) (en banc).[3]

Lohr provides the framework by which the MDA's express preemption clause is applied to state law tort claims. Lohr, of course, is wondrously complex, comprising two separate majorities. Five justices found state law actions, including state law duties of general applicability, preempted when they impose conditions on a device manufacturer which differ from or add to federal requirements. Lohr, 518 U.S. at 509-11 (O'Connor, J., Rehnquist,

[3]"When analyzing questions of federal law, the [MDL] transferee court should apply the law of the circuit in which it is located." In re Temporomandibular Joint Implants Prod. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996). Thus, Eighth Circuit law controls.

C.J., Scalia, J., and Thomas, J., concurring and dissenting), 503-05 (Breyer, J., concurring in part). As Justice Breyer said in his concurring opinion, "if a jury were to find negligence in the use of a wire longer than one inch in the manufacture of a hearing aid when the FDA had required a two inch wire, there would be federal preemption as surely as if a state regulation were to impose such a limitation." Brooks, 273 F.3d at 796 (quoting Lohr, 518 U.S. at 504 (Breyer, J., concurring)).

But all nine of Lohr's Justices ultimately found defective design claims concerning § 510(k)-cleared devices survived § 360k(a) preemption because there were no specific federal requirements with which such claims could conflict.[4] Lohr, 518 U.S. at 493-94 (majority opinion), 513 (O'Connor, J., concurring in part and dissenting in part). Five justices also held the plaintiff's manufacturing and labeling claims survived a preemption challenge, because the FDA's manufacturing and labeling requirements were general in nature rather than device specific, and because the device had not gone through the PMA process.

[4]The Lohr device was not PMA reviewed. Its approval was obtained under the less rigorous § 510(k) premarket notification process. The justices all agreed the § 510(k) process established no federal requirements for the design of medical devices, because the § 510(k) process simply reflected the FDA's conclusion that a new device was substantially equivalent to a pre-existing device. Lohr, 518 U.S. at 493-94 (majority opinion), 513 (O'Connor, J., concurring in part and dissenting in part).

Id. at 497-500 (majority opinion); Id. at 505-07 (Breyer, J., concurring in part and concurring in the judgment).

Two main common law preemption principles arise from Lohr: first, a Court must consider whether there are any device-specific federal requirements imposed on the medical device manufacturer; second, if there are such requirements, the Court must determine whether the state common-law claim would "impose a requirement different from or in addition to" the specific federal requirement. Id. at 511; Brooks, 273 F.3d at 794. The federal and state requirements must be "carefully compared" to ascertain whether a conflict exists. Lohr, 518 U.S. at 500; Brooks, 273 F.3d at 794.

The Brooks court considered these principles in the case of a PMA approved product, as opposed to the Lohr court's § 510(k) approval. The Brooks court found the two processes "by no means comparable," Brooks, 273 F.3d at 795 (quoting Lohr, 518 U.S. at 478). The Eighth Circuit recognized that, while the § 510(k) process usually takes 20 hours, "PMA review typically requires 1,200 hours of rigorous testing for device safety." Brooks, F.3d 273 at 795. As the FDA, through its PMA process, had issued specific directives concerning the product labeling in Brooks, the court found plaintiff's failure to warn claim would interfere with federal requirements. Brooks, 273 at 796. Drawing on Justice Breyer's inch-long wire example, the court held a jury finding of negligent failure to warn would effectively impose a different

labeling requirement from that established by the FDA; thus, the claim was preempted. Id.

With these principles in mind, this Court considers whether the MDL plaintiffs' state law claims would impose upon Medtronic any requirement different from those imposed upon it by the FDA/PMA device-specific approvals.

a. Device-specific Federal Requirements

As a threshold matter, the Court considers whether the FDA has established specific federal requirements upon Medtronic's Marquis devices. Medtronic, of course, claims its PMA submissions and the FDA-issued approvals constitute preemptive device-specific federal requirements, particularly as they relate to every facet of the Marquis devices design, including the batteries. (See Samsel Aff. Exs. B-D.) Plaintiffs reply that the PMA process imposes no device-specific preempting requirements.

The majority of circuits hold that the FDA's PMA approval constitutes a specific federal requirement. Riegel v. Medtronic, Inc., 451 F.3d 104, 118 (2d Cir. 2005); Gomez v. St. Jude Med. Daig Div., Inc., 442 F.3d 919, 929 (5th Cir. 2006); McMullen v. Medtronic, Inc., 421 F.3d 482, 487-88 (7th Cir. 2005); Horn v. Thoratec Corp., 376 F.3d 163, 169-70 (3d Cir. 2004); Brooks, 273 F.3d at 795-96;[5] Kemp v. Medtronic, Inc., 231 F.3d 216, 226-28

[5]This Court considers Brooks to be among the cases holding the PMA process imposes specific federal requirements. In doing so, it recognizes that another Judge in this District, in In re St. Jude,

(6th Cir. 2000).[6] In Brooks, the Eighth Circuit, speaking through the Honorable Diana E. Murphy, said, "[t]hrough its approval of the PMA application . . . and continuing series of directives, the [FDA] imposed specific federal requirements on [the manufacturer]." Brooks, 273 F.3d at 798.

Once a Class III device manufacturer receives PMA approval, the manufacturer is barred from making any changes affecting the device's safety and effectiveness without obtaining further FDA approval. This obligation to adhere to the standards set forth in its individual FDA-approved PMA constitutes a set of federal, device-specific requirements. Riegel, 451 F.3d at 118. "It is the totality of the design, manufacturing processes, and labeling – when coupled with the prohibition against modifying them – that

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2004 WL 45503 (D. Minn.), found to the contrary. This Court respectfully departs from its brother's analysis. When Brooks carefully compared its plaintiff's state law claims with the federal requirements, it did not separate itself from the cases holding the PMA process imposes federal requirements on a manufacturer. Brooks, instead, cited and relied on those cases. Finally, it carefully distinguished the single case which found a PMA does not impose federal requirements. See Brooks, 273 F.3d at 795-96 (citing Martin v. Medtronic, 254 F.3d 573, 582 (5th Cir. 2001); Kemp, 231 F.3d at 230; Mitchell v. Collagen Corp., 126 F.3d 902, 913-14 (7th Cir. 1997); Papike v. Tambrands, Inc., 107 F.3d 737, 742 (9th Cir. 1997); distinguishing Goodlin v. Medtronic, 167 F.3d 1367 (11th Cir. 1999)).

[6]Only the Eleventh Circuit has held FDA approval of a PMA Supplement does not establish device-specific federal requirements. Goodlin, 167 F.3d at 1367.

represents the specific federal requirement." Kemp, 231 F.3d at 228.[7]

The Code of Federal Regulations states, "[a] device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80 (2005). Thus, the Court finds that through the PMA process, the FDA has established specific federal requirements for the Marquis devices' design, testing, intended use, manufacturing methods, performance standards, and labeling. See Horn, 376 F.3d at 169-70.

This finding does not, however, end the inquiry, for "common law claims are only preempted to the extent that they threaten to interfere with specific federal requirements." Brooks, 273 F.3d at 795 (citing Lohr, 518 U.S. at 500-01).

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[7]At this point, the MDL plaintiffs make an interesting point: they claim that in the case of devices like the Marquis products, the FDA process makes it impossible to describe or delineate the federally-mandated design. They base their argument on the fact that only Medtronic's original 1988 Model 7271 defibrillator went through the full PMA approval process. Every succeeding Medtronic defibrillator device has been approved through the less-rigorous PMA Supplement process, with significant modifications at each step. The defendant argued in response that each device need no longer have defined statements of all of its specific elements; it is the approved device – as a whole – which constitutes the preemptive "requirements." This raises the interesting question of how, exactly, a Court is to find Justice Breyer's "two-inch wire," and then discern whether the state claim calls for another of one-inch.

b. Conflicting State Requirements

The Court now considers whether plaintiffs' common law and state law-based claims impose state requirements "different from" or "in addition to" those required by the FDA. Lohr, 518 U.S. at 514 (O'Connor, J., concurring in part and dissenting in part). Drawing upon Justice Breyer's exemplar, the Court asks whether plaintiffs' claims present "one-inch wire" requirements in conflict with "two-inch wire" requirements the PMA approval may have imposed upon Medtronic's product. See Lohr, 518 U.S. at 504 (Breyer, J., concurring). Ultimately, Medtronic must show plaintiffs' state claims would require it to design, manufacture, or label its devices in a manner inconsistent with its PMA specifications.

Medtronic, first, claims the simple fact that it has obtained PMA approval shields it from any state law claims at all – Medtronic effectively argues the PMA renders each of plaintiffs' state law claims a "one-inch wire." It says, once there is PMA approval, almost no state law claim can be maintained. Plaintiffs reply that a common law claim does not impose any additional requirements, because a jury would not compel Medtronic to modify its approved device; it would merely impose "general obligations" which do not implicate medical device preemption. In plaintiffs' view, almost no state law claim would ever be preempted.

The Court considers each such argument to be overly simplistic. Jury verdicts can, and do, impose their own

requirements on device manufacturers. Plaintiffs' cite Lohr for their argument to the contrary,[8] without noting this was not its majority holding. Five of Lohr's justices agreed that state law duties of general application can impose conditions which differ from or are in addition to those imposed by federal requirements. Lohr, 518 U.S. at 509-11 (O'Connor, J., Rehnquist, C.J., Scalia, J., and Thomas, J., concurring and dissenting), 503-05 (Breyer, J., concurring in part). Such common-law requirements may fall within the MDA's preemption clause. Geier v. Am. Honda Motor Co., 529 U.S. 861, 867 (2000) (citing Lohr). Medtronic's argument also fails, however, because it has entirely failed to demonstrate how plaintiffs' state law claims would actually impose conflicting requirements upon it.

Medtronic also asks the Court to look past evidence, which if believed, tends to show it withheld critical information from the FDA while seeking the PMA Supplement approval for its newly-designed battery. Plaintiffs have produced credible evidence indicating that – after Medtronic discovered the design defect, and confirmed the discovery through patients' device failures, and after obtaining FDA approval for the modified battery – Medtronic

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[8]Plaintiffs also rely on Bates v. Dow Agrosciences LLC, 544 U.S. 431 (2005). But Bates considered the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). FIFRA imposes a different regulatory scheme, one which does not mandate specific federal-agency approval or requirements. Accordingly, this Court does not find Bates's preemption analysis to be apposite in a § 360k case. Reigel, 451 F.3d at 14; McMullen, 421 F.3d at 487.

continued to ship and sell devices containing the defective battery. In doing so, it failed to notify the FDA, physicians, or patients that the battery was defective. There is evidence showing Medtronic sought PMA approval for three new devices, but continued to use the known-to-be defective battery in them. Medtronic did not advise the FDA that it knew – for longer than a year – that the Chi 4420L had exhibited a "previously undetected failure mode." Lacking such knowledge, the FDA approved Medtronic's PMA Supplement applications. Only after Medtronic issued its February, 2005, "Dear Doctor" letter did the FDA order the recall.

It defies logic, and flies in the face of Congress's decision to impose a regime strictly regulating medical device manufacturers, to think Congress intended the result Medtronic advocates. See Lohr, 518 U.S. at 587. If the Court adopted Medtronic's view, once a medical device manufacturer obtains PMA approval, it would be insulated from liability even if it chose to conceal data from the FDA to maintain its PMA approval. Neither Lohr nor the FDA regulatory scheme can be stretched so far.

i. Parallel Requirements

Plaintiffs claim Medtronic violated FDA regulations, including 21 C.F.R. §§ 803.50, 803.53, 814.3, 814.39, and 814.84. Their common law claims of failure to warn, negligence, strict liability, misrepresentation by omission, and negligence per se are premised on those violations. The Court finds plaintiffs' state law causes

of action alleging failure to comply with FDA regulations are not subject to preemption; these claims merely impose parallel requirements, but impose no requirements different from, or in addition to, the federal requirements. Lohr, 518 U.S. at 495-97; Brooks, 273 F.3d at 798-99; Horn, 376 F.3d at 179; Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090, 1101 (6th Cir. 1997). "Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*." Lohr, 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part) (emphasis in original). Thus, state law claims which make a party liable for damages for failure to comply with federal law are not preempted.

Defendant's claim that Brooks bars these claims is unavailing. In Brooks, plaintiff's claims of liability for violations of FDA regulations were dismissed for failure to provide evidence showing that failure; they were not dismissed on preemption grounds. 273 F.3d at 799. Here, plaintiffs have offered as yet unrebutted evidence from which a factfinder could find Medtronic violated several PMA and post-approval FDA regulations. These include allegations that Medtronic: improperly manufactured the devices (Parisian Aff. ¶ 18);[9] failed to comply with PMA approval

[9]Medtronic claims plaintiffs' negligent manufacturing claims are actually design defect claims in disguise. At this early point in the litigation, the Court cannot agree. Plaintiffs' evidence, if believed, tends to show failures of quality assurance and possible failures to manufacture its devices in accord PMA approved

requirements (Id. ¶ 16, 30); failed to comply with FDA reporting obligations (Id.); misrepresented and concealed information during the FDA approval process (Id. ¶ 19); and failed to timely warn patients and physicians of known risks concerning the Marquis devices (Id. ¶ 30).

Medtronic vigorously denies these claims – and the Court expresses no opinion as to which side's version is correct – but there is no question that there are unresolved fact issues here. For these reasons, and to the extent plaintiffs' claims are premised on violations of FDA requirements, their claims of failure to warn, negligence, strict liability, misrepresentation by omission, and negligence per se, are not preempted.

ii. Failure to Warn

Plaintiffs claim Medtronic failed to warn patients and physicians of the known battery flaw which caused premature battery depletion in its Marquis devices. Federal regulations allow a manufacturer to voluntarily recall products and change labels without prior FDA approval, when needed to enhance the safety of medical devices. Lohr, 518 U.S. at 497 n. 16 (citing 21 C.F.R. §§ 814.39(d)(1) and (2) (1995)). In situations where the FDA is aware of a certain risk, and has approved a particular warning concerning that risk, any claim of inadequate warning which might

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standards, (Parisian Aff. ¶ 18). These factual allegations establish issues of fact for trial. The claim survives summary judgment. See Reigel, 451 F.3d at 123.

require a label differing from the FDA-prescribed language is preempted. Brooks, 273 F.3d at 796-98. But in the instance where a defendant discovers information subsequent to FDA approval which would lead a reasonable manufacturer to warn the medical community before the device is implanted into patients, a failure to warn claim is not preempted. Kemp, 231 F.3d at 236-37.

In Brooks, the Eighth Circuit carefully examined whether the FDA was aware of the risk at issue when it approved the language on the label, and whether the claim that the risk might occur was scientifically valid. Brooks, 273 F.3d at 797. Because, in that case, the FDA was aware of and considered the claimed risk when it prescribed the label warning, plaintiff's failure to warn claim was preempted. Id. at 798. This reasoning "implies that if the FDA had not been aware of the risk, plaintiff Brooks' failure to warn claim would not have been preempted." In re St. Jude, 2004 WL 45503 at *11.

Here, Medtronic discovered the battery defect in early 2003, but made no report to the FDA. In the face of this perceived defect, it thereafter submitted PMA Supplement applications for three new devices containing the battery without disclosing the possibility of this defect to the FDA. Medtronic redesigned the Chi 4420L battery in October, 2003, and when it sought FDA approval for the modification, it opted to describe the reason for its redesign as battery shorting, a "known failure mode." Plaintiffs

argue this language was a knowing effort to disguise the fact that Medtronic had not only discovered this failure, but had, itself, called it a "previously undetected failure mode." They claim Medtronic's documentation in support of the newly-designed battery insinuated that the modification was a mere improvement on the old battery, rather than alerting the FDA to the fact that it knew the Chi 4420L battery had failed by reason of a previously unknown defect. Medtronic had received field-report notices of Chi 4420L battery failures between February and April, 2004. By this time, it had received reports from physicians who had dealt with the problem in their patients. In the face of C.F.R. § 803.50(a)(2)'s requirement that a manufacturer must make an FDA report "no later than 30 calendar days" after it "become[s] aware of information, from any source, that reasonably suggests that a device [it] market[s] . . . has malfunctioned . . . ," Medtronic still made no report.

This was close to a year after Medtronic had observed this failure in its own bench testing. Even so, Medtronic did not report the premature battery depletion problem to the FDA until approximately one year later, and it did not publicly warn physicians and their patients of the defect until February, 2005. In light of these presently unrebutted facts, the Court finds plaintiffs have adduced facts which show a triable issue as to whether Medtronic had actual knowledge of this defect -- evidence

it either disguised or hid from the FDA. From this evidence, a reasonable trier of fact could find Medtronic knew of this defect for a substantial period prior to advising the FDA of the defect. For these reasons, plaintiffs' failure to warn claim survives the preemption challenge.

iii. Implied Warranty

Plaintiffs claim Medtronic breached its implied warranty to consumers because its devices were unsafe and unfit for their intended use. Implied warranty claims are "based on the accepted standards of design and manufacture of the product." Mitchell, 126 F.3d 915. Because Medtronic's Marquis devices underwent the PMA process, their design and manufacturing criteria were FDA approved. Therefore, it could be possible that "[a] state judgment for breach of implied warranty that rested on allegations about standards other than those permitted by the FDA would necessarily interfere with the PMA process and, indeed, supplant it." Id. Such is not the case here.

First, plaintiffs allege Medtronic deviated from its PMA manufacturing standards, and thus manufactured and sold a defective device. If these facts are proven at trial, a jury could conclude Medtronic breached its implied warranty to patients. By holding Medtronic to the manufacturing requirements imposed by the FDA, such a jury verdict would not impose any different or additional requirements on Medtronic. See Brooks, 273 F.3d at 798-99.

Therefore, to the extent plaintiffs allege Medtronic breached its implied warranty due to the fact that the devices were manufactured in a manner inconsistent with its PMA-approved standards, the claim survives summary judgment.

More importantly, even if Medtronic did not violate its PMA requirements, the FDA's own implementing regulations demonstrate that warranty claims which arise under state laws of general applicability are not preempted. The applicable regulation states: "[t]he following are examples of State or local requirements that are not regarded as preempted . . . requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as . . . the Uniform Commercial Code ["UCC"] (warranty of fitness))." 21 C.F.R. § 801.1(d). Because Minnesota, along with most other states, has adopted the UCC implied warranty provision, plaintiffs' implied warranty claim is not preempted. In re St. Jude, 2004 WL 45503 at *11.

iv. Express Warranty

According to plaintiffs, Medtronic expressly warranted to the public, through promotional statements and product literature, that its ICDs were safe and highly reliable. As a result of continuing sales and marketing campaigns which touted the safety of its products while knowing of the possible defect and risk of product

failure, plaintiffs argue Medtronic breached these express warranties.

Medtronic responds that, because it sold its devices with FDA-mandated labeling, any claim depending on the incompleteness of that information would impose a requirement different from, or in addition to, those of the FDA. Despite Medtronic's argument, plaintiffs express warranty claims survive preemption for two reasons. First, to the extent plaintiffs' breach of express warranty claim is predicated on Medtronic's failure to adhere to FDA labeling or packaging requirements, the claim is not preempted. See Brooks, 273 F.3d at 798-99.

Second, while the FDA may approve the devices' product label, Medtronic is silent on the issue of whether the FDA imposes requirements for its promotional statements. There is no showing that a jury verdict based on voluntary express representations by Medtronic would interfere with its PMA obligations. See Mitchell, 126 F.3d at 915. Moreover, express warranties "arise from the representations of the parties." Id. "[A]ny requirements imposed by the warranty are created by the warrantor and [are] not imposed by state law." Davenport v. Medtronic, Inc., 302 F. Supp. 2d 419, 433 (E.D. Pa. 2004); see also Cipollone, 505 U.S. at 526. Because Medtronic has voluntarily undertaken these requirements and they are not state-imposed – "the *sine qua non* of preemption under § 360k" – plaintiffs' express warranty claims are not preempted by

the MDA. Steele v. Depuy Orthopaedics, Inc., 295 F. Supp. 2d 439, 455 (D.N.J. 2003) (quotation omitted).

v. Consumer Protection Statutes

Plaintiffs also seek to recover under various Minnesota false advertising and deceptive trade practice statutes, as well as several other states' consumer protection statutes. These claims are premised on Medtronic's purportedly misleading statements regarding the safety of its devices. Again, Medtronic does not claim the FDA regulates its advertising and promotional materials concerning the devices. Thus, to the extent the PMA does not address these materials, a jury verdict based on these statutes would not conflict with the PMA, and plaintiffs' claims are not preempted. Mitchell, 126 F.3d at 915. Alternatively, to the extent these materials departed from the PMA specifications, they also survive preemption. Id. Finally, like state requirements under the UCC, the FDA implementing regulations specifically exclude state unfair trade practices claims from preemption. 21 C.F.R. § 801.1(d); In re St. Jude, 2004 WL 45503 at *11. For all these reasons, plaintiffs' claims based on the various states' consumer protection statutes are not subject to MDA preemption

In summary, other than brandishing its PMA approval, Medtronic has failed to point to any preempted "one-inch wires" in any of plaintiffs' claims. Plaintiffs' claims either contain parallel requirements, or involve areas not covered by the PMA. Their

claims do not impose any requirements different from or in addition to those contained in their PMA. Thus, none of plaintiffs' claims are expressly preempted.

2. Implied Preemption

Medtronic further claims that, even if plaintiffs' claims are not expressly preempted, they are nonetheless impliedly preempted. When analyzing a state statute under the implied preemption doctrine, a court may not find a state law preempted "unless it conflicts with federal law or would frustrate the federal scheme," or unless a court discerns "from the totality of the circumstances that Congress sought to occupy the field to the exclusion of the States." Bldg. and Constr. Trades Council v. Associated Builders and Contractors, 507 U.S. 218, 224 (1993). The Court should presume "that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." New York State Conference of Blue Cross & Blue Shield Plans v. Travelers Ins. Co., 514 U.S. 645, 655 (1995) (internal quotation omitted).

Here, Medtronic points to the Supreme Court's decision in Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 350 (2001). Medtronic claims Buckman forecloses any inquiry into the FDA regulatory process. It claims any review of MDA compliance is exclusively lodged in the FDA. Medtronic says it received PMA approval for the Marquis devices employing the Chi 4420L battery,

and the FDA has never found or cited it for a regulatory violation. From this, Medtronic argues implied preemption applies precluding plaintiffs' claims. The Court declines to read Buckman so broadly.

As an initial matter, the claim at issue in Buckman was actual "fraud-on-the-FDA," and not state tort claims involving the plaintiffs' personal injuries. The case rested on a separate footing, because Buckman's defendant manufacturer had already settled with the plaintiffs – the remaining defendant was an FDA consultant who presented the application to the FDA. See Daniel W. Sigelman, Is Fraud on the FDA a Dead Letter After Buckman v. Plaintiffs' Legal Committee?, 2 ATLA-CLE 2483 (2001). Buckman's holding cannot be considered without recognizing its facts. The MDA has a comprehensive scheme for dealing with fraud on the FDA. Its scheme permits consumers to petition the FDA to take action against wrongdoing. Buckman, 531 U.S. at 348. Of course, states have no traditional interest in policing fraud against federal agencies. Id. at 347 (quoting Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947)). The present case is an entirely different situation.

Plaintiffs do not complain of fraud on the FDA. Rather, they claim they, themselves, were deceived and injured by: (a) Medtronic's actions in continuing to sell devices with the possibly-defective Chi 4420L battery for implantation into plaintiffs; (b) Medtronic's failure to advise patients and

physicians about the defect; and (c) Medtronic's failure to inform them that a safer model ICD was available. (Compl. ¶¶ 13-15.) States may not be concerned about protecting federal agencies, but states have a strong interest in protecting their citizens from fraud and personal injuries. The Supreme Court in Lohr recognized "the historic primacy of state regulation of matters of health and safety." Lohr, 518 U.S. at 485. This state interest counsels against finding implied preemption of plaintiffs' state law causes of action. See Buckman, 531 U.S. at 347.

Buckman is further distinguished because it dealt with medical devices being used "off-label." There is no suggestion that the Chi 4420L-bearing devices were being used outside their label restrictions. This obviates Buckman's expressed concerns regarding off-label usage of medical devices as "an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." Buckman, 531 U.S. at 350.

Finally, were the Court to accept Medtronic's expansive reading of Buckman, it would place itself outside the legion of cases upholding parallel requirements to federal violations as actionable under state law. See e.g. Lohr, 518 U.S. at 495-97; Brooks, 273 F.3d at 798-99; Horn, 376 F.3d at 179; Martin, 105 F.3d at 1101. Buckman makes clear that, under Lohr, state law causes of action which parallel federal safety requirements are not

preempted, whereas a mere violation of the FDCA does not provide the basis for a claim in and of itself. 531 U.S. at 353. Thus, plaintiffs may use evidence – if they are able to produce it – of Medtronic's efforts to manipulate the regulatory process in order to prove their negligence and strict liability claims, but they may not bring an independent claim for relief based on fraud-on-the-FDA. See In re St. Jude, 2004 WL 45503 at *13; Dawson ex rel. Thompson v. Ciba-Geigy Corp., USA, 145 F. Supp. 2d 565, 573 (D.N.J. 2001). All plaintiffs' claims are based on state statutes or traditional tort causes of action; they seek no recovery for a fraud-on-the-FDA claim. For these reasons, the Court finds no basis in Buckman to find an implied preemption of plaintiffs' claims.

c. Another Possibility: No Preemption at All

Finally, but importantly, it is possible that Medtronic's own actions and inactions placed it entirely beyond the scope of FDA PMA approval protection. Congress has chosen, and FDA regulations impose, a scheme under which the manufacturer – not the government – determines a medical device to be safe and efficacious. See 21 C.F.R. §§ 803, et. seq., 814.39. Under this model, the manufacturer bears the highest duty to develop, produce, and offer in the marketplace products it knows to be safe. The FDA has only the most limited role in independently obtaining the information it needs; the duty to develop and fully disclose information

concerning a medical device's safety falls upon the manufacturer. Id.

Here, the Court makes no finding, but plaintiffs argue that, once Medtronic's bench-testing suggested, and field reports confirmed, an early-charge-depletion flaw in Chi 4420L battery-bearing devices, the company bore a Congressionally-imposed affirmative duty to disclose this information to the FDA posthaste. When it opted against doing so – and worse, elected to seek approval for more devices bearing a medical Trojan horse and continued to sell Chi 4420L-bearing devices it knew could be flawed for implantation into patients – plaintiffs' claim Medtronic placed itself beyond the ambit of federal preemption protection. See 21 C.F.R. § 814.82(c) ("Failure to comply with any post approval requirement constitutes a ground for withdrawal of approval of a PMA."); March 1, 2002 FDA Approval letter for S23, Ex.-V ("Failure to comply with the conditions of approval invalidates the approval order.") At this early point in the litigation, the Court cannot entirely reject such an argument.

This is a condition Justice Breyer never contemplated in Lohr. He never considered the possibility of a manufacturer which knows, but fails to disclose, that the FDA's "required two inch wire" is not only no longer safe and efficacious, it is defective, corrosive, and barbed. At this point, the manufacturer's knowing failure to disclose its own positive knowledge of danger hidden in

an approved medical device has its own effect: the company's failure to exhibit absolute probity could be found to have knowingly deprived the FDA of information needed to confer its approval for the device to be implanted in humans. If proven, such a failure to fully comply with Congress's self-disclosure scheme may have deprived Medtronic of federal preemption protection altogether.

III. Conclusion

For the foregoing reasons, the Court finds defendant has failed to show plaintiffs' claims are preempted by federal law. As a result, the Court concludes plaintiffs' state-law claims remain viable.

Accordingly, defendant's motion for summary judgment [Docket No. 74] is denied.

IT IS SO ORDERED.

Dated: November 28, 2006

s/ James M. Rosenbaum
JAMES M. ROSENBAUM
United States Chief District Judge