SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF RICHMOND DCM PART 3

Index No.: 101698/12
Motion No.: 1

JAMES MESSNER and SANDRA MESSNER,

Plaintiffs

against

DECISION & ORDER

HON. JOSEPH J. MALTESE

MEDTRONIC, INC.,
DR. KOUROSH ASGARIAN,
THE HEART INSTITUTE and
STATEN ISLAND UNIVERSITY HOSPITAL,

Defendants

The following items were considered in the review of this motion to dismiss:

Papers	Numbered
Notice of Motion and Defendant's Affidavits Annexed	1
Defendant's Memorandum of Law	2
Plaintiffs' Affirmation in Opposition	3
Defendant's Reply Memorandum of Law	4
Exhibits	Attached to Papers

In this product liability and medical malpractice action, the defendant, Medtronic, Inc., moves to dismiss plaintiffs' complaint by asserting that this court does not have jurisdiction over the subject matter, and that the pleadings fail to state a viable cause of action because those claims are expressly preempted by the 1976 Medical Device Amendments (MDA) of the Federal Food Drug and Cosmetics Act (FDCA) in the United States Code at 21 U.S.C. § 301 et. seq.

Medtronic also moves to dismiss the plaintiffs' claims for breach of contract, breach of express warranty and punitive damages because they are legally insufficient in that they failed to state a claim upon which relief can be granted. Medtronic further asserts that plaintiffs' failure to warn claim is barred by New York's "learned intermediary" doctrine, and for such other and further relief as this court deems just and proper. Medtronic's motion is granted in part and denied in part.

Facts

On or about October 15, 2009, the plaintiff, James Messner, underwent an invasive mitral valve replacement surgery at The Heart Institute located at Staten Island University Hospital (SIUH). At The Heart Institute, Dr. Kourosh Asgarian, a cardiac thoracic surgeon, selected and placed a Mosaic Porcine Heart Valve that was manufactured by the defendant Medtronic, Inc. into Mr. Messner's chest. Over the course of the next 18 months, plaintiff suffered with chronic upper respiratory issues, such as difficulty breathing, recurrent plural effusions, a pneumothorax, shortness of breath and fatigue. Subsequent medical testing revealed a leak in the heart valve that was placed into the plaintiff's body.

On March 18, 2011, the plaintiff was required to undergo another invasive heart surgery to replace the allegedly defective heart valve. The surgeon, Dr. Naka, stated in his Operative Report and Discharge Summary that the Medtronic Porcine Heart Valve had an "anterior dehiscence" (opening of a closed wound) with a "hole" in its leaflet (flap) that was causing plaintiff's "leak" and the resultant injuries.

Plaintiffs' Contentions

The plaintiff, James Messner and his wife sued Medtronic, the manufacturer of the heart valve, the original surgeon, Dr. Asgarian, who selected and used the heart valve, The Heart Institute and SIUH. Plaintiffs alleged in their Verified Amended Complaint that Medtronic's Mosaic Porcine Heart Valve should not have been placed into commerce and sold to the public with an "anterior dehiscence" and "hole" in its leaflet. Plaintiffs claim that Medtronic's medical device was defectively designed and/or defectively manufactured and did not perform as intended. Plaintiffs contend that the defect is a clear and undisputed deviation from the federal "requirement," which mandates that any medical device designed and manufactured be safe and effective and be free from defects in accordance with the Food and Drug Administration's (FDA) Current Good Manufacturing Practices (GMP) contained in Sections 820.50, 820.80, 802.1(7), and in the Code of Federal Regulations at 21 C.F.R. §3.2 (e)(1) and §(2). The plaintiffs asserted that the FDA has the power and the authority to withdraw any approved medical device if the manufacturer failed to comply with the Current Good Manufacturing Practices.

Plaintiffs further alleged in their Verified Amended Complaint that United States Code "requirements" mandate that the manufacturers of medical devices, such as Medtronic, Inc., adhere to the FDA's "strictest regulation" in its design and manufacturing process, since the devices create a potential for unreasonable risk of illness or injury (21 U.S.C. 360c(a)(1)(C)(ii)). They also claim that the MDA requires that a manufacturer of medical devices submit full reports of all investigations regarding the safety and effectiveness of their medical device, and must report any failures regarding their product in accordance with Section 803.50(a) of the GMP; 21 C.F.R. 814.84; and the Safe Medical Device Act (SMDA). Plaintiffs claim that Medtronic failed to disclose any reports regarding the safety and effectiveness of the Mosaic Porcine Heart Valve.

In addition, the Verified Amended Complaint alleges that defendant, Medtronic, Inc., failed to comply with federal regulations by not reporting the history of failed Mosaic Porcine Heart Valves; and that such failure resulted in injury to the plaintiff because it failed to warn the users of the valves, such as physicians, of the risks before they utilized those valves in their patients.

Plaintiffs argue in opposition to Medtronic's motion to dismiss that the federal requirement that medical devices be designed and manufactured without defect, and perform as intended, "parallel" the plaintiff's New York state common law claims that the defendant's product be placed into commerce without a defect. Moreover, the plaintiffs aver that they have not alleged that the defendant violated any state requirement that is "different from, or in addition to, any federal requirement" mandated under federal law. Therefore, plaintiffs assert that they have multiple viable, non-preemptive causes of action against the defendant Medtronic, Inc.

The plaintiffs assert that they have reviewed relevant studies between 2001 and 2005, which revealed that Medtronic's Mosaic Procine Heart Valves have failed and caused injury at an alarming rate for many years prior to plaintiff's exposure to this medical device. Plaintiffs further assert that as a result of the defective nature of the defendant's Mosaic Porcine Heart Valve, some hospitals have prohibited physicians from using that valve.

Plaintiffs acknowledge that pursuant to the 1976 Medical Device Amendments, Medtronic is not permitted to alter or change the design and/or manufacturing process of a medical device once it has been approved by the FDA. However, plaintiffs argue that they have not had the opportunity to receive any written discovery and have not conducted any depositions of defendant Medtronic's employees. Therefore, they contend that it is impossible for plaintiffs to ascertain whether Medtronic altered or changed the manufacturing process of the subject medical device, or gave additional warnings to physicians, or their patients, without discovery of those facts.

Lastly, plaintiffs contend that defendant's motion must be denied, as a matter of law, since it failed to include an affidavit from an individual with personal knowledge or information regarding whether any changes or alternations have been made to the subject medical device, since the time of its approval.

In this pre-answer, pre-discovery motion, Medtronic moves to dismiss plaintiffs' complaint based upon the New York Civil Practice Law and Rules (CPLR), sections 3211(a) 1, 2 and 7 in that a defense is founded upon documentary evidence; failure to state a cause of action; and that this court lacks jurisdiction over the subject matter, which is governed by federal law. Since no documentary evidence other than case law has been presented by Medtronic, its application pursuant to CPLR 3211(a) 1 cannot be considered. However, this court will now review the motion with reference to CPLR 3211(a) 2 and 7.

Discussion

Federal Preemption

Medtronic asserts that the 1976 Medical Device Amendment is an express preemption statute that precludes state common law claims that are in addition to the requirements imposed upon a medical device manufacturer in the pre-market approval process by the Federal Food and Drug Administration. Therefore, Medtronic argues that this court has no jurisdiction over that federally regulated field [CPLR §3211(a) 2]. Medtronic contends that the plaintiff cannot state a cause of action against it as the manufacturer of the medical device.

In 1976, Congress enacted the Medical Device Amendments to the Food Drug and Cosmetics Act that contained an explicit preemption clause that provides 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) (emphasis added).

The implementing regulation in 21 CFR §808.1 (d) provides:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements... The following are examples of State or local requirements that are not regarded as preempted by [§ 360l]:
>
> **...**
>
> (2) [Section 360k] *does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act* (emphasis added).

The U.S. Constitution in Article 1 Section 8 lists the specific "enumerated powers" of the U.S. Congress, which includes regulating commerce among the states. The "Supremacy Clause" in Article VI, Clause 2 of the U.S. Constitution states that:

> This Constitution, and the laws of the United States which shall be made in pursuance thereof; and all treaties made, or which shall be made, under the authority of the United States, shall be the supreme law of the land; and the judges in every state shall be bound thereby, anything in the Constitution or laws of any State to the contrary notwithstanding.

Lastly, the Tenth Amendment, the "delegated powers" clause states that:

> The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.

Amongst the delegated powers of the Tenth Amendment are the "police powers" where the states, not the federal government, maintain the laws governing the health and welfare of the people. The U.S. Supreme Court recognized this division of power when it stated that, "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons," *Metropolitan Life Ins. Co. v. Massachusetts*, 471 U.S. 724, 756 (1985). Yet, the federal government for over a century has encroached into the area of protecting the health of the American people under the rationale that food and drugs frequently crossed state borders and therefore, should be regulated by the federal government.

Congress enacted the Food and Drug Act of 1906, which prohibited the manufacture or shipment in "interstate commerce" of any adulterated or misbranded food or drug. (See, 34 Stat. 768.) In 1938 Congress expanded the 1906 Act to include misbranded or adulterated medical devices and cosmetics in the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA). The FDCA provided for premarket approval of new drugs, but it did not authorize any control over the introduction of new medical devices. Advancements in technology and medicine developed new medical equipment such as heart pacemakers and artificial heart valves. Like any new products, some medical devices failed to function properly resulting in serious injuries and death. Without national regulation, medical devices were sold in the medical marketplace with little oversight other than violations of state common law causes of actions for negligence, strict liability and whatever body of products liability regulations existed within the given state. Numerous lawsuits from the 50 states with similar and dissimilar product liability laws ensued. Congress recognized the need for regulations of medical devices. Thereafter, manufacturers also complained that they were overwhelmed by complying with the pre-market approval process for the FDA for their initial approval of their medical devices and also being subjected to the product liability laws of the 50

states. After numerous lawsuits, several medical device manufacturers announced that they would cease manufacturing medical devices. (See generally, Finck, The Effectiveness of FDA Medical Device Regulation, 7 U.C.D.L. Rev. 293, 297-301 (1974); H.R. Rep. No. 94-853, at 7.)

Express preemption is explicitly stated by the Congress in its legislation. Implied preemption includes field and conflict preemption. The United States Supreme Court has decided three preemption cases concerning the Medical Device Act (MDA). The rule that emerges from these cases is that the MDA does not preempt state-law claims for violating a state-law duty that "parallels" a federal-law duty under the MDA.

Medtronic v. Lohr

In *Medtronic, Inc. v. Lohr*, (518 U.S. 470 [1996]) the Lohrs sued Medtronic for numerous state-law negligence claims, including a claim alleging failure to warn the "plaintiff or her physicians of the tendency of the pacemaker to fail, despite knowledge of other earlier failures." The Supreme Court held that the MDA did not preempt the Lohrs' state-law claim alleging that Medtronic negligently failed to warn "plaintiff or her physicians" of the known dangers of its pacemaker. The Court's analysis rested on the state-law duties, upon which the Lohrs relied escaped preemption "because their generality leaves them outside the category of requirements that § 360k (MDA) envisioned to be 'with respect to' specific devices such as pacemakers." (*Id.* at 502.) *Medtronic v. Lohr* allows certain state-law causes of action that parallel federal safety requirements, but it does not stand for the proposition that any violation of the FDCA will support a state-law claim.

In *Lohr*, the U.S. Supreme Court held that:

> [A]ny understanding of the scope of a preemption statute must rest primarily on "a fair understanding of congressional purpose." ... Congress' intent, of course, primarily is discerned from the language of the preemption statute and the "statutory framework" surrounding it. *Lohr,* 518 US at 485-86.

The High Court in *Lohr* also held there was no "field" preemption. Medtronic argues that the plain language of the statute preempts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices. However, Justice Breyer concurring in *Lohr* wrote:

> [I cannot] find any indication that either Congress or the FDA intended the relevant FDA regulations to occupy entirely any relevant field. *Id.* at 508.

The Supreme Court also held that there was no conflict preemption. Conflict preemption exists when a state requirement actually conflicts with a federal requirement, making it impossible to comply with both requirements (See, *Fla. Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 [1963]), or when a state requirement "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." The MDA's implementing regulation provides that state requirements are not preempted if they "are equal to, or substantially identical to, requirements imposed by or under the act" 21 C.F.R. §808.1(d)(2). Justice Stevens wrote in Part IV of *Lohr* that state requirements that fall within the regulatory definition do not conflict with the MDA:

> Nothing in § 360k denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements... The presence of a damages remedy does not amount to the additional or different "requirement" that is necessary under the statute; rather, it merely provides another reason for manufacturers to comply with identical existing "requirements" under federal law.

Buckman Co. v. Plaintiffs' Legal Committee

In *Buckman Co. v. Plaintiffs' Legal Comm.* (531 U.S. 341 [2001]), the plaintiffs brought a state-law negligence suit for damages alleging injuries resulting from orthopedic bone screws, a Class III medical device. Buckman was a consulting company that plaintiffs alleged had made fraudulent misrepresentations to the FDA in the course of obtaining pre-market approval for its client, the manufacturer (*Id.* at 343). The court characterized the plaintiffs' state-law claims against Buckman as "fraud-on-the-FDA claims" (*Id.* at 348). Such claims conflict with, and are therefore impliedly preempted by the MDA. The conflict stems from the fact that the federal statutory scheme

amply empowers the FDA to punish and deter fraud against the Administration. That authority is used by the FDA to achieve a delicate balance of statutory objectives without any need for assistance from injured individuals asserting common law claims for damages.

Riegel v. Medtronic

The Riegels sued Medtronic for damages under New York state law after an FDA-approved Class III balloon catheter lead that was placed into the plaintiff's coronary artery ruptured. Plaintiffs alleged that the catheter was defective under state law and sued in the U.S. District Court for the Northern District of New York.

When the U.S. District Court was initially faced with a motion to dismiss the plaintiff's complaint based upon federal preemption, it did not dismiss the plaintiff's claims for negligent manufacturing, the loss of consortium derivative of negligent manufacturing and breach of express warranty. Judge Kahn's ruling allowed those claims to proceed to discovery reasoning that if Medtronic was negligent and did not comply with the FDA approved design and manufacturing specifications when it manufactured the device, there would be no conflict between the state requirement and the federal requirement; and consequently, no federal preemption.

The trial judge also ruled that if express warranties were made based upon express representations, such claims do not interfere or conflict with federal requirements imposed through the FDA, pre-market approval process. (See, *Mitchell*, 126 F.3d at 915.) Since the consortium claim was derivative of the primary claims allowed to proceed it was not ripe for dismissal (2002 WL 3423093 (N.D. N.Y.).

At the conclusion of discovery, Medtronic once again moved for summary judgment to dismiss the remaining negligent manufacturing and breach of express warranty claims, along with the derivative consortium claims. However, this time Judge Kahn found that: (1) neither the plaintiffs, nor their agents, relied on any express warranties; and (2) any express warranties were disclaimed. Neither the plaintiffs, nor their doctor, or the hospital as their agents had any knowledge

of any warranties when Mr. Riegel underwent the heart procedure. As to the negligent manufacturing claim, the District Court found that the plaintiffs did not have the actual allegedly defective balloon, and thus did not have any direct evidence of negligent manufacture. Moreover, plaintiffs failed to negate the possibility that other causes other than the negligent manufacture may have caused the balloon in the catheter to burst. It was undisputed that the plaintiff's physician exceeded the maximum recommended 8 atmospheres to 10 atmospheres when inflating the balloon catheter. Moreover, it was contraindicated to use a balloon for Riegel's condition without having used a Rotoblater to remove the heavy calcified spicules. The court concluded from that evidence that no fair minded trier of fact would reasonably conclude that the plaintiff excluded those other causes of the burst. Accordingly, the court dismissed those remaining causes of action along with the consortium claim (*Riegel v. Medtronic, Inc*., 2003 WL 25556778 [N.D.N.Y.]).

The U.S. Court of Appeals for the Second Circuit affirmed the U.S. District Court (*Riegel v. Medtronic, Inc*., 451 F.3d 104 [2nd Cir. 2006]) and held that:

> (1) state requirements applicable to medical devices that have entered the market pursuant to Food and Drug Administrations (FDA) premarket approval (PMA) process are preempted under MDA;
>
> (2) plaintiff's negligence, strict liability, and breach of implied warranty claims were preempted;
>
> (3) *negligent manufacture claims were not preempted*;
>
> (4) *but plaintiff failed to exclude manufacturer's proffered alternate causes for product failure, precluding recovery for negligent manufacture* (emphasis added).

Justice Antonin Scalia writing for an 8-1 majority of the U.S. Supreme Court held that plaintiffs' claims were expressly preempted by the MDA because the New York state law imposed a more stringent safety requirement than federal law (552 U.S. 312 at 325 [2008]).

It is interesting to note that shortly after President Obama was inaugurated on May 20, 2009, he issued an Executive Order on preemption. He stated, "throughout our history, state and local governments have frequently protected health, safety and the environment more aggressively than has the national government." President Obama directed the heads of Executive Departments and Agencies to review their rules and regulations with respect to federal preemption of state law and to amend such regulations to reflect the President's policy that federal and state law should act concurrently to promote the general welfare (74 Fed. Reg. 24693).

Also in 2009, when both houses of the Congress were controlled by the President's political party, Senator Edward Kennedy of Massachusetts and Congressman Henry Waxman of California introduced the Medical Device Safety Act of 2009, H.R. 1346/S. 540 that would have reversed *Riegel v. Medtronic* by adding a provision to the FDCA, which stated that federal approval of a medical device has no effect on liability under state law. The new subsection to 21 U.S.C. § 360k would state:

> (c) No Effect on Liability Under State Law – Nothing in this section shall be construed to modify or otherwise affect any action for damages or the liability of any person under the law of any State.

Ironically, this bill was not incorporated into the extensive Patient Protection and Affordable Care Act of 2010 and neither bill has seen any reported action since the subcommittee hearings in 2009.

Parallel Claims

In *Medtronic v. Lohr,* the Supreme Court held that:

> 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. §360k(a)(1). Thus, § 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 (*Lohr*, 518 U.S. at 495) (emphasis added).

While the Supreme Court claims that the MDA will allow "parallel claims" to be brought under state common law, it does not delineate what "parallel claims" would survive federal preemption. Product liability law is primarily state common law and statutory law. The typical causes of action that are asserted in a product liability case are: negligence, breach of express warranty, breach of implied warranty and strict liability (*Denny v. Ford Motor Co.*,. 87 NY2d 248 [1995]; *Voss v. Black & Decker Manufacturing Co.*, 59 NY2d 102 [1983]).

Strict liability includes: design defects, manufacturing defects and inadequate warnings (*Speller ex. rel. Miller v. Sears Roebuck & Co.*, 100 NY2d 38 [2003]). Strict liability grew out of judge made law to facilitate recovery for personal injuries caused by defective products. Courts found that manufacturers and sellers implied that their product was merchantable and fit for ordinary purpose. Implied warranties of strict liability eliminated the need for the injured plaintiff to prove negligence by the manufacturer or seller who breached a duty of care owed to all foreseeable users. But more specifically:

> A manufacturer of a product owes a duty to use reasonable care in the manufacture of the product so that it will be reasonably safe for its intended or foreseeable uses. Reasonable care means that degree of care that a reasonably prudent manufacturer of such a product would use in the making, inspecting and testing of the product, and its materials in order to produce a reasonably safe product. (See 1NY PJI 3d 2:125 at 774 [2013]; *Gebo v. Black Clawson Co.*, 92 NY2d 387 [1998].)

Express warranty is defined by UCC §2-313(1)(a) as follows:

> Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.

If the product does not confirm to the representation, the warranty is breached.

Justice Scalia highlights in *Riegel* that "the MDA provides that no state may establish or continue in effect *with respect to a device. . . any requirement*" relating to safety or effectiveness that is different from or in addition to federal requirements §360(a) (emphasis added) *(Id*. at 328). He

continued that "the Riegel's suit depends upon New York's continuing in effect general tort duties" with respect to Medtronic's catheter.

While one could well argue that New York product liability law parallels and is indistinguishable from the federal requirements of the FDA's current Good Manufacturing Practices and the applicable regulations in the Code of Federal Regulations or the Safe Medical Device Act, the High Court has ruled that medical device manufacturers will not be exposed to damages claims by injured plaintiffs, but will only be subject to enforcement by the FDA who reviews and approves their products.

Yet, three U.S. Circuit Courts of Appeal have held that, in cases dealing with violations of the MDA outside the pre-market approval process, the MDA does not preempt state-law causes of action for damages in which the state-law duty "parallels" the federal-law duty under the MDA. (See, *Hughes v. Boston Scientific Corp*., 631 F.3d 762 (5th Cir. 2011); *Bausch v. Stryker Corp*., 630 F.3d 546 (7th Cir. 2010), *cert. denied*, 132, S.Ct. 498 (2011); *Stengel v. Medtronic, Inc.*, 704 F3d 1224 (9th Cir., 2013). In *Stengel*, the Ninth Circuit espoused that:

> The idea that Congress would have granted civil immunity to medical device manufacturers for their violations of federal law that hurt patients is, to say the least, counter-intuitive.

The Eighth Circuit has also addressed preemption holding that the MDA preempted the plaintiffs' failure-to-warn claims (See, *In re Medtronic, Inc., Sprint Fidelis Leads Products Liability Litigation*, 623 F.3d 1200 [8th Cir. 2010]). First, plaintiff sought to enforce state-law requirements that would have required Medtronic "to give *additional* warnings, precisely the type of state requirement that is 'different from or in addition to' the federal requirement" *(Id.* at 1205) (quoting *Riegel*, 552 U.S. at 330). Second, the plaintiff sought to bring actions based solely on the MDA rather than on state law, which the court found foreclosed by *Buckman*. At no point did the court address a state-law claim based on a state-law duty that paralleled a federal-law duty. Hence, *Sprint Fidelis* (8th Cir.) is not inconsistent with *Hughes* (5th Cir.), *Bausch* (7th Cir.) or Stengel (9th Cir).

The New York Supreme Court Appellate Division, Second Department in *Mitaro v. Medtronic, Inc*. (73 AD3d 1142 [2010]), affirmed the trial court's dismissal of the plaintiff's complaint concerning a defectively designed implantable cardiac defibrillator (ICD), which is a small medical device implanted into a patient's chest to monitor heart rhythm abnormalities. Citing to the then recently decided U.S. Supreme Court case of *Riegel v. Medtronic, Inc*. (552 US 312 [2008]), the trial court held that the plaintiff's claims for strict liability for failure to warn and instruct, defective design, negligence, breach of implied warranty, misrepresentation and fraud, unjust enrichment and violations of the New York General Business Law and the Medicare Secondary Payer statute were dismissed. However, the trial court did not dismiss the claims of strict liability due to a manufacturing defect and the breach of express warranty (23 Misc3d 1122(A), 886 NYS2d 71 [Sup. Ct. Westchester Cty, 2009]). The Appellate Division, Second Department merely affirmed the trial court's decision in a short, two-page decision, thereby leaving the manufacturing defect claim and the express warranty claim for discovery and a possible jury trial.

Here, Medtronic moves to dismiss the plaintiff's complaint before interposing any answer, or providing an affidavit from a person with actual knowledge of the facts of this case. Discovery has not been conducted to demonstrate whether the manufacturing process was negligently conducted resulting in a product with an unapproved hole in its leaflet that would violate federal safety statutes and regulations. Moreover, if Medtronic knew of the unapproved alteration or defect in the valve leaflet, did it warn the physician users and consumers? Medtronic moves to dismiss all of the causes of action against it based on a broad assertion of federal preemption. This court finds that application to be too broad and premature which is not in keeping with the intent of the federal preemption section of the MDA, and its interpretation by the U.S. Supreme Court and other appellate courts.

The design of the heart valve had been approved by the FDA. It is not the role of an injured plaintiff, or a jury, in either a state of federal court to substitute their judgment of the quality of the design of a Class III medical device that has undergone pre-market approval by the FDA, as had this

heart valve in question. Consequently, plaintiffs' claims based upon strict liability for defective design, negligence, the implied warranties of merchantability or fitness for use (UCC 2-314), as well as fitness for a particular purpose (UCC 2-315) and improper labeling, are preempted by the statute and regulations and are dismissed.

It is not the role of FDA to monitor the defendant's manufacturing of the approved design of the heart valve to ascertain what quality control measures are in place or to spot check the production line. Under the federal system, the manufacturer of a medical device self monitors the products it places into commerce for use by physicians in their medical operations upon consumers such as the plaintiff herein.

However, here there may have been negligence in the manufacturing process that deviated from the premarket approval of the design and method of manufacturing. If there was an alteration or defect in the heart valve when it left Medtronic's control, it may be liable for placing a defectively manufactured product with a hole in the leaflet into the marketplace in violation of the aforesaid federal safety statutes and regulations that caused a leak and subsequent harm to the plaintiff.

In the event Medtronic could not have produced the preapproved designed medical device without creating a hole in the leaflet, then it had a legal duty to report that fact to the FDA. If the product was coming off the assembly process in a manner not intended by the FDA premarket approval of its design and manufacturing specifications, then additional warnings may have been necessary to the users of that medical device. While Medtronic could not change the labeling of the heart valve without FDA approval, if it knew of such defects, it could have sought an amendment to labeling and issued additional warnings by way of letters to surgeons and hospitals or had their company sales representatives warn physicians who use these valves on their patients. The physicians, as the "learned intermediaries," should have the necessary information to make informed judgments of whether to use such a heart valve or to select another product. If the heart valve was damaged by the surgeon or the hospital staff during the operation, then the surgeon and/or the

hospital may be liable to the plaintiff. Consequently, it is premature to dismiss the negligent manufacturing claims against Medtronic until discovery as to the nature and cause of the hole in the heart valve that caused injury to the plaintiff.

Clearly, the federal statutory preemption of Class III medical devices does not grant a manufacturer absolute immunity from liability for its negligence in the manufacturing of premarket approved medical devices. All that the express preemption does is preclude plaintiffs from substituting state statutes or state common law product liability causes of action that are different from those imposed by federal law and regulation upon the manufacturer.

If this court were to dismiss the manufacturer of a defective medical device based on their claim of blanket federal preemption without exploring how the heart valve came to have a hole in its leaflet, which caused injury to the plaintiff, then only the surgeon and the hospital would remain potentially liable in this action. That would leave the surgeon and hospital without any recourse to the manufacturer that may have allowed a defectively manufactured product to leave its control, and place it into the medical marketplace without any warnings of the arguably unintended, yet unapproved manufacturing alteration. Consequently, the uninformed physician may not be able to act as the learned intermediary in choosing to use a defective valve by inserting it into the unsuspecting patient. This was not the Congressional intent of the preemption clause in the MDA, nor does it comport with the Supreme Court's interpretation of federal preemption.

In this case, the plaintiffs' claims which specifically cite to violations of federal law and regulations are disbursed over several causes of actions, which may be duplicative. Nonetheless, the plaintiffs' claims of negligence in the manufacturing process resulting in a manufacturing defect, specifically a hole in one of the leaflets of the valve, and the failure to adequately warn the users, the learned intermediary physicians of such defect shall survive. In addition, the consortium claims, which is a derivative claim, shall also survive. Moreover, if the plaintiffs can demonstrate any express warranties made by Medtronic to the surgeons or hospital, or to them directly, then the breach of express warranties shall not be dismissed.

Punitive Damages

In New York punitive damages may not be considered until there is a finding of compensatory damages. Consequently, it is premature to consider the application to dismiss those counts seeking punitive damages.

It should be noted, however, that in the Second Department after a finding of compensatory damages, the plaintiff must prove by "clear and convincing" evidence and not by a mere preponderance of the evidence that the defendant was liable for wanton and reckless or malicious conduct that represents a high degree of immorality and shows such wanton dishonesty as to imply a criminal indifference to civil obligations. (See, *Randi A.J. v. Long Island Surgi-Center*, 46 AD3d 74 [2d Dep't 2007]; *Orange and Rockland Utilities, Inc. v. Muggs Pub. Inc*., 292 AD2d 580 [2d Dep't 2002].)

The New York Pattern Jury Instruction summarizes the standards for punitive damages:

> The purpose of punitive damages is not to compensate the plaintiff but to punish the defendant for wanton and reckless, or malicious acts and thereby to discourage the defendant and other companies from acting in a similar way in the future.
>
> An act is malicious when it is done deliberately with knowledge of the plaintiff's rights, and with the intent to interfere with those rights. An act is wanton and reckless when it demonstrates conscious indifference and utter disregard of its effect upon the health, safety and rights of others.
>
> (See, 1 NY PJI 3d 2:278 at 811-813 (2013).)

All other causes of action are dismissed in accordance with CPLR §3211(a) 2 and 7. The defendants have not produced any documents in compliance with CPLR § 3211a(1), therefore that section is inapplicable at this time.

Accordingly, it is hereby:

ORDERED, that the motion of the defendant Medtronic, Inc., to dismiss all counts of the plaintiffs' complaint against Medtronic, Inc. is granted except:

1. That plaintiff's claims for negligent manufacture and inspection of the Mosaic Porcine Heart Valve that produced a manufacturing defect, specifically a hole in one of the leaflets which was a deviation from the FDA approved design and federal safety requirements and regulations as contained in the First and Second Causes of Action are not dismissed; and

2. That the plaintiffs' express warranty claims contained in the Third Cause of Action are not dismissed; and

3. That the plaintiffs' claims of failure to warn regarding the existence of a hole in the leaflet of the subject medical device with adequate and sufficient notice of the risk of injury of said defect contained in the Fifth Cause of Action are not dismissed; and

4. That the plaintiffs' claims concerning a failure to provide warnings regarding the existence of a hole in the leaflet of the subject medical device and failure to provide adequate and sufficient notice of the risk of injury of said defect contained in the Sixth Cause of Action are not dismissed; and

5. That the plaintiffs' claims concerning a lack of adequate warnings regarding the existence of a hole in the leaflet of the subject medical device contained in the Seventh Cause of Action are not dismissed; and

6. That the plaintiffs' request for punitive damages contained in the Fourteenth Cause of Action is not dismissed; and

7. That the plaintiff, Sandra Messner's derivative claim for loss of society, companionship, consortium and financial support contained in the Fifteenth Cause of Action is not dismissed; and it is further

ORDERED, that all of the defendants shall promptly interpose their answers to the plaintiffs' complaint.

ENTER,

DATED: April 9, 2013

Joseph J. Maltese
Justice of the Supreme Court