UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

CATHERINE GRAVITT and TRAVIS GRAVITT,	)	
	)	
Plaintiffs,	)	17 C 5428
	)	
vs.	)	Judge Gary Feinerman
	)	
MENTOR WORLDWIDE, LLC,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION AND ORDER

Catherine and Travis Gravitt, a married couple, filed this suit in the Circuit Court of Cook County, Illinois, against Mentor Worldwide, the manufacturer of a silicone breast implant called MemoryGel, which the Food and Drug Administration ("FDA") has classified as a Class III medical device. Doc. 1-2. Catherine brings claims under Illinois tort law for Mentor's alleged noncompliance with the FDA's premarket approval process for Class III devices, alleged failure to warn consumers of the risks posed by MemoryGel implants, and allegedly defective design and manufacture of the implants. Travis brings a loss of consortium claim. Mentor removed the suit to federal court, Doc. 1, and now moves under Federal Rule of Civil Procedure 12(b)(6) to dismiss the complaint, Doc. 11. The motion is granted in part and denied in part.

Background

In resolving a Rule 12(b)(6) motion, the court assumes the truth of the operative complaint's well-pleaded factual allegations, though not its legal conclusions. *See Zahn v. N. Am. Power & Gas, LLC*, 815 F.3d 1082, 1087 (7th Cir. 2016). The court must also consider "documents attached to the complaint, documents that are critical to the complaint and referred to in it, and information that is subject to proper judicial notice," along with additional facts set

forth in Plaintiffs' brief opposing dismissal, so long as those additional facts "are consistent with the pleadings." *Phillips v. Prudential Ins. Co. of Am.*, 714 F.3d 1017, 1019-20 (7th Cir. 2013). The facts are set forth as favorably to Plaintiffs as those materials allow. *See Pierce v. Zoetis, Inc.*, 818 F.3d 274, 277 (7th Cir. 2016). In setting forth those facts at the pleading stage, the court does not vouch for their accuracy. *See Jay E. Hayden Found. v. First Neighbor Bank, N.A.*, 610 F.3d 382, 384 (7th Cir. 2010).

A. MemoryGel

Mentor manufactures a product called MemoryGel, a breast implant made of silicone gel. Doc. 1-2 at ¶ 6. The FDA has classified silicone breast implants as Class III medical devices—a classification reserved for devices that pose an especially significant risk to patients. *Id*. at ¶¶ 15-16. Under 21 U.S.C. § 360e, a Class III device manufacturer must obtain premarket approval ("PMA") from the FDA before marketing the device to the public. *Id*. at ¶ 16. As part of the PMA process, the manufacturer must provide the agency with a description of the manufacturing process and a summary of studies addressing the device's risks and benefits. *Id*. at ¶¶ 17(b), (d); *see* 21 U.S.C. § 360e. The manufacturer must also provide the agency with "[a]ny other data or information relevant to an evaluation of the safety and effectiveness of the device known or that should be reasonably be known to the manufacturer from any source." Doc. 1-2 at ¶ 17(g); *see* 21 U.S.C. § 360e.

In a letter dated November 17, 2006 (the "November 2006 letter"), the FDA provided Mentor with PMA for the use of MemoryGel as a breast augmentation device. *Id*. at ¶ 20; Doc. 12-1. In connection with that approval, and pursuant to its authority under 21 C.F.R. §§ 814.80 and 814.82, the FDA required Mentor to conduct six-post approval studies designed to address issues not raised during the PMA process. Doc. 1-2 at ¶ 21; Doc. 12-1 at 3-5. Specifically, the

FDA required Mentor to conduct: (1) a core post-approval study to assess the long-term clinical performance of breast implants among women who had participated in the studies supporting the company's PMA application; (2) a large post-approval study to assess long-term outcomes and identify rare adverse events among a new sample of 40,000 patients who had not participated in the earlier studies; (3) a device failure study to describe the modes and causes of failure of MemoryGel implants; (4) a focus group study to improve the form and content of patient labeling; (5) an annual physician-informed decision survey to monitor how patient labeling is distributed to women considering silicone gel breast implants; and (6) an adjunct survey to provide performance and safety information about silicone gel implants from 1992 to 2006, when the agency barred new patients from being treated with such implants. Doc. 1-2 at ¶ 21; Doc. 12-1 at 3-5. Pertinent here, the November 2006 letter required that Mentor "continue [the] Core Study until all patients have completed their 10-year evaluation" and report that study's results for ten years, and include 41,900 Mentor silicone gel patients in the large post-approval study. Doc. 12-1 at 3.

Mentor conducted the required follow-up studies, albeit with some omissions and other lacunae. As for participants in the core study who had MemoryGel implants for at least nine years, Mentor's follow-up rate did not exceed 59 percent. Doc. 1-2 at ¶ (30)(a)(2). Mentor reported study results for only six years rather than the required ten. *Id*. at ¶ 30(a)(3). Mentor reported the reasons for re-operation for only 36 percent of those members of the primary augmentation cohort who had undergone a subsequent operation. *Id*. at ¶ 30(a)(4). For the revision augmentation cohort, Mentor reported only the most common reason for re-operation. *Id*. at ¶ 30(a)(5). As for the primary construction cohort, Mentor provided information about the reasons for re-operation for only 53 percent of those participants within the cohort who required

re-operation, and also "downplayed" reasons for re-operation within the revision reconstruction cohort. *Id*. at ¶¶ 30(a)(6)-(7). Similarly, as to participants in the adjunct study—also divided into cohorts—Mentor reported data on only 37 percent of the reconstruction cohort, 50 percent of the revision reconstruction cohort, and 33 percent of the revision augmentation cohort. *Id*. at ¶ 30(f)(2).

Mentor's other post-PMA studies had similar deficiencies. For the large post-approval study, Mentor recruited 41,451 patients, approximately 500 fewer than the November 2006 letter required. *Id*. at ¶ 30(b)(2); Doc. 12-1 at 3. After three years, Mentor's follow-up rate was 21 percent; after seven years, the rate had declined to approximately 20 percent; and after ten years, Mentor reported no follow-up rate. Doc. 1-2 at ¶¶ 30(b)(2)-(3). Mentor's summary report on the device failure study also had limitations—it did not provide a sample size, results, findings, safety data, recommendations for follow-up studies, or proposed changes to labeling. *Id*. at ¶ 30(c)(2). Likewise, in its summary of findings for the informed decision post-approval study, Mentor did not provide the study's sample size and disclosed information for only one year. *Id*. at ¶ 30(e)(2). Mentor's focus group study involved only 35 women. *Id*. at ¶ 30(d)(5). Overall, halfway through the ten-year post-PMA study period, more than 50 percent of the 80,000 initial participants were dropped or eliminated; of the participants who remained, significant numbers reported systemic ailments attributable to MemoryGel rupture. *Id*. at ¶ 31.

Apart from the six required post-PMA studies, federal regulations required Mentor to report certain other information to the FDA, including information suggesting that MemoryGel may have caused or contributed to a patient's death or serious injury and any complaints about MemoryGel's performance or adverse health consequences, along with procedures for reviewing complaints and ensuring compliance with FDA regulations. *Id*. at ¶ 24 (citing, among other

regulations, 21 C.F.R. §§ 803.50, 814, 820.20, 820.198, 820.100). Notwithstanding those obligations, "[u]pon information and belief, a Mentor chemist of 15 years reported to the FDA that Mentor's implants are more likely to break than the company had reported," and Mentor "knew of these risks" but nevertheless "covered up the information by terminating studies, sponsoring only self-serving research, and misrepresenting the risks presented by its products." *Id*. at ¶¶ 32-33. In addition, Mentor failed "to revise its product labeling after becoming aware of otherwise undisclosed dangers in its MemoryGel products." *Id*. at ¶ 27. In particular, Mentor knew that the risk that MemoryGel implants would "bleed"— releasing toxic chemicals into patients' bodies—was substantially higher than publicly reported. *Id*. at ¶¶ 37-41.

Mentor's process for manufacturing MemoryGel was also deficient, leading the FDA to cite the company for compliance failures six times from May 2000 to December 2007. *Id*. at ¶¶ 35-36. Mentor manufactured MemoryGel with nonconforming products and failed to conduct appropriate risk analyses and quality-control tests. *Ibid*.

B. Catherine's Experience With MemoryGel

After giving birth in 2008, Catherine experienced a significant reduction in breast volume, and her physician recommended breast augmentation surgery. *Id*. at ¶ 44. Catherine initially underwent saline breast implantation surgery. *Id*. at ¶ 45. After a series of complications, she underwent revision, or curative, implantation surgery, during which MemoryGel implants were implanted. *Id*. at ¶ 46. Since that time, Catherine has experienced symptoms causing her "extreme suffering," including severe skin rashes and acne, blackouts and periods of disorientation, memory loss, muscle soreness, extreme fatigue, abnormal thyroid levels, drowsiness, and anxiety and depression. *Id*. at ¶ 49. Those symptoms caused Catherine

to leave school and forgo a career. *Ibid*. In 2011 and 2013, Catherine gave birth to two children who, unlike her first child, were born with significant birth defects. *Id*. at ¶¶ 53-54.

By 2016, Catherine's condition had substantially worsened. *Id*. at ¶ 55. She could not stay awake, felt weak and fatigued, and continued to suffer memory lapses, disorientation, flu-like symptoms, and skin rashes. *Ibid*. An ultrasound examination revealed a lump in Catherine's breast that appeared to be composed of leaked silicone, and a subsequent MRI confirmed that at least one implant had ruptured. *Id*. at ¶ 58. Earlier medical tests also showed elevated levels of bromine and other toxins in her blood stream. *Id*. at ¶ 51.

Ultimately, in Fall 2016, Catherine underwent a third round of surgery—this time, to remove the MemoryGel implants. *Id*. at ¶ 60. Surgeons also removed some of Catherine's lymph nodes, which were contaminated with silicone. *Ibid*. Since that time, Catherine's breast region and armpits have been very swollen and painful, and later tests suggested that additional lymph nodes had been contaminated. *Id*. at 61. As a result of Catherine's health problems, Travis has taken full responsibility for supporting and managing the household. *Id*. at ¶ 119.

Plaintiffs allege that, had Catherine been advised of the risks posed by MemoryGel—risks that Mentor actively concealed—she would not have consented to breast augmentation surgery using MemoryGel implants. *Id*. at ¶ 48. Likewise, Plaintiffs allege that, had Catherine been aware of those risks, she would have recognized more quickly the link between her symptoms and a possible silicone leak. *Id*. at ¶ 49. Plaintiffs claim that Catherine's injuries—and Travis's loss of consortium—are attributable to Mentor's tortious conduct. *Id*. at ¶ 63.

Discussion

Plaintiffs' claims arise under Illinois tort law. Doc. 1-2 at ¶¶ 66-122. Counts I (negligence) and III (strict product liability) allege that Mentor breached its duty to Catherine in

manufacturing and marketing Memory Gel—in particular, by failing to warn Catherine and her physicians, either directly or through reports to the FDA, of the true risks associated with MemoryGel implants. *Id*. at ¶¶ 66-80; 99-117. Count II (strict product liability under a failure to warn theory) similarly alleges that Mentor breached its duty to Catherine by failing to warn her and her physicians that MemoryGel was more "vulnerable to degradation, deterioration, ruptures, and leakage" than the company had reported, and thus that it was more likely to cause injury than publicly known. *Id*. at ¶¶ 81-98. Count IV alleges that Mentor's actions resulted in Travis's loss of consortium. *Id*. at ¶¶ 118-22.

Mentor contends that Catherine's claims should be dismissed as expressly preempted under 21 U.S.C. § 360k(a)(1) or as impliedly preempted under *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). Mentor adds that Travis's loss-of-consortium claim fails because it is derivative of Catherine's legally insufficient claims.

Plaintiffs submit that Rule 12(c), not Rule 12(b)(6), is the proper vehicle for moving to dismiss state law claims on federal preemption grounds. Doc. 18 at 6-7; *see Brownmark Films, LLC v. Comedy Partners*, 682 F.3d 687, 690 n.1 (7th Cir. 2012) ("Though district courts have granted Rule 12(b)(6) motions on the basis of affirmative defenses and this court has affirmed those dismissals, we have repeatedly cautioned that the proper heading for such motions is Rule 12(c), since an affirmative defense is external to the complaint."); *Bausch v. Stryker Corp.*, 630 F.3d 546, 561 (7th Cir. 2010) ("Preemption is an affirmative defense, and pleadings need not anticipate or attempt to circumvent affirmative defenses.") (citations omitted). Little rides, however, on the distinction Plaintiffs draw. As an initial matter, a Rule 12(c) motion for judgment on the pleadings "is governed by the same standards as a motion to dismiss for failure to state a claim under Rule 12(b)(6)." *Lodholtz v. York Risk Servs. Grp., Inc.*, 778 F.3d 635, 639

(7th Cir. 2015). Thus, in either case, "a complaint must 'state a claim to relief that is plausible on its face.'" *Ibid*. (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

Moreover, the Seventh Circuit has held—in the context of Rule 12(b)(6) motions based on a statute of limitations affirmative defense—that "dismissal is proper without further pleading" provided that "it is plain from the complaint that the defense is indeed a bar to the suit." *Jay E. Hayden Found.*, 610 F.3d at 383; *see also Collins v. Vill. of Palatine*, 875 F.3d 839, 842 (7th Cir. 2017) ("Although the statute of limitations is an affirmative defense, dismissal under Rule 12(b)(6) … is appropriate if the complaint contains everything necessary to establish that the claim is untimely."); *Chi. Bldg. Design, P.C. v. Mongolian House, Inc.*, 770 F.3d 610, 613-14 (7th Cir. 2014) ("[A] motion to dismiss based on failure to comply with the statute of limitations should be granted only where "the allegations of the complaint itself set forth everything necessary to satisfy the affirmative defense.") (citation and internal quotation marks omitted); *Indep. Tr. Corp. v. Stewart Info. Servs. Corp.*, 665 F.3d 930, 935 (7th Cir. 2012) ("[W]hen a plaintiff's complaint nonetheless sets out all of the elements of an affirmative defense, dismissal under Rule 12(b)(6) is appropriate."); *Balmes v. Ill. Bell Tel. Co.*, 2016 WL 1019764, at *3 (N.D. Ill. Mar. 15, 2016) ("[N]o rule categorically prohibits courts from ruling on arguments about timeliness on Rule 12(b)(6) motions."). That is the case here as to Mentor's preemption defense. In addition, due to the undersigned judge's participation in the Mandatory Initial Discovery Pilot Project, *see* Standing Order Regarding Mandatory Initial Discovery Pilot Project at ¶ A.3, Plaintiffs also now have the benefit of Mentor's answer, which explicitly raises federal preemption as an affirmative defense. Doc. 19 at 50, 54. Accordingly, the court will consider Mentor's Rule 12(b)(6) motion as filed.

"There are no special pleading requirements for product liability claims in general, or for Class III medical device claims in particular. The federal standard of notice pleading applies, so long as the plaintiff alleges facts sufficient to meet the … 'plausibility' standard applied in" *Twombly* and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). *Bausch*, 630 F.3d at 558. "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." *Id*. at 558 (quoting *Iqbal*, 556 U.S. at 678). "In applying that standard to claims for defective manufacture of a medical device in violation of federal law, moreover, district courts must keep in mind that much of the product-specific information about manufacturing needed to investigate such a claim fully is kept confidential by federal law." *Ibid*.

A. Express Preemption

Although the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301 *et seq.*, "has long required FDA approval for the introduction of new drugs into the market," it was only with the passage of the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360c *et seq.*, which amended the FDCA, that Congress "imposed a regime of detailed federal oversight" on medical device manufacturers—an area that had traditionally been left to the States. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315 (2008). The MDA contains an express preemption provision, codified at 21 U.S.C. § 360k(a), which provides, with certain exceptions not relevant here:

> [N]o 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)(1) (emphasis added). Under that provision, "[m]edical device manufacturers who subject their Class III devices to the rigorous premarket approval process are

protected by federal law from civil liability so long as they *comply* with federal law." *Bausch*, 630 F.3d at 550. However, "[t]hat protection does not apply where the patient can prove that she was hurt by the manufacturer's *violation* of federal law." *Ibid*.

The Supreme Court has twice addressed the scope of express preemption under § 360k(a). In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court held that "[n]othing in § 360k denies [a State] the right to provide a traditional damages remedy for violations of common-law duties" as to products granted PMA "when those duties parallel federal requirements." *Bausch*, 630 F.3d at 551 (quoting *Lohr*, 518 U.S. at 495). In *Lohr*, then, "the Court gave lower courts clear instructions to allow [state law tort] claims to proceed when they are based on claimed violations of federal law." *Id*. at 552. A decade or so later, the Court held in *Riegel* "that, to the extent the state tort law underlying the [plaintiffs'] claims would require a manufacturer's device to be safer (but perhaps less effective) than the model device approved by the FDA, those requirements would 'disrupt[] the federal scheme no less than state regulatory law to the same effect.'" *Ibid*. (second alteration in original) (quoting *Riegel*, 552 U.S. at 325). Unlike in *Lohr*, the Court in *Riegel* "found that the state requirements implicit in the [plaintiffs'] common law claims were different from or in addition to the federal requirements and [thus] were preempted under section 360k." *Ibid*.; *see also McMullen v. Medtronic, Inc.*, 421 F.3d 482, 490 (7th Cir. 2005) (concluding that the plaintiff's state law claim was preempted because it "would impose on [the defendant] a requirement that is in addition to federal requirements"). *Riegel* "took care, however, to limit its holding to claims that the device at issue 'violated state tort law *notwithstanding compliance with the relevant federal requirements*.'" *Bausch*, 630 F.3d at 552 (quoting *Riegel*, 552 U.S. at 330).

Against that legal backdrop, Mentor contends that Catherine's claims should be dismissed because the complaint "is devoid of any well-pled allegations that the premarket-approved implant at issue in this case was not designed, manufactured, and labeled in accordance with the specifications approved by the FDA through the PMA process." Doc. 12 at 15. To determine whether Mentor is correct, it is instructive to examine the Seventh Circuit's decision in *Bausch*, which held the plaintiff's claim to fall outside the preemptive scope of § 360k(a).

The plaintiff in *Bausch* alleged that the hip-replacement device at issue—known by its brand name, Trident—"was implanted in her body six days after the [FDA] informed the defendants that a component of the Trident hip system was 'adulterated' and that the [defendants'] manufacturing processes failed to comply with federal standards." 630 F.3d at 549. The *Bausch* plaintiff further alleged that, by the time the Trident system was implanted into her body, the defendants had received numerous complaints "that the Trident was failing after it was implanted." *Id*. at 559. The defendants subsequently "recalled a component of the Trident bearing the same catalogue number as the one that had been implanted in [the plaintiff's] body." *Id.* at 549. Given these alleged design and manufacturing defects, the plaintiff claimed "that the Trident product was unreasonably dangerous, causing [her] to suffer an unstable right hip, pain, suffering, disability, and what is euphemistically called 'revision' surgery—in [the plaintiff's] case a second major operation in which the Trident product was removed and replaced with a different product." *Id*. at 558-59. The Seventh Circuit held that because the plaintiff's state law claim "that she was injured by [the defendant's] violations of federal law in manufacturing the device implanted in her hip … would not impose on defendants any requirement 'different from, or in addition to, any requirement' imposed by federal law," the claim was not preempted. *Id*. at 553 (quoting 21 U.S.C. § 360k(a)((1)).

Plaintiffs' allegations here are largely of a different kind. The parties agree that the express requirements set forth in the FDA's November 2006 letter qualify as federal law for purposes of the preemption analysis. Doc. 12 at 15; Doc. 18 at 4; *see* 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."); 21 C.F.R. § 814.82(a) ("FDA may impose postapproval requirements in a PMA approval order or by regulation at the time of approval of the PMA or by regulation subsequent to approval."); 21 C.F.R. § 814.82(c) ("Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA."). The key question, then, is whether Plaintiffs have alleged that Mentor violated any of those requirements, or any other requirements set forth by regulation or statute.

Plaintiffs allege that Mentor's execution of the studies required by the November 2006 letter was deficient in numerous respects—from the number of study participants, to the follow-up rate, to the nature of the data reported. As noted, Plaintiffs allege that Mentor failed to make certain disclosures regarding possible reasons why women in the core study underwent re-operation. Doc. 1-2 at ¶¶ 30(a)(4)-(7). Plaintiffs do not allege, however, that the November 2006 letter or any other federal law required Mentor to provide more detailed reasons for re-operation than it actually provided. *Ibid*.; *see* Doc. 12-1 at 3. The same is true of other studies. Plaintiffs allege, for example, that the large post-approval study's follow-up rate after the third year was 21%, declining further in year seven (20%) and year ten (0%). Doc. 1-2 at ¶¶ 30(b)(2)-(3). But the November 2006 letter does not require any particular follow-up rate for that study. Rather, apparently contemplating attrition, the letter requires only that Mentor disclose "the follow-up rates versus the stated goals." Doc. 12-1 at 3. Likewise, although Plaintiffs allege that

Mentor's summary of findings for the device failure and informed decision studies had certain limitations, they do not allege that those limitations violated any terms of the November 2006 letter or other requirement of federal law. Doc. 1-2 at ¶¶ 30(c)(2), 30(e)(2); *see* Doc. 12-1 at 4. Plaintiffs similarly allege that Mentor's adjunct post-approval study reported on fewer than half the patients within certain study cohorts, but not that this violated the FDA's requirements, including those in the November 2006 letter, for such studies. Doc. 1-2 at ¶ 30(f)(2); *see* Doc. 12-1 at 5. And while Plaintiffs imply that Mentor's enrollment of only 35 women in its focus group study was inadequate, nowhere do they allege that Mentor violated the agency's regulatory baseline (if any), or any requirements in the November 2006 letter, for the number of participants in a post-PMA focus group study. Doc. 1-2 at ¶ 30(d)(5); *see* Doc. 12-1 at 4.

These features (or, rather, non-features) of Plaintiffs' complaint distinguish the above-referenced allegations from those in *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026 (N.D. Ill. 2016). There, the defendant was alleged to have "received hundreds of adverse reports regarding" its product, which it then concealed from the agency. *Id*. at 1029. Thus, the *Laverty* complaint alleged not that the required follow-up studies were faulty, but instead that the defendant did not report information concerning the product's performance that it, in fact, possessed. *Laverty* concluded that because the plaintiffs "alleged that [the defendant] failed to disclose information relevant to the safety and effectiveness of its device *in violation of the rules the FDA set forth as a condition of premarket approval*," they had pleaded a violation of federal law and thus stated the type of claim permitted by *Lohr*. *Id*. at 1033 (emphasis added).

Here, by contrast, the above-referenced methodological defects in Mentor's post-PMA studies are not alleged to have violated federal law or hidden important facts from the FDA. To the contrary, Plaintiffs acknowledge that Mentor's post-approval studies revealed a nontrivial

risk of rupture: "[S]ince Mentor began post-approval studies in 2007, Mentor found 43.5% of implants retrieved from patients participating in the large post-approval study had ruptures, and 25% of 97 implants that were explanted and returned to Mentor for evaluation from August 2000 to August 2009 in the Core Study had ruptured." Doc. 1-2 at ¶ 42.

Nonetheless, the complaint does allege that Mentor violated federal law with respect to certain other aspects of its post-PMA studies: (1) that Mentor's core study follow-up rate after nine years was no more than 59 percent, Doc. 1-2 at ¶ 30(a)(2), despite the November 2006 letter's requirement that Mentor "continue [its] Core Study until *all* patients have completed their 10-year evaluation," Doc. 12-1 at 3 (emphasis added); (2) that Mentor reported results for the core study for only six years, rather than the ten years required by the November 2006 letter, Doc. 1-2 at ¶ 30(a)(3); Doc. 12-1 at 3; and (3) that Mentor included some 500 fewer patients in its large post-approval study than the 41,900 required by the November 2006 letter, Doc 1-2 at ¶ 30(b)(2); Doc. 12-1 at 3. The complaint also alleges that "a Mentor chemist of 15 years reported to the FDA that Mentor's implants are more likely to break than the company had reported," and that the company therefore knew, but "failed to warn consumers, healthcare providers, and the FDA[,] that a significant gel bleed was a potential risk of MemoryGel" implants, in violation of 21 C.F.R. §§ 803.50 and 814. Doc 1-2 at ¶¶ 24(a)-(b), 32-33, 40-41. Finally, the complaint alleges that Mentor's manufacturing facilities failed to comply with applicable agency regulations, and that, after inspecting its facilities, the FDA cited Mentor for its compliance failures on six separate occasions. Doc. 1-2 at ¶¶ 24(d)-(f) (citing 21 C.F.R. § 820); 35-36. Because Plaintiffs plausibly allege that those shortcomings in Mentor's post-PMA testing and manufacturing processes violated federal law, those claims are not preempted

by § 360k(a). *See Bausch*, 630 F.3d at 556; *Laverty*, 197 F. Supp. 3d at 1033; *Hornbeck v. Medtronic, Inc.*, 2014 WL 2510817, at *3-4 (N.D. Ill. June 2, 2014).

B. Implied Preemption

Plaintiffs may proceed with those claims, however, only if they pass through a second legal filter. As *Bausch* explained, the Supreme Court in *Buckman* held that the FDCA impliedly preempts "'fraud-on-the-agency' claims, *i.e.*, claims not related to a field of law that states had traditionally occupied, from claims based on state law tort principles." 630 F.3d at 557. Thus, under *Buckman*, federal law preempts a plaintiff's claims to the extent they seek to deploy state law in the service of "[p]olicing fraud against federal agencies" based on statements that federal law required the defendant to make to the agency. 531 U.S. at 347. The reason, *Bausch* noted, is that federal law already "empowers the FDA to deter and punish fraud" and that, as a result, "the 'balance sought by the [FDA] can be skewed by allowing fraud-on-the-FDA claims under state tort law.'" 630 F.3d at 557 (quoting *Buckman*, 531 U.S. at 348). Applying these principles, *Buckman* concluded that because the plaintiff's state law claims that the defendant "made fraudulent representations to the FDA as to the intended use" of the relevant product, 531 U.S. at 346-47, were based "solely" on "FDCA disclosure requirements," federal law impliedly preempted them, *id*. at 352-53.

That said, *Buckman* does not preempt claims like those asserted in *Bausch*—"tort law claims based on manufacturing defects" or the manufacturer's failure to warn of the product's known and unacceptable risks. 630 F.3d at 557. Thus, although the *Bausch* defendants contended that there was no "'traditional state tort law' claim for an 'adulterated' product in so many words," the Seventh Circuit explained that "the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their

products by complying with federal law." *Ibid*. It follows, the Seventh Circuit held, that "evidence showing a violation of federal law shows that the device is adulterated and goes a long way toward showing that the manufacturer breached a duty under state law." *Ibid*.; *see also Buckman*, 531 U.S. at 352-53 (distinguishing the claims in *Buckman* from those in *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984), which were "not based on any sort of fraud-on-the-agency theory, but on traditional state tort law principles of the duty of care owed by the producer of plutonium fuel pins to an employee working in its plant," and those in *Lohr*, which "arose from the manufacturer's alleged failure to use reasonable care in the production of the product").

Here, several of Plaintiffs' claims that survive express preemption—that Mentor's core study follow-up rate was 59 percent rather than the required 100 percent, that Mentor reported results for the core study for six years rather than the required ten years, and that Mentor recruited 500 fewer patients than the number required for its large post-approval study—are impliedly preempted under *Buckman* because those shortcomings breached no "well-recognized duty owed to [Catherine] under state law," such as "the duty of a manufacturer to use due care in manufacturing a medical device." *Bausch*, 630 F.3d at 558. Rather, as in *Buckman*, those claims are unconnected to any traditional state tort duty, and thus "the existence of [the relevant] federal enactments is a critical element in their case." 531 U.S. at 353. The complaint contains no allegation to the effect that, had Mentor kept better track of core study participants, reported on the results of the core study for a longer time period, or recruited the requisite number of participants for its large post-approval study, the company would have been any more likely to reveal the dangers of MemoryGel. Thus, unlike in *Bausch*, Mentor's violations of those federal reporting requirements do not tend to make it more likely that Mentor breached a state law duty.

See Bausch, 630 F.3d at 557; *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1235 (9th Cir. 2013) (Watford, J., concurring) ("Central to the Court's reasoning in *Buckman* was that the state law claim there 'exist[ed] *solely* by virtue' of the federal enactments, because state law traditionally had no role to play in policing 'the relationship between a federal agency and the entity it regulates'") (alterations in original) (quoting *Buckman*, 531 U.S. at 347, 353); *Vincent v. Medtronic, Inc.*, 221 F. Supp. 3d 1005, 1011 (N.D. Ill. 2016) ("To the extent that Vincent brings claims based solely on Medtronic's noncompliance with the FDA's supplemental premarket approval procedures, those claims are impliedly preempted.").

The same holds true for Plaintiffs' claim that "Mentor routinely maintained manufacturing facilities that failed to comply with applicable law and regulations," for which the FDA cited Mentor from 2000-2007. Doc. 1-2 at ¶¶ 35-36. Whatever the nature of Mentor's compliance failures, Plaintiffs do not connect them to an allegation that MemoryGel was defectively manufactured, and thus fail to connect them to a traditional state tort duty of the kind recognized in *Bausch*. *See Bausch*, 630 F.3d at 557 (noting that "the federal definition of adulterated medical devices is tied directly to the duty of manufacturers to avoid foreseeable dangers with their products by complying with federal law"). Accordingly, to the extent that Plaintiffs' state law tort claims are based on Mentor's alleged violations of reporting obligations set forth in the November 2006 letter, or of federal regulations concerning the maintenance of its manufacturing facilities, the claims are impliedly preempted.

That leaves Plaintiffs' allegation that Mentor had information suggesting that MemoryGel ruptures were more frequent than what it reported to the FDA, and thus that Mentor "concealed its knowledge of known safety risks," including the risk of MemoryGel implants bleeding, "from the FDA and the public." Doc. 1-2 at ¶ 32-33, 40-41. As in *Bausch*, this

allegation concerns a violation of federal law, insofar as Class III device manufacturers must report to the agency whenever they "receive or otherwise become aware of information, from any source, that reasonably suggests that a device [they] market: (1) May have caused or contributed to a death or serious injury or (2) Has malfunctioned and this device or a similar device … would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a). And, crucially, as in *Bausch*, this allegation is distinct from those at issue in *Buckman*. Much like the "well-recognized … [state law] duty of a manufacturer to use due care in manufacturing a medical device" recognized in *Bausch*, 630 F.3d at 553, the allegation that Mentor underreported MemoryGel's tendency to rupture pertains to the state law duty of a manufacturer to inform regulators and the public when it has reason to know that a product is riskier than initially believed. *See id*. at 558 (noting that "Illinois treats a violation of a statute or ordinance designed to protect human life or property as prima facie evidence of negligence"); *see also Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 43 (Ill. 2002) (upholding failure-to-warn liability under Illinois law where the manufacturer of IV tubing connectors was aware of the risk of using a particular type of connector in certain medical applications, but "gave the medical community no warning at all about the need" to use a different connector in those applications); *Proctor v. Davis*, 682 N.E.2d 1203, 1211-15 (Ill. App. 1997) (upholding failure-to-warn liability under Illinois law where the defendant knew that the drug was an "insoluble, toxic material, which, because of its insolubility, when inserted in the eye, became … very difficult, if not impossible to remove" and therefore was unsuited to periocular use, but nevertheless "encouraged and participated in disseminating misleading information" concerning the drug's off-label periocular use); *In re Testosterone Replacement Therapy Prod. Liab. Litig. Coordinated Pretrial Proceedings*, 2017 WL 1836443, at *7-8 (N.D.

Ill. May 8, 2017) (holding, on summary judgment, that because "claims grounded in traditional state law principles of liability, such as negligence, failure to warn, strict product liability, and fraud that predate the relevant FDCA requirements" are not preempted under *Buckman*, the plaintiffs' off-label marketing claims were not preempted because they involved alleged "misrepresentations about the safety and efficacy of [the product]" and so did not "depend on a finding that [the defendant] violated the FDCA or FDA regulations"); *Laverty*, 197 F. Supp. 3d at 1035 ("Illinois does recognize a claim for failure to warn predicate on a product manufacturer's failure to disclose known defects.") (citing cases); *Rosenstern v. Allergan, Inc.*, 987 F. Supp. 2d 795, 801-03 (N.D. Ill. 2013) (denying dismissal of the plaintiff's negligence and failure-to-warn claims under Illinois law where the plaintiff alleged that the defendant "failed to warn [her] and her physicians of the risk of using Botox to treat" her condition and "breached its duty to [her] … [by] failing to provide [her] and [her] health care providers with sufficient information as to the product's known dangers and risks") (last alteration in original, internal quotation marks omitted); *Sellers v. Boehringer Ingelheim Pharm., Inc.*, 881 F. Supp. 2d 992, 1007-10 (S.D. Ill. 2012) (same, applying Illinois law).

To be sure, Plaintiffs' claim that Mentor underreported the frequency of MemoryGel ruptures is less developed than the allegations of adulteration and lack of compliance in *Bausch*. *See* 630 F.3d at 549, 558-59. Still, the Seventh Circuit has made clear that the substantial information asymmetries facing plaintiffs in products liability cases involving Class III medical devices will tend to limit their capacity at the pleading stage to precisely delineate the nature of the defect. *See id*. at 560 (noting, among other things, that plaintiffs may need discovery even to determine whether their claims are design defect claims or manufacturing defect claims, and emphasizing that certain data relevant to a product liability claim against a Class III medical

device manufacturer are "kept confidential as a matter of federal law"). Thus, to the extent that Plaintiffs allege that Mentor deliberately underreported the tendency of MemoryGel implants to rupture, the absence of additional detail does not "show a failure to comply with Rule 8" and therefore cannot form the basis for "a dismissal under Rule 12(b)(6)." *Id*. at 560. As the Seventh Circuit emphasized in *Bausch*, Rule 9(b)'s particularity requirement does not apply to the kinds of claims at issue here. *Ibid*.

Plaintiffs' allegation that Mentor underreported the frequency of MemoryGel ruptures is sufficient to support their negligence and product liability claims. *See Engelhard v. Wyeth Consumer Healthcare Ltd*., 2015 WL 1159442, at *2 (N.D. Ill. Mar. 11, 2015) ("To establish that drug manufacturers failed to adequately warn under Illinois law, Plaintiff must show that (1) Defendants had a duty to warn; (2) Defendants knew or should have known of the danger but failed to warn Plaintiff of the fact; (3) the omission of such information made the warning inadequate and the drug defective; and (4) this defect proximately caused Plaintiff's injuries.") (citing *Northern Trust Co. v. Upjohn Co.*, 572 N.E.2d 1030, 1037 (Ill. App. 1991)); *Sellers*, 881 F. Supp. 2d at 1009 ("In Illinois, product liability cases asserting negligence fall under the standard of common law negligence. The plaintiff in this case must therefore allege 'the existence of a duty of care owed by the defendant, a breach of that duty, an injury that was proximately caused by that breach, and damages.'") (quoting *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 263 (Ill. 2007)). Were Plaintiffs to prove that Mentor concealed the true rate of rupture of MemoryGel implants, Mentor may have breached its state law duty to warn potential customers—and their physicians—of the product's risks. Doc. 1-2 at ¶¶ 71-72, 86-88, 104-05; *see Hansen*, 764 N.E.2d at 43; *Proctor*, 682 N.E.2d at 1211-15; *Laverty*, 197 F. Supp. 3d at 1035; *Rosenstern*, 987 F. Supp. 2d at 801-04; *Sellers*, 881 F. Supp. 2d at 1007-10. Moreover, as

to causation, the complaint plausibly alleges both that Catherine would not have consented to the implant procedure if she had known the true risk of device rupture and that, were they informed that the risks of MemoryGel implants were higher than disclosed, Catherine's physicians would not have recommended that she undergo the MemoryGel implant procedure. Doc. 1-2 at ¶¶ 48-49, 76-77, 91-92, 97, 109-110, 116; *see Rosenstern*, 987 F. Supp. 2d at 801-02 (holding similar allegations sufficient to allege proximate cause under Illinois law); *Sellers*, 881 F. Supp. 2d at 1010 (same). And because the court concludes that Catherine's claims are viable, Travis's loss of consortium claim survives as well.

Conclusion

Mentor's motion to dismiss is granted in part and denied in part. Plaintiffs may proceed with Catherine's claim that Mentor violated its state tort law duties by concealing that the risk of gel bleed associated with MemoryGel was higher than the company publicly revealed, and with Travis's associated consortium claim. Plaintiffs' other claims are dismissed, though the dismissal is without prejudice. *See Runnion ex rel. Runnion v. Girl Scouts of Greater Chi. & Nw. Ind.*, 786 F.3d 510, 519 (7th Cir. 2015) ("Ordinarily, … a plaintiff whose original complaint has been dismissed under Rule 12(b)(6) should be given at least one opportunity to try to amend her complaint before the entire action is dismissed."). Plaintiffs have until February 1, 2018 to file an amended complaint. If Plaintiffs file an amended complaint, Mentor shall respond by February 15, 2018. If Plaintiffs do not file an amended complaint, the dismissal of the other claims will convert automatically to a dismissal with prejudice.

January 11, 2018

United States District Judge