Risavich v Heart Rhythm Consultants
2010 NY Slip Op 33813(U)
February 1, 2010
Supreme Court, Suffolk County
Docket Number: 08-14183
Judge: Jr., John J.J. Jones

[* 1]

SHORT FORM ORDER

INDEX No. 08-14183

SUPREME COURT - STATE OF NEW YORK
I.A.S. PART 10 - SUFFOLK COUNTY

PRESENT:

Hon. JOHN J.J. JONES, JR.
Justice of the Supreme Court

MOTION DATE 7-22-09
ADJ. DATE 10-7-09
Mot. Seq. # 005 - MG

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JASON RISAVICH a disabled adult by his adoptive MOTHER, FRANCES RISAVICH and JASON RISAVICH AND FRANCES RISAVICH INDIVIDUALLY,

Plaintiffs,

- against -

HEART RHYTHM CONSULTANTS, ST. CATHERINES OF SIENA HOSPITAL, GEORGE CARAYANNOPOULOUS, M.D., SAVERIO BARBERA, M.D., THOMAS McBREARTH, M.D., NORTH SUFFOLK CARDIOLOGY ASSOCIATES, LYUDMILA KHALODOROVA, M.D., MEDTRONICS, INC., and JOHN DOES "1" - "50",

Defendants.

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Upon the following papers numbered 1 to 46 read on this motion for summary judgment; Notice of Motion/ Order to Show Cause and supporting papers 1 - 16; Notice of Cross Motion and supporting papers __; Answering Affidavits and supporting papers 17 - 27; 28 - 36; 37 - 38; Replying Affidavits and supporting papers 39 - 45; Other 46, confidential documents under seal; (~~and after hearing counsel in support and opposed to the motion~~) it is,

ORDERED that the motion by defendant Medtronic, Inc. for summary judgment dismissing the complaint against it is granted.

Defendant Medtronic is one of the world's largest manufacturers of medical devices, including implantable cardiac defibrillators (ICDs), which are small devices implanted in patients' chests to monitor heart rhythm abnormalities. They do so through small wires called leads that on one end are attached to the ICD and on the other end are attached directly to the patient's heart muscle through a coronary vein. If electrodes on the leads detect that the patient's heart is out of rhythm, the ICD sends an electric shock to the heart muscle through the leads in order to correct the problem. In 2004, the U.S. Food and Drug Administration (FDA) approved the Sprint Fidelis lead manufactured by Medtronic. On October 26, 2005, a Sprint Fidelis lead model number 6949 manufactured by defendant Medtronic was implanted in plaintiff Jason Risavich's heart.

Plaintiff Jason Risavich, a disabled adult, by his adoptive mother, Frances Risavich, commenced this instant action against defendants to recover damages. Plaintiffs allege that as a result of the defective lead wire, plaintiff Jason Risavich suffered electrical shocks to his heart and body, and was forced to undergo a surgical procedure to remove the lead. The complaint seeks to recover damages under theories of negligence, products liability, breach of warranty and medical malpractice. It also asserts a derivative cause of action on behalf of Frances Risavich for loss of her son's companionship. Plaintiffs allege, in part, that Medtronic was negligent in the distribution and manufacturing of Sprint Fidelis leads, and that it negligently failed to provide for a safety feature to protect plaintiff in the event of lead wire fracture or lead wire malfunction.

Defendant Medtronic now moves for summary judgment dismissing the complaint against it on the ground that all of plaintiffs' tort claims are preempted by the Medical Device Amendments Act ("MDA") to the Federal Food, Drug, and Cosmetic Act (FDCA) (*see* 21 U.S.C.§360c et seq.). In support of the motion, Medtronic submits, among other things, the pleadings, affidavits of Michael Merkiewicz and Tim Samsel, a copy of an approval letter from the FDA, and copies of the FDA's website showing a search of the agency's pre-market approval database. Mr. Merkiewicz's affidavit states that he is an engineering manager for defendant Medtronic. He states that he has reviewed the manufacturing traceability records for the Fidelis lead model 6949 that was implanted in plaintiff's heart, and the record confirms that the lead was manufactured in accordance with the specifications and procedures approved by the FDA through the premarket approval (PMA) process. In Mr. Samsel's affidavit, he states that he is currently employed by defendant Medtronic as Vice President, Quality and Regulatory, Cardiac Rhythm Disease Management. He states that on November 3, 2003, Medtronic submitted an application for premarket approval for Fidelis 6949 as a PMA supplement. He states that the FDA granted Medtronic premarket approval to sell the Fidelis 6949 leads on June 8, 2004.

Plaintiffs oppose the motion and argue that as defendant Medtronic hindered plaintiffs' discovery efforts, summary judgment should be denied. Plaintiffs also argue that Medtronic's evidence does not establish that the subject lead was made in conformity with the specifications and processes approved by the FDA. In opposition, plaintiffs submit, among other things, a copy of the pleadings, a copy of the order of the Court dated January 20, 2009 (Jones, J), and a copy of Medtronic's motion to dismiss. Co-defendants Thomas Mcbrearth, M.D., North Suffolk Cardiology Associates, Lyudmila Khalodorova,

M.D., and Saverio Barbera, M.D., also oppose Medtronic's motion for summary judgment.

State law tort claims against a manufacturer of an allegedly defective medical device which has received premarket approval (PMA) from the FDA are generally exempted by the preemption clause enacted in §360k (a) of the MDA of 1976 (*see* ***Riegel v Medtronic, Inc.***, 552 US 312 [2008]; ***In re Medtronic Inc.***, 592 FSupp2d 1147 [2009]). The MDA includes an express pre-emption provision that states, in relevant part, 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 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 USCS §360k). Devices receiving the most federal oversight are those classified as Class III, and the MDA established two separate and fundamentally different statutory processes for approving those medical devices: the PMA process and the §510(k) process (*see* ***Riegel v Medtronic, Inc.***, *supra*). Premarket approval is a rigorous process whereby the FDA spends an average of 1,200 hours reviewing each application, and grants premarket approval only if it finds there is a "reasonable assurance" of the device's "safety and effectiveness" (***Riegel v Medtronic, Inc.***, *supra*; ***Medtronic, Inc. v Lohr***, 518 US 470 [1996]). However, to limit the competitive advantage of devices which were already on the market before the MDA's effective date, those devices were "grandfathered" and exempt from PMA. A new device need not undergo premarket approval if the FDA finds it is "substantially equivalent" to a grandfathered device and this process is the §510(k) (*see* ***Riegel v Medtronic, Inc.***, *supra*; ***Medtronic, Inc. v Lohr***, *supra*).

The only causes of action that are not preempted by the MDA are those claims that "would not create requirements that are different from or in addition to the federal requirements," but instead parallel the federal requirements. (*see* ***Riegel v Medtronic, Inc.***, *supra*; ***Horowitz v Stryker Corp.***, 613 FSupp2d 271 [2009]; ***Colombini v Westchester County Health Care Corp.***, 23 Misc3d 1122(A), 2009 NY Slip Op 51555U [2009]; ***Mitaro v Medtronic***, 24 Misc3d 1222(A), 2009 NY Slip Op 50888U [2009]). Pre-market approval of a medical device by the FDA imposes "requirements" under the FDCA, because the device must be "made with almost no deviations from the specifications in [the PMA] application (*see* ***Riegel v Medtronic, Inc.***, *supra*; ***In re Medtronic Inc.***, *supra*). Furthermore, permitting a plaintiff's claims to proceed would impose requirements "different from, or in addition to" the requirements imposed via the PMA process (*see* ***Riegel v Medtronic, Inc.***, *supra*; ***In re Medtronic Inc.***, *supra*). In analyzing whether a claim is preempted by the MDA, a court must first find that federal requirements are imposed on the particular medical device (*see* ***Riegel v Medtronic, Inc.***, *supra*; ***Horowitz v Stryker Corp.***, *supra*). If so, the court must then determine whether the plaintiff's claims are based on a state requirement that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" (*see* ***Riegel v Medtronic, Inc.***, *supra*; ***Horowitz v Stryker Corp.***, *supra*). Claims which impose requirements that are either different from, or in addition to, the federal regulations are preempted (*see* ***Riegel v Medtronic, Inc.***, *supra*; ***Horowitz v Stryker Corp.***, *supra*).

Defendant Medtronic has established that the Sprint Fidelis lead model number 6949 is a Class III device, which was approved through the FDA's PMA process. Federal requirements attach specifically to the Sprint Fidelis lead, as it has successfully completed the rigorous PMA process. Here,

plaintiffs' claims concerning products liability, negligence, and breach of warranty against Medtronic are state requirements which relate to safety and effectiveness and are "different from or in addition to" the federal requirements as imposed by the PMA process, making them subject to preemption. State tort law that requires a manufacturer's medical devices to be safer, but potentially less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect (*see* ***Riegel v Medtronic, Inc.***, *supra*).

The Court rejects plaintiffs' contention that the instant case does not fall within the parameters of ***Riegel***. Plaintiffs argue that the Sprint Fidelis lead model number 6949 was only subjected to a "supplemental" process, rather than the PMA process, and thus the decision in ***Riegel*** is not applicable. However, once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness (*see* ***Riegel v Medtronic, Inc.***, *supra*). If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial applications (*see* ***Riegel v Medtronic, Inc.***, *supra*). The FDA has determined that devices entering the market after it has been granted PMA offers a reasonable assurance of safety and effectiveness and, therefore, state tort claims are preempted (*see* ***Riegel v Medtronic, Inc.***, *supra*; ***Medtronic, Inc. v Lohr***, *supra*). Here, Medtronic submitted an application for supplemental premarket approval for the Fidelis lead model number 6949, and the FDA granted premarket approval to sell those leads in 2004.

Moreover, plaintiffs' counsel's bald assertion that Medtronic did not follow FDA-approved manufacturing procedures and requirements, and that this failure caused plaintiff's injury, is insufficient to raise a triable issue of fact (*see* ***Chambers v Osteonics Corp*** 109 F3d 1243 [1997]; ***Horowitz v Stryker Corp.***, *supra*). Plaintiffs' pleadings provide no factual basis for their claims that Medtronic failed to comply with FDA regulations (*see* ***Bell Atlantic Corp. v Twombly***, 550 US 544 [2007]; ***Horowitz v Stryker Corp.***,*supra*). Plaintiffs also argue that Medtronic's alleged violations of New York Uniform Commercial Code statutes such as warranty of fitness and strict liability are not preempted as per 21 C.F.R. §808.1. In order to recover under a breach of warranty of fitness claim, plaintiffs must establish that the Fidelis lead was not "reasonably fit for the ordinary purpose for which it was intended" (*see* ***Denny v Ford Motor Co.***, 87 NY2d 248, 639 NYS2d 250 [1995]). If plaintiff were to succeed in such a claim, a jury would have to find that Medtronic breached the implied warranty of fitness by manufacturing a medical device that was unsafe in its federally approved design or manufacture. As the safety and effectiveness of the leads are matters solely for the FDA, and because the FDA determined the leads to be safe and effective when granting PMA, such claims are preempted (*see* ***In re Medtronic Inc.***, *supra*; ***Covert v Stryker Corp.***, 2009 WL 2424559 [M.D. N.C. 2009]). Accordingly, defendant Medtronics' motion for summary judgment is granted. The action is severed and shall continue against the remaining defendants.

Dated: 1 Feb. 2010

J.S.C.

____ FINAL DISPOSITION __X__ NON-FINAL DISPOSITION