UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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HECTOR ILARRAZA,

Plaintiff,

-against-

MEDTRONIC, INC.,

Defendant.
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MEMORANDUM AND ORDER

CV 09-3264

(Wexler, J.)

APPEARANCES:

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WEXLER, District Judge

This is a personal injury action brought by Plaintiff Hector Ilarraza ("Plaintiff") for injuries allegedly sustained as result of a defectively manufactured medical device. Presently before the court is the motion of Defendant Medtronic, Inc. ("Medtronic") to dismiss pursuant to

Rule 12(b)(6) of the Federal Rules of Civil Procedure. For the reasons set forth below, the motion is granted.

BACKGROUND

I. Factual Allegations of the Complaint

The allegations of the complaint, accepted as true in the context of this motion to dismiss, follow.

In 1998, Plaintiff underwent a pelvic MRI that revealed the presence of a non-cancerous, inoperable giant cell tumor of the sacrum. The continuing presence of the tumor resulted in severe pain to Plaintiff's pelvis, back and legs. In February of 2003, to help to relieve the pain, Plaintiff underwent surgery to implant a pain relief device. That device, manufactured by Medtronic, is known as an Intrathecal Drug Delivery System (a "Medication Pump"). The implanted Medication Pump consists of a pump and a catheter, surgically implanted under the skin, that stores and delivers pain medication. This method of delivery allows for direct delivery of pain medication into the space surrounding the spinal canal.

Plaintiff used the Medication Pump without incident from the time of its implantation in 2003, until 2008, when he alleges that he began to experience withdrawal symptoms. He describes his symptoms as similar to those experience by a long-term narcotics user who suddenly stops receiving the drug. A CT scan revealed that Plaintiff's symptoms were the result of a break in the catheter portion of the implanted Medication Pump. Plaintiff alleges that the fracture to the catheter occurred in July of 2008. He states that the fracture has resulted in past pain and expenses, and will cause him future physical and mental pain, as well as substantial medical expenses.

II. Plaintiff's Asserted Cause of Action

The complaint that is presently before the court is Plaintiff's First Amended Complaint (the "Amended Complaint"). While Plaintiff's initial complaint contained generally pled state law causes of action sounding in breach of warranty, and strict product liability, the Amended Complaint contains a single cause of action. For reasons that will become clear after review of relevant federal law, the Amended Complaint asserts only a claim referred to as "Negligence Per Se (A 'Parallel Action')." This cause of action alleges that Medtronic failed to manufacture the Medication Pump in a "reasonable and prudent manner," and in accord with federally prescribed Current Good Manufacturing Practices ("CGMP's"). The Amended Complaint goes on to list eleven federal regulations alleged to have been violated in the manufacture of the Medication Pump.

III. The Motion to Dismiss

Medtronic seeks dismissal of the Amended Complaint. In support of its motion, Medtronic argues that dismissal is required because Plaintiff's allegations of negligent manufacture fail to raise a plausible claim as required by the pleading standard of Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955 (2007). Even assuming that Plaintiff raised facts sufficient to state a claim of negligent manufacture, Medtronic argues that dismissal is nonetheless required as a matter of preemption under the clear standards of the Medical Device Amendments to the Food Drug and Cosmetics Act ("FDCA"), as interpreted by the United State Supreme Court in Riegel v. Medtronic, Inc., 128 S. Ct. 999 (2008). Finally, Medtronic asserts preemption pursuant to 21 U.S.C. § 337(a), of the FDCA, which provides that all actions to enforce the FDCA are to be only "in the name of the United States."

After discussion of the legal standards, the relevant statutory framework, and legal precedent, the court will turn to the merits of the motion.

DISCUSSION

I. Standards For Motions to Dismiss

In Bell Atlantic Corp. v. Twombly, 127 S. Ct. 1955 (2007), the Supreme Court rejected the "oft-quoted" standard set forth in Conley v. Gibson, 355 U.S. 41, 78 (1957), that a complaint should not be dismissed, "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." Id. at 45-46. The court discarded the "no set of facts" language in favor of the requirement that plaintiff plead enough facts "to state a claim for relief that is plausible on its face." Twombly, 127 S. Ct. at 1974, see also Ashcroft v. Iqbal, 129 S. Ct. 1937, 1949-50 (2009).

While heightened factual pleading is not the new order of the day, Twombly holds that a "formulaic recitation of the elements of a cause of action will not do. Factual allegations must be enough to raise a right to relief above the speculative level, on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." Williams v. Berkshire Fin. Grp. Inc., 491 F. Supp.2d 320, 324 (E.D.N.Y. 2007), quoting, Twombly, 127 S. Ct. at 1959. In the context of a motion to dismiss, this court must, as always, assume that all allegations set forth in the complaint are true and draw all inferences in favor of the non-moving party. Watts v. Services for the Underserved, 2007 WL 1651852 *2 (E.D.N.Y. June 6, 2007). The court must ensure, however, that the complaint sets forth "enough facts to state a claim to relief that is plausible on its face." Twombly, 127 S. Ct. at 1974. A pleading that does nothing more that recite facts and bare legal conclusions is insufficient to "unlock the doors of discovery . . . and

only a complaint that states a plausible claim for relief survives a motion to dismiss." Iqbal, 129 S. Ct. at 1950. While a Rule 12 motion is directed only to the sufficiency of the pleading, the court determining the motion may rightfully consider written documents attached to the complaint as well as documents incorporated thereto by reference and those of which plaintiff had knowledge and relied upon in commencing the action. See Brass v. Amer. Film Techn., Inc., 987 F.2d 142, 150 (2d Cir. 1993); Watts, 2007 WL 1651852 *2.

II. Statutory Background and Preemption

A. The Medical Device Amendments

The Medical Device Amendments ("MDA") to the FDCA give the Food and Drug Administration ("FDA") the authority to regulate medical devices like the Medication Pump. See generally 21 U.S.C. §360c et seq. The MDA's statutory scheme creates three levels of scrutiny to be applied to various medical devices before they are approved for marketing. See 21 U.S.C. § (a)(1). The highest level of scrutiny is applied to a device that is "purported or represented to be for a use in supporting human life or for a use which is of substantial importance in preventing impairment of human health, or presents a potential unreasonable risk of illness or injury . . . ." 21 U.S.C. §360(1)(c)(ii). Such devices are deemed to be "Class III" medical devices.

Class III medical devices are subject to the premarket approval process established by the MDA. That process is designed to "provide reasonable assurance" of the device's safety and efficacy. 21 U.S.C. §360(a)(C(ii)(II). The MDA premarket approval of Class III medical devices is a "rigorous" process that typically requires submission of a multivolume application that includes reports of safety and efficacy studies, an explanation of the devices' components as well as details regarding the its manufacturing, packaging and installation. See generally 21 U.S.C.

§360e; Riegel, 128 S. Ct. at 1004. It is only after premarket approval that the manufacturer may begin to manufacture and market the device. After premarket approval, there can be no change in the design, manufacturing or labeling of a medical device that would affect safety or effectiveness of the device, absent further review and approval by the FDA. Riegel, 128 S. Ct. at 1005.

B. Preemption

The MDA was passed in response to the introduction of sophisticated medical devices, the risks of which were not properly managed by state law tort systems. See Riegel, 128 S. Ct. at 1003. The statute's comprehensive review process ensures the safety and efficacy of medical devices that were previously subject to a patchwork of state tort law. See Riegel, 128 S. Ct. at 1003. To ensure uniformity in the safety and efficacy standards to which medical devices would be held, Congress included an express preemption provision in the statute. That section of the MDA provides, in relevant part, that:

> no State or political subdivision of a State may establish or continue in effect with respect to [medical devices covered by the MDA] any requirement –
>
> (1) which is different from or in addition to, any requirement applicable under [the MDA] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or any other matter included in a requirement applicable to the device

21 U.S.C. §360k(a).

The Supreme Court has considered the question of whether the MDA preemption provision bars a state law tort action based upon common law principles of negligence, breach of warranty and strict liability. In Riegel, the Court held clearly that such claims were barred by the

preemption clause of the MDA. The Court focused on the fact that the MDA preemption clause bars the imposition only of requirements that "are different from, or in addition to" requirements imposed by Federal law. Riegel, 128 S. Ct. at 1011. The imposition of the tort standards of fifty different states would clearly run afoul of the statutory preemption.

The Court went on to hold that the MDA preemption provision does not bar a state from imposing a damages remedy for a claim premised on the violation of federal law. In such a lawsuit, the plaintiff would seek damages for the violation of federal, and not state law – duties that the Court referred to as "parallel" to FDA requirements. Riegel, 128 S. Ct. at 1011. Thus, the court left open a narrow class of state court actions that could seek damages for injuries alleged to have been caused by federally regulated medical devices. Such lawsuits can be referred to as "parallel" actions. See In re Medtronic, Inc. Sprint Fidelis Leads Products Liability Litigation, 592 F. Supp.2d 1147, 1152 (D. Minn. 2009) (referring to narrow "back door" left open by Riegel). The court turns to consider whether the Amended Complaint states such a claim.

III. Disposition of the Motion

At the outset, the court notes that the parties agree that the Medication Pump is designated as a "Class III" medical device that gained premarket approval pursuant to the MDA process. Plaintiff's reference to his claim as "Negligence Per Se (A 'Parallel Action')," is a clear recognition of the applicability of the MDA preemption of any state law claim. The only question before the court is therefore whether the Amended Complaint sufficiently states a parallel claim, or must be dismissed.

A. Plaintiff's Claims of Federal Violations

In an effort to state a claim that his injury was caused by the violation of federal law, the

Amended Complaint cites to the alleged violation of several federal regulations promulgated pursuant to the MDA. Specifically, Plaintiff alleges a violation of the following regulations:

21 C.F.R. § 820.20 Management responsibility

(b) Organization. Each manufacturer shall establish and maintain an adequate organizational structure to ensure that devices are designed and produced in accordance with the requirements of this part.
(2) Resources. Each manufacturer shall provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of this part.

(3) Management representative. Management with executive responsibility shall appoint, and document such appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for:

(i) Ensuring that quality system requirements are effectively established and effectively maintained in accordance with this part

21 C.F.R. § 820.25 Personnel

(a) General. Each manufacturer shall have sufficient personnel with the necessary education, background, training, and experience to assure that all activities required by this part are correctly performed.

(b) Training. Each manufacturer shall establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities. Training shall be documented.

(1) As part of their training, personnel shall be made aware of device defects which may occur from the improper performance of their specific jobs.
(2) Personnel who perform verification and validation activities shall be made aware of defects and errors that may be encountered as part of their job functions.

21 C.F.R. § 820.50 Purchasing controls

(a) Evaluation of suppliers, contractors, and consultants. Each manufacturer shall establish and maintain the requirements, including quality requirements, that must be met by suppliers, contractors, and consultants. Each manufacturer shall:

(1) Evaluate and select potential suppliers, contractors, and consultants on the basis of their ability to meet specified requirements, including quality requirements. The evaluation shall be documented.

21 C.F.R. § 820.70 Production and process controls

(a) General. Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:
(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;
(2) Monitoring and control of process parameters and component and device characteristics during production;
(3) Compliance with specified reference standards or codes;
(4) The approval of processes and process equipment; and
(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples.

(h) Manufacturing material. Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.
(i) Automated processes. When computers or automated data processing systems are used as part of production or the quality system, the manufacturer shall validate computer software for its intended use according to an established protocol. All software changes shall be validated before approval and issuance. These validation activities and results shall be documented

21 C.F.R.§ 820.80 Receiving, in-process, and finished device acceptance

(d) Final acceptance activities. Each manufacturer shall establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria. Finished devices shall be held in quarantine or otherwise adequately controlled until released. Finished devices shall not be released for distribution until: (1) The activities required in the DMR are completed; (2) the associated data and documentation is reviewed; (3) the release is authorized by the signature of a designated individual(s); and (4) the authorization is dated

21 C.F.R. § 820.100 Corrective and preventive action

(a) Each manufacturer shall establish and maintain procedures for implementing

corrective and preventive action. The procedures shall include requirements for:

(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems

21 C.F.R. § 820.160 Distribution

(a) Each manufacturer shall establish and maintain procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before devices are released for distribution. Where a device's fitness for use or quality deteriorates over time, the procedures shall ensure that expired devices or devices deteriorated beyond acceptable fitness for use are not distributed

21 C.F.R. § 820.181 Device master record

Each manufacturer shall maintain device master records (DMR's). Each manufacturer shall ensure that each DMR is prepared and approved in accordance with § 820.40. The DMR for each type of device shall include, or refer to the location of, the following information:

(c) Quality assurance procedures and specifications including acceptance criteria and the quality assurance equipment to be used.

B. Plaintiff Fails to State A Parallel Claim

Despite the sheer volume of the material upon which Plaintiff relies, he fails to state a parallel claim. This is because no regulation relied upon refers specifically to the medical device at issue here. Instead, each regulation cited is nothing more than a general statement of a CGMP's. It has been recognized that these standards "are intended to serve only as 'an umbrella quality system' providing 'general objectives' medical device manufacturers must seek to achieve." Horowitz v. Stryker Corp., 613 F. Supp.2d 271, 278-79 (E.D.N.Y. 2009) (citations omitted); accord In re Medtronic, 592 F. Supp.2d at 1157 (referring to CGMP's as "simply too

generic, standing alone, to serve as the basis for plaintiff's manufacturing defect claims"). These regulations are purposefully broad so as to apply to a broad range of medical devices. The regulations are to be tailored by each manufacturer of a device to apply to their particular safety and efficacy needs. See id. The intentionally vague and open-ended nature of the regulations relied upon is the precise reason why they cannot serve as the basis for a parallel claim. Since these regulations are open to a particular manufacturer's interpretation, allowing them to serve as a basis for a claim would lead to differing safety requirements that might emanate from various lawsuits. This would necessarily result in the imposition of standards that are "different from, or in addition to" those imposed by the MDA – precisely the result that the MDA preemption provision seeks to prevent. Accord In re Medtronic, 592 F. Supp.2d at 1158; see also Funk v. Stryker Corp., 2009 WL 4281389 *9 (S.D. Tex. 2009) (complaint dismissed on preemption ground where plaintiff set forth nothing more than conclusory allegations of wrongdoing). Accordingly, where, as here, a plaintiff relies on nothing more that CGMP's in support of a parallel cause of action, preemption bars the claim.

The broad nature of the federal regulations relied upon also leads to the conclusion that Plaintiff's claim cannot withstand the pleading requirements of Twombly. As noted, those standards require dismissal of complaints that do nothing more than engage ion a "formulaic recitation of the elements of a cause of action . . . ." Twombly, 127 S. Ct. at 1965. Where, as here, the plaintiff has done nothing more that recite unsupported violations of general regulations, and fails to tie such allegations to the injuries alleged, the complaint is properly dismissed.

This court is not the first to hold that the general pleading of CGMP violations is insufficient to state a "plausible" parallel claim not subject to dismissal on the ground of

preemption. In Horowitz, the court noted that such pleading did not push the complaint into the realm of what is plausible. There, the court noted that to state a plausible parallel claim, the plaintiff was required to show a link between a specific federal violation, and plaintiff's injury. There, as here, the plaintiff could not show that any alleged manufacturing violation was linked to the injury alleged.[1] See also Bausch v. Stryker Corp., 2008 WL 5157940 *6 (N.D. Ill. 2008); Parker v. Stryker Corp., 584 F. Supp.2d 1298, 1301 (D. Colo. 2008) (conclusory allegations insufficient to state a plausible claim under Twombly).

The court is aware of the case upon which Plaintiff chiefly relies, that reached a different result. See Hofts v. Howmedica Osteonics Corp., 597 F. Supp.2d 830 (S.D. Ind. 2009). The court declines to follow that court's analysis, and instead follows the larger number of courts that have rejected the sufficiency of pleading nothing more than the violation of CGMP's in support of a parallel claim. See Covert v. Stryker Corp., 2009 WL 2424559 *13 (C.D. Ca. 2009) (noting that cases rejecting Hofts are "more persuasive with regard to the pleading standards of Twombly").

Contrary to the notion that the court's holding here will make it impossible to state a plausible parallel claim at the pleading stage, the court contrasts the facts and pleadings in cases that have, indeed, stated such claims. In Purcel v. Advanced Bionics, 2008 WL 3874713 (N.D. Tex. 2008), for example, the plaintiff successfully stated a parallel claim. There, it was alleged that a particular malfunction causing plaintiff's injury was the result of an unapproved supplier's

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[1] Indeed, Horowitz rested on somewhat firmer ground since it relied on particular manufacturing violations that had been cited by the FDA. The failure to connect those violations to plaintiff's injuries, however, was fatal to the pleading. See Horowitz, 613 F. Supp. 2d at 282.

modification of a component part of the regulated device. Purcel, 2008 WL 3874713 *1. Unlike the pleading here, the pleading with respect to the modification in Purcel alleged that defendant violated a particular federal specification referring to the device at issue. Similarly, in Rollins v. St. Jude Medical, 583 F. Supp.2d 790 (W.D. La. 2008), the plaintiff stated a parallel claim where he was able to point to the alleged violation of premarketing packing requirements applicable to the particular medical device at issue. See Rollins, 583 F. Supp.2d at 800-01.

These sufficiently pled parallel claims cases are easily distinguishable from the Amended Complaint. Here, Plaintiff fails to set forth any specific problem, or failure to comply with any FDA regulation that can be linked to the injury alleged. Indeed, in view of the long period of time during which the device at issue functioned without incident, the allegation that general manufacturing violation caused the particular problem here seems all the more remote. Under these circumstances, and for the reasons set forth above, the court holds that Plaintiff's claim is preempted, and fails to allege a plausible claim as required by Twombly. It must therefore be dismissed.

CONCLUSION

For the foregoing reasons, Defendant's motion to dismiss the complaint is granted. The Clerk of the Court is directed to close the file in this matter.

SO ORDERED.

LEONARD D. WEXLER
UNITED STATES DISTRICT JUDGE

Dated: Central Islip, New York
December 28, 2009