UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

LESLIE CACCIA and ALLISON CACCIA,	)	
Plaintiffs	)	
vs.	)	CAUSE NO. 3:13-CV-73 RLM
BIOMET, INC., et al.,	)	
Defendants	)	

OPINION and ORDER

This cause is before me on the motion of Biomet, Inc. and Biomet Orthopedics, LLC (collectively, Biomet) to dismiss the plaintiffs' complaint in its entirety under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim.[1] Biomet also asks me to take judicial notice of documents submitted in support of its motion. In response, Leslie and Allison Caccia ask me to convert the motion to dismiss to one for summary judgment based on Biomet's reliance on the exhibits it attached to the motion to dismiss, and then defer ruling on the summary judgment motion until they have had a reasonable opportunity to conduct necessary discovery. Oral argument was held on June 17, and I took the matter under advisement. Having reviewed the parties' submissions and arguments, I deny the motion to dismiss and the parties' related requests.

[1] The Caccias' complaint contains claims of negligence, strict products liability (manufacturing defect, design defect, inadequate warning), breach of express warranty, breach of implied warranty, negligent misrepresentation, violation of consumer protection laws, and loss of consortium.

Federal Rule of Civil Procedure 12(b)(6) allows a defendant to seek dismissal of a complaint, or a portion of a complaint, that states no claim upon which relief can be granted. A court deciding a Rule 12(b)(6) motion must accept "the well-pleaded facts in the complaint as true, but legal conclusions and conclusory allegations merely reciting the elements of the claim are not entitled to this presumption of truth." McCauley v. City of Chicago, 671 F.3d 611, 616 (7th Cir. 2011). I must draw all reasonable inferences in favor of the plaintiffs without engaging in fact-finding. Reger Dev., LLC v. National City Bank, 592 F.3d 759, 763 (7th Cir. 2010). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.' A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (*quoting* Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007)). Under the pleading standard of Federal Rule of Civil Procedure 8(a), a complaint needn't contain "detailed factual allegations," but the complaint's allegations "must be enough to raise a right to relief above the speculative level" and give the defendant fair notice of the claims being asserted and the grounds upon which they rest. Bell Atl. Corp. v. Twombly, 550 U.S. at 555.

Resurfacing Surgeries

Biomet asserts that the Caccias' state law claims relating to Mr. Caccia's hip surgeries should be dismissed as preempted by the Medical Device Amendments, 21 U.S.C. § 360c *et seq.*, to the Food, Drug and Cosmetic Act, 21 U.S.C. § 301 *et seq.* Biomet hypothesizes, and the plaintiffs seem to agree, that (i) Mr. Caccia's hip resurfacing surgeries (right hip, 2007; left hip, 2008) involved use of the Biomet ReCap Femoral Resurfacing System ("ReCap System"), which, at the time of Mr. Caccia's surgeries, was approved by the FDA under the Investigational Device Exemption process to be part of a clinical investigation to assess the safety and effectiveness of the system, and (ii) Mr. Caccia wasn't part of the IDE study of the ReCap System. Based on that understanding, Biomet maintains the preemption provision of the MDA and the IDE regulations bar the Caccias' claims.

Manufacturers who want to investigate the safety and effectiveness of a new medical device and generate the data necessary to obtain premarket approval for the device must apply to the FDA for permission to undertake a clinical investigation pursuant to the requirements and regulations governing IDEs. 21 U.S.C. § 360j(g)(2). "The IDE process allows a manufacturer with an experimental device to obtain FDA approval for the device with a less rigorous review process than usual. The purpose of the exemption is to encourage experimentation that would lead to new developments. *See* 21 U.S.C. § 360j(g). In order to obtain an IDE, a manufacturer must provide the FDA with information about, among other things, the device, its manufacture, and the experimental plan for its use."

Chambers v. Osteonics Corp., 109 F.3d 1243, 1245 (7th Cir. 1997). IDE devices remain under the FDA's supervision during the clinical trial process.

Biomet says the FDA evaluated and approved its ReCap System as part of the "rigorous requirements" of the IDE process, so the numerous regulations relating to IDE devices govern the ReCap System. *See* 21 C.F.R. §§ 812.1–812.150. Thus, Biomet says, the Caccias' state law claims relating to the system are preempted by the express preemption provision of the MDA, which states 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 U.S.C. § 360k(a).

Riegel v. Medtronic, Inc., 552 U.S. 312 (2008), established the procedure for deciding whether state law claims are preempted: the court must determine if the federal government has established requirements applicable to the device at issue and, if so, whether the common-law claims are based on state law requirements that relate to the safety and effectiveness of the device and are different from or in addition to the federal requirements. 552 U.S. at 321-322. The Riegel Court held that premarket approval "is specific to individual devices" and so "imposes 'requirements' under the MDA," 552 U.S. at 322-323, and that reference in the statute to a "state's requirements" includes its common law duties. 552 U.S. at

324. Biomet maintains the preemption provision deemed applicable to PMA devices in Riegel applies equally to devices approved and used pursuant to an IDE: "[P]roduct liability claims challenging the safety and efficacy of devices received in investigational studies are in conflict with FDA requirements and preempted since 'the standards implicit in the state tort actions would be different from or in addition to those requirements of both the FDCA and the IDE regulations.'" Memo., at 8 (*quoting* Gile v. Optical Radiation Corp., 22 F.3d 540, 545 (3d Cir. 1994)).

Biomet contends that Mr. Caccia's participation in the clinical study of the ReCap System wasn't required for preemption to bar his claims. Biomet says the appropriate analysis should focus on "the FDA approval process and requirements and not on the actions or the mindset of the physician." Reply, at 6. Biomet relies on Dawson v. Howmedica, Inc., 886 F. Supp. 1402 (E.D. Tenn. 1995), in which Mr. Dawson, like Mr. Caccia, received an implant while an IDE was in place but wasn't a participant in the investigational study of the device. Biomet cites to the Dawson court's conclusion that the doctor's "use of the device is not the focus. Rather, the focus must be upon the extensive federal requirements to which the [IDE device] had been subjected and the fact that plaintiffs' claims would establish state requirements different from or in addition to those extensive federal requirements." 886 F. Supp. at 1408 n.8.

Biomet also cites to Berish v. Richards Medical Co., 928 F. Supp. 185 (N.D.N.Y. 1996), involving a similar fact scenario in which Mr. Berish, like Mr.

Caccia, wasn't a participant in the clinical trial of the implanted IDE device. The Berish court, relying on Dawson v. Howmedica, agreed with the Dawson court's conclusion that the preemption analysis shouldn't focus on the use of the device, but rather on the federal requirements applied to the device in the IDE process. 928 F. Supp. at 191 (*quoting* Dawson, 886 F. Supp. at 1048 n.8). The Berish court found "no support" for plaintiff's contention that "if the doctor who performed the procedure was not part of the IDE test study, the device is not subject to an IDE." 928 F. Supp. at 191.

I can't agree with Biomet's discounting that Mr. Caccia wasn't part of the clinical study of the ReCap System, even when considering Dawson and Berish — cases that aren't binding and which I don't find persuasive.[2] The applicable regulations provide that the IDE process "permits a device that otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device." 21 C.F.R. § 812.1(a). The regulations contain "procedures for the conduct of

[2] The other cases Biomet relies on to support its claim that preemption should bar the Caccias' state law claims are distinguishable – those cases involved plaintiffs who were participants in the IDE clinical studies of the devices at issue. *See, e.g.,* Martin v. Telectronics Pacing Sys., Inc., 105 F.3d 1090 (6th Cir. 1997) (plaintiff was part of investigational study); Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir. 1994) (same); Slater v. Optical Radiation Corp., 961 F.2d 1330 (7th Cir. 1992) (same); Blinn v. Smith & Nephew Richards, Inc., 55 F. Supp. 2d 1353 (N.D. Fla. 1999) (plaintiff was part of clinical trial and signed consent form acknowledging same); Chmielewski v. Stryker Sales Corp., 966 F. Supp. 839, 841 (D. Minn. 1997) ("In accordance with FDA requirements for IDEs, plaintiff signed an informed consent form prior to surgery."); Hunsaker v. Surgidev, 818 F. Supp. 744 (M.D. Pa. 1992) (plaintiff was participant in clinical study); Burgos v. Satiety, Inc., No. 10-CV-2680, 2010 WL 4907764 (E.D.N.Y. Nov. 30, 2010) (plaintiff part of IDE clinical trial); Touchet v. Ace Medical Co., No. Civ. A 96-3534, 1998 WL 531887 (E.D. La. Aug. 24, 1998) (same).

clinical investigations of [IDE] devices," 21 C.F.R. § 812.1(a), applicable "to all clinical investigations" of those devices. 21 C.F.R. § 812.2(a). The regulations further define an "investigational device" as a device "that is the object of an investigation," 21 C.F.R. § 812.3(g); an "investigation" as "a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device," 21 C.F.R. § 812.3(h); and a "subject" as "a human who participates in an investigation, either as an individual on whom or on whose specimen an investigation device is used or as a control." 21 C.F.R. § 812.3(p). The regulations contain specifics for conducting and monitoring the clinical trial, maintaining records of the use of the device in the trial, permitting inspections by the FDA of the device and records of the study, and preparing progress and final reports addressing all aspects of the approved investigation. 21 C.F.R. §§ 812.40-812.150. While the IDE regulations exempt an approved device from complying with certain FDA requirements, those exemptions apply to devices approved for use in clinical investigations. *See* 21 C.F.R. § 812.1(a).

The FDA approved Biomet's ReCap System under the IDE process for use in a specific clinical trial to determine the device's safety and effectiveness. 21 U.S.C. § 360j(g); 21 C.F.R. § 812.1 *et seq.* Use of the ReCap System outside the controlled study, *i.e.*, without proper monitoring, record-keeping, and FDA oversight, wouldn't advance the aims of the clinical trial. A clinical study "is not worthwhile if it is not conducted using agreed-upon standards and procedures. The results of an uncontrolled experiment would not be a reliable indicator of the

usefulness and safety of the proposed device, defeating the reason for granting the IDE in the first place." Chambers v. Osteonics Corp., 109 F.3d 1243, 1248 (7th Cir. 1997); *see also* In re Orthopedic Bone Screw Products Liability Litigation, No. MDL 1014, 1999 WL 33740509, at *3 (E.D. Pa. Jan. 11, 1999) (An investigational device "may not be promoted for commercial distribution or test marketed outside the IDE." (*citing* 21 C.F.R. § 812.7(a)); In re Orthopedic Bone Screw Products Liability Litigation, No. MDL 1014, 1996 WL 221784, at *2 (E.D. Pa. Apr. 8, 1996) (approval of an investigational device "does not amount to FDA approval to market the device to the general public").

The PMA process imposes specific requirements applicable to a device for preemption purposes, *see* Riegel v. Medtronic, Inc., 552 U.S. at 322-323 ("[P]emarket approval is specific to individual devices. And it is in no sense an exemption from federal safety review – it *is* federal safety review."), but in the IDE process, the FDA doesn't make any finding that the device provides a reasonable assurance of safety and effectiveness; the IDE process allows an investigation to evaluate and determine the safety and effectiveness of a device and imposes requirements for use of the device in the approved study – requirements that wouldn't apply to devices used outside the study. *See* English v. Mentor Corp., 67 F.3d 477, 480 (3d Cir. 1995) ("The FDA had initially granted an Investigational Device Exemption to Mentor, permitting it to test its prosthesis on human subjects; [plaintiff], however, did not receive a device as part of an IDE test study and thus Mentor cannot rely on IDE regulations in support of its argument that

[plaintiff's] state tort claims are preempted."), vacated on other grounds, 518 U.S. 1030 (1996). The parties have agreed that Mr. Caccia didn't receive the ReCap System as part of the clinical trial of the device; it would be a reasonable inference that the components used in Mr. Caccia's resurfacing surgeries were available to his doctor via the 510(k) notification process. Thus, 21 U.S.C. § 360k(a) wouldn't exempt the Caccias' state law claims. *See* Lohr v. Medtronic, Inc., 518 U.S. 470, 493-494 (1996) (Section 510(k) premarket notification process imposes no "requirements" specific to the device).

I'm not persuaded that a manufacturer that obtains IDE status for a device to be used in a controlled investigational setting is, during the time the study is being conducted, exempt from liability for use of that device outside the clinical trial. Pursuant to the IDE, the manufacturer is charged with use of the device in a controlled setting to gather information and statistics to determine the safety and effectiveness of the device – use outside the study wouldn't advance the purpose of the clinical trial or provide the information necessary for a reliable determination of the safety and effectiveness of the device. Because Mr. Caccia didn't receive the ReCap System as part of the IDE study, Biomet can't rely on the IDE regulations to support its claim that the Caccias' state claims are preempted. *See* McMullen v. Medtronic, Inc., No. 2:03-CV-5, 2004 WL 2538642, at *4 n.3 (S.D. Ind. Sept. 16, 2004) ("But under 21 C.F.R. § 812.2(a), IDE regulations apply only, with certain enumerated exceptions inapplicable to this case, to clinical investigations of devices to determine safety and effectiveness of which Mr.

McMullen was not a participant."). Biomet's request to dismiss the Caccias' state law claims relating to Mr. Caccia's resurfacing surgeries must be denied.

Hip Replacement Surgeries

Biomet also seeks dismissal of the Caccias' state law claims concerning Mr. Caccia's hip replacement arthroplasties – surgeries the parties say involved retention of the M2a-Magnum Acetabular Shell and replacement of the ReCap Femoral Resurfacing Component with a Taperloc femoral stem and an M2a-Magnum modular head – based on preemption because, Biomet says, the FDA "evaluated the ReCap Femoral Resurfacing Component and the M2a-Magnum Acetabular Shell as part of the rigorous requirements of an Investigational Device Exemption to study the ReCap Femoral Resurfacing System." Memo., at 1-2. Biomet notes that the M2a-Magnum PF Cups used in Mr. Caccia's resurfacing procedures weren't removed or replaced during the second surgeries and claims that even though different components (*i.e.*, the Taperloc femoral stem and the M2a-Magnum Modular Head) were substituted into the hip replacement systems in the second surgeries, those new components served the same purpose as those removed. Biomet concludes that because the M2a-Magnum PF Cups that had been "implanted and evaluated for their performance with other components during the IDE remained in [Mr. Caccia] throughout all times relevant to this lawsuit . . . those components should also be covered by preemption." Reply, at 4-5; *see also* Memo., at 10-11.

I can't agree with Biomet's argument that the law affords different preemption status to individual parts of a total system or, as in this case, coupling one component (the M2a-Magnum PF Cup) of an IDE-approved device (the ReCap System) with other components (the Taperloc femoral stem and the M2a-Magnum Modular Head) to create a different system – the M2a-Magnum Hip Replacement System – converts the second system's status to IDE status for preemption purposes. In fact, I addressed that scenario with defense counsel at the hearing on the motion to dismiss:

> THE COURT: So your position is, any component that's within the IDE, there's preemption for use of it, even outside the study and even outside the system?
>
> MR. WINTER: No, Your Honor. It's as a system. . . . So when you combined those two to create the ReCap System that is subject to the IDE, that creates preemption. If you had just taken the resurfacing piece and didn't put in a cup, that would be a 510(k) use not entitled to preemption. But it's when you put the system together . . . when it's a combination of the two different components and that makes up a product that you want to get PMA clearance by an IDE, preemption applies, so you have to use them, the system, together.

Hrg. Tr. [docket # 43], at 5-6.

"To require that a distinction be drawn between the approval process of the individual components of a system and the system itself, would, it seems, add a level of complication to the medical device approval process not anticipated by Congress, the FDA, or medical device manufacturers." Lewkut v. Stryker Corp., 724 F. Supp. 2d 648, 656 (S.D. Tex. 2010). "It makes no sense – indeed, it would

probably be impossible – to pick apart the components of a medical device and apply different preemption analyses to different components." Riley v. Cordis Corp., 625 F. Supp. 2d 769, 780 (D.Minn. 2009); *see also* Gross v. Stryker Corp., 885 F. Supp. 2d 466, 487 (W.D. Penn. 2012) ("[T]he focus remains on the approved device and whether plaintiff's claims challenge the effectiveness of the approved device."). I deny Biomet's request for preemption of the Caccias' claims relating to the M2a-Magnum Hip Replacement System based on the IDE status of one component of that total hip replacement system.

Conclusion

Based on the foregoing, I DENY Biomet's motion to dismiss the entirety of the Caccias' complaint on preemption grounds [docket # 10], DENY Biomet's request to take judicial notice of the exhibits to their motion, and DENY as unnecessary the Caccias' request to convert this motion to one for summary judgment.

SO ORDERED.

ENTERED: August 21, 2013

/s/ Robert L. Miller, Jr.
Judge, United States District Court