THE STATE OF NEW HAMPSHIRE
JUDICIAL BRANCH
SUPERIOR COURT

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NOTICE OF DECISION

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Case Name: **Kelly Ann Murray, et al v Kathleen Hogan, MD, et al**
Case Number: **226-2013-CV-00600**

Enclosed please find a copy of the court's order of February 02, 2015 relative to:

ORDER ON DEPUY ORTHOPAEDICS, INC. AND JOHNSON & JOHNSON'S MOTION FOR SUMMARY JUDGMENT

February 02, 2015

Marshall A. Buttrick
Clerk of Court

(564)

C: Paul M. Monzione, ESQ; Winslow Kirk Abbott, Jr., ESQ; Rebecca H. Gallup, ESQ; David R Schmahmann, ESQ; Robyn S Maguire, ESQ; Amato A DeLuca, ESQ; Noel B Dumas, ESQ

THE STATE OF NEW HAMPSHIRE

HILLSBOROUGH, SS.
SOUTHERN DISTRICT

SUPERIOR COURT
No. 2013-CV-00600

Kelly Ann Murray and Richard Murray

v.

Kathleen Hogan, M.D.; New Hampshire Orthopaedic Center; Southern New Hampshire Medical Center; Southern New Hampshire Health System, Inc.; Keith Somen; DePuy Orthopaedics, Inc.; Johnson & Johnson

ORDER ON DEPUY ORTHOPAEDICS, INC. AND JOHNSON & JOHNSON'S MOTION FOR SUMMARY JUDGMENT

The plaintiffs, Kelly Ann Murray and Richard Murray, filed this eight-count complaint against the above-captioned defendants, seeking damages under a variety of theories. Relevant here, the plaintiffs brought negligence, products liability, and loss of consortium claims against DePuy Orthopaedics, Inc. ("DePuy") and Johnson & Johnson (collectively the "DePuy defendants"). Dr. Hogan has also filed a contribution cross-claim against the DePuy defendants. Currently pending before the Court is the DePuy defendants' motion for summary judgment, to which the plaintiffs object. In addition, Dr. Hogan and New Hampshire Orthopaedic Center partially object. For the reasons set forth below, the Court finds and rules as follows.

Background

For the purposes of this motion only, the Court views the following relevant evidence from the record in the light most favorable to the non-moving parties. In January of 2010, Mrs. Murray underwent a total knee replacement surgery at Southern New Hampshire Medical Center. During the surgery, Dr. Hogan implanted an artificial rotating platform P.F.C. Sigma Knee ("RP Knee") in Mrs. Murray's left knee. Keith

Somen, a representative from DePuy, was in the operating room and assisted in preparing the RP Knee for insertion. The RP Knee at issue is manufactured by DePuy, which is a subsidiary of Johnson & Johnson.

Following the surgery, Mrs. Murray experienced significant pain and stiffness. She then underwent a second corrective surgery on October 21, 2011 at Lahey Clinic. The doctor performing that surgery—Dr. Lawrence Specht—noted that on the existing RP Knee, the "5 degree of valgus alignment bolt was set for the contralateral side, contributing to the varus deformity." (Pls.' Obj. Summ. J. at 2–3.) Put differently, the RP Knee implanted during the first surgery had settings for a right knee instead of a left knee. Despite the corrective surgery, Mrs. Murray continued to experience extreme pain and stiffness. In July of 2013, her left leg was surgically amputated above-the-knee.

Consequently, the plaintiffs filed suit in October of 2013, alleging several claims against the DePuy defendants, including: (1) negligence/medical malpractice; (2) strict liability/manufacturing defect; (3) strict liability/design defect; (4) strict liability/failure to warn; (5) breach of express warranty; (6) breach of implied warranty; and (7) loss of consortium. The DePuy defendants now move for summary judgment, asserting that all of the plaintiffs' claims against them are preempted by federal law. The plaintiffs object, arguing that federal preemption does not apply because: (1) the RP knee in question did not meet federal regulations, and thus they are entitled to discovery on that issue; and (2) the DePuy defendants are vicariously liable for the conduct of Mr. Somen.[1]

[1] Dr. Hogan and New Hampshire Orthopaedic Center also object to the entry of summary judgment on any claim of vicarious liability.

Standard of Review

"Summary judgment shall be rendered forthwith if the pleadings [and] affidavits filed [ ] show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." RSA 491:8-a, III (2010). The Court decides "summary judgment rulings by considering the affidavits and other evidence in the light most favorable to the non-moving party." Mbahaba v. Morgan, 163 N.H. 561, 568 (2012) (citation omitted). "If this review does not reveal any genuine issues of material fact, i.e., facts that would affect the outcome of the litigation, and if the moving party is entitled to judgment as a matter of law" then summary judgment is proper. Id.

Analysis

I. Federal Preemption

"The federal preemption doctrine is based upon the Supremacy Clause in Article VI of the United States Constitution." N.H. Att'y Gen. v. Bass Victory Comm., 166 N.H. ___, ___ (Oct. 15, 2014) (slip op. at 4) (citations omitted). "Article VI provides that federal law 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." Id. (citation omitted). "Under this principle, Congress has the power to preempt state law." Id. (citation omitted). "Consideration of issues arising under the Supremacy Clause starts with the assumption that the historic police powers of the States are not to be superseded by Federal Act unless that is the clear and manifest purpose of Congress." Id. (citation omitted). "Accordingly, the purpose of Congress is the ultimate touchstone of pre-emption analysis." Id. (citation omitted). "To that end, courts look to the language of the pre-emption statute and the statutory framework

surrounding it as well as the structure and purpose of the statute as a whole, as revealed not only in the text, but through the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect interested parties." Id. (citation omitted).

The DePuy defendants argue that the plaintiffs' claims are preempted by the Federal Food, Drug, and Cosmetic Act ("FDCA" or the "Act"), codified at 21 U.S.C. § 360k, and enforced by the Federal Food and Drug Administration ("FDA"). The FDCA "has long required FDA approval for the introduction of new drugs into the market." Riegel v. Medtronic, Inc., 552 U.S. 312, 315 (2008). "Until the statutory enactment at issue here, however, the introduction of new medical devices was left largely for the States to supervise as they saw fit." Id. (citation omitted). "The regulatory landscape changed in the 1960's and 1970's, as complex devices proliferated and some failed." Id. In the view of many, the common-law tort system failed "to manage the risks associated with dangerous devices." Id. (citation omitted). As a result, "[s]everal States adopted regulatory measures . . . requiring premarket approval of medical devices." Id. (citation omitted). Eventually, however, "Congress stepped in with passage of the Medical Device Amendments of 1976 [ ] which swept back some state obligations and imposed a regime of detailed federal oversight." Id. at 316.

The regulatory regime created by the Act "established various levels of oversight for medical devices, depending on the risks they present." Id. "Class I, which includes such devices as elastic bandages and examination gloves, is subject to the lowest level of oversight." Id. "Class II, which includes such devices as powered wheelchairs and surgical drapes, is subject in addition to 'special controls' such as performance

standards and postmarket surveillance measures." Id. "The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators." Id. "In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.'" Id. (citing 21 U.S.C § 360c(a)(1)(C)(ii)).

Here, it is undisputed that the RP Knee is considered a Class III medical device. Unless a device existed before the enactment of the Act (or is substantially similar to one that pre-dates the Act),[2] any Class III medical device must go through an extensive premarket approval ("PMA") process in order to be marketed to the public. The PMA process "provide[s] reasonable assurance of [the medical device's] safety and effectiveness," 21 U.S.C. § 360c(a)(1)(C)(ii)(II), and is "rigorous," Riegel, 552 U.S. at 317 (quotation omitted). In order to obtain PMA, "[a] manufacturer must submit what is typically a multivolume application." Id. (citation omitted). "It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant;

[2] In Medtronic, Inc. v. Lohr, 518 U.S. 470, 477–78 (1996), Justice Stevens noted that: "Not all, nor even most, Class III devices on the market today have received premarket approval because of two important exceptions to the PMA requirement. First, Congress realized that existing medical devices could not be withdrawn from the market while the FDA completed its PMA analysis for those devices. The statute therefore includes a 'grandfathering' provision which allows pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA. Second, to prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market, the Act also permits devices that are 'substantially equivalent' to pre-existing devices to avoid the PMA process."

a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling." Id. at 317–18 (internal quotations and citations omitted). "Before deciding whether to approve the application, the agency may refer it to a panel of outside experts, and may request additional data from the manufacturer." Id. at 318 (citations omitted). Ultimately, "[t]he 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.'" Id. (citations omitted).

"Once a device has received PMA, the [Act] 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." Id. at 319. "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 application." Id. Moreover, "[a]fter [receiving PMA], the devices are subject to [ongoing] reporting requirements." Id. (citation omitted). "These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of, and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred." Id. (citations omitted). "The

FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that a device is unsafe or ineffective under the conditions in its labeling." Id. at 319–20.

The RP Knee in this case came to the market through this "rigorous" PMA process. According to the affidavit of DePuy employee Kathy Harris, the initial version of the RP Knee was intended for use in the "New Jersey Total Knee System." (Harris Aff. Supp. Mot. Summ. J. ¶ 18.) In 1983, DePuy first submitted a PMA for that use. On July 11, 1984, the FDA's independent advisory committee recommended approval of the application. (Id. ¶ 27.) In 1985, the FDA approved the RP Knee for use with the Total Knee System. Throughout the years, DePuy sought and received several approvals from the FDA to modify and improve the RP Knee. Relevant here, in 2000, DePuy started the PMA process to secure FDA approval of the RP Knee for use in P.F.C. Sigma Knee System. DePuy later supplemented that application with minor modifications ("Supplement 74"). (Id. ¶ 31.) On June 22, 2000, the FDA approved the Supplement 74 PMA application. In 2003, DePuy again sought approval for additional minor modifications to the RP Knee ("Supplement 84"). The FDA approved the Supplement 84 PMA application on June 10, 2003. (Id. ¶ 34.) Ms. Harris avers, and the plaintiffs do not contest by affidavit or otherwise, that the "RP Knee components implanted in Mrs. Murray were manufactured and sold by DePuy in conformance with the design and manufacturing specifications in DePuy's PMA Supplements 74 and 84 and with the design and manufacturing specifications included in the FDA's [PMA] of DePuy's submissions . . . ." (Id. ¶ 37.) In other words, it is undisputed that the RP Knee at issue in this case was subject to and approved through the PMA process.

Given the extensive review and design process for PMA approval of Class III devices, DePuy argues that the Act preempts any state-law claims relating to the design and functionality of the RP Knee. In making this argument, it relies on Section 360k(a) of the Act, which states:

> Except as provided in subsection (b)[3] 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) (emphases added).

In Riegel, the Supreme Court was faced with a similar argument. In that case, the plaintiffs brought an action against the manufacturer of a heart catheter after the catheter ruptured during surgery. The complaint alleged that the catheter "was designed, labeled, and manufactured in a manner that violated New York common law." Riegel, 552 U.S. at 321. The Riegel Court held that Section 360k(a) established a two-pronged test for determining if state law claims are preempted. First, a court must determine whether the Federal Government has imposed "requirements" on the device. Id. If so, the next inquiry is whether the state law claims impose requirements "different from, or in addition to" the federal ones and whether the requirements relate to "safety and effectiveness" or to "any other matter included in a requirement applicable to the device." Id. at 321–22 (citing 21 U.S.C. § 360k(a)).

[3] "The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from pre-emption." Riegel, 552 U.S. at 316. None of the parties have argued that that subsection applies here.

In Riegel, the Court answered the first question in the affirmative by finding that the PMA process imposes "requirements" in the case of Class III devices. Id. at 322. In considering the second prong of the analysis, the Court held that common law causes of action for negligence and strict liability also impose "requirements" and are therefore preempted by the Act. Id. at 323–25. The Court reasoned that [a] "State tort law that requires a manufacturer's catheters to be safer [ ] than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect." Id. at 325. Thus, Riegel stands for the proposition that Section 360k(a) bars state law claims when: (1) the device at issue had been subject to the PMA process; and (2) the claims relate to the device's safety and effectiveness and are different from or in addition to the federal requirements. Id.

Given the Riegel decision, it is clear to the Court that the plaintiffs' direct liability claims against the DePuy defendants are preempted by Section 360k(a). In order to succeed on their claims, the plaintiffs would be required to show that the RP Knee "was unsafe or ineffective despite the PMA process, thereby interfering with the requirements already established by the [Act], which has preempted safety and effectiveness determinations for a device." Williams v. Cyberonics, Inc., 388 Fed. App'x. 169, 171 (3d Cir. 2010). Put differently, "[a]llowing these claims to go forward would result in the imposition of different or additional requirements related to the safety or effectiveness of a device" and thus run afoul of the preemption provision in Section 360k(a). Gross, 858 F. Supp. 2d at 488. Accordingly, the DePuy defendants' motion for summary judgment on any claims premised on direct liability is GRANTED.

Nonetheless, the Riegel Court, in interpreting the Act, carved out a narrow exception to Section 360k(a) preemption. The Court held that "[Section] 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." 552 U.S. at 330. As might be expected, in opposing summary judgment, the plaintiffs assert that they have brought one of these so-called "parallel claims" under the narrow exception. Specifically, the plaintiffs state in their objection that "[a]t some point during the manufacture, design, setup, preparation, or insertion of Mrs. Murray's prosthesis, said prosthesis was erroneously set for a right knee yet it was inserted and intended for her left leg. Depending on when and how this took place, it was likely a deviation from FDA regulations." (Pls.' Obj. Mot. Summ. J. at 7.)

Had this allegation been in the complaint, the plaintiffs *may* have sufficiently raised a parallel claim. However, the complaint makes no explicit mention of a parallel claim, nor does it outline sufficient facts to support such a claim. See Trinity EMS v. Coombs, 166 N.H. 523, 525 (2014) (in determining whether a claim is actually pled, the Court "must rigorously scrutinize the complaint to determine whether, on its face, it asserts a cause of action."). There are no allegations that the DePuy defendants violated FDA regulations. The plaintiffs did not (and do not) cite any specific federal regulations that the DePuy defendants may have violated. Instead, the complaint, on its face, only alleges the types of tortious behavior that is preempted by the Riegel Court's interpretation of Section 360k(a). Nonetheless, the plaintiffs are permitted to file an amended complaint should they wish to bring a parallel claim. See Bausch v. Stryker

Corp., 630 F.3d 546 (7th Cir. 2010) (district court erred by not allowing plaintiff leave to amend complaint to better articulate and/or allege parallel claim).

II. Vicarious Liability

Next, the plaintiffs, Dr. Hogan, and New Hampshire Orthopaedic Center oppose summary judgment on the issue of vicarious liability. The plaintiffs maintain that the DePuy defendants are vicariously liable for the acts of their "employee or agent who was in the operating room on January 20, 2010 and failed to see that [the RP Knee] was properly set for Mrs. Murray's left knee." (Pls.' Obj. Mot. Summ. J. at 4.) In moving for summary judgment on this issue, the DePuy defendants do not claim that Riegel preemption would apply to a claim of vicarious liability under the circumstances of this case.[4] Rather, they assert that the plaintiffs failed to properly articulate such a claim in the complaint.[5] The Court disagrees. Although not pled as a separate paragraph or count, the vicarious liability claim can be fairly construed from the allegations in the complaint. For instance, the complaint states that "[a]t all relevant times, Defendant Keith Somen was an employee, agent, and/or servant of Defendant DePuy Orthopaedics, Inc." (Compl. ¶ 9.) It also states that "Keith Somen, a DePuy Orthopaedics, Inc. and/or Johnson & Johnson representative, was in the operating room during the surgery for the purpose of, among other things, providing technical guidance." (Id. ¶ 11.) Taking these allegations, the other facts from the complaint, "and

[4] Nor could they. See Adkins v. Cytyc Corp., No. 4:07CV00053, 2008 WL 2680474 (W.D. Va. July 3, 2008) (Riegel does not preempt claim of vicarious liability); Reed v. Medtronic, Inc., No. B245625, 2014 WL 1930221, at *4–5 (Cal. App. May 15, 2014) (same); Medtronic, Inc. v. Malander, 996 N.E.2d 412, 419 (Ind. Ct. App. 2013) (vicarious liability claim not preempted because "[s]uch a claim does not challenge the design, manufacture, and labeling of the [PMA] device so as to implicate Riegel preemption, but rather challenges negligence by a corporate agent acting as a de facto physician's assistant during a surgical procedure") (citation omitted).

[5] Although the DePuy defendants argue this point in their motion for summary judgment, their argument is better analyzed in the context of a motion to dismiss. The Court will therefore treat it as such.

all reasonable inferences drawn therefrom," the Court finds that the plaintiffs have sufficiently stated a claim for vicarious liability.[6] Williams v. O'Brien, 140 N.H. 595, 597 (1995) (citation omitted). Because the DePuy defendants offer no other argument in favor of summary judgment on this issue, their motion for summary judgment on any vicarious liability claims for the acts of Mr. Somen is DENIED.

So ordered.

Date: February 2, 2015

Hon. Jacalyn A. Colburn,
Presiding Justice

[6] Although not required, in the event the plaintiffs amend their complaint to allege a parallel claim, the Court suggests they restate their vicarious liability claim in more explicit terms.