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. Mentor removed the suit to federal court, Doc. 1, and the court granted in part and denied in part Mentor's motion under Federal Rule of Civil Procedure 12(b)(6) to dismiss the complaint, Docs. 32-33 (reported at 289 F. Supp. 3d 877 (N.D. Ill. 2018)). Plaintiffs then filed an amended complaint; as in the original complaint, 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, and Travis brings a loss of consortium claim. Doc. 37.

Mentor moves under Rule 12(b)(6) to dismiss the amended complaint. Doc. 38. The motion is granted in part and denied in part. The reader will note that much of this opinion replicates the court's first opinion, a congruence due largely to the fact that the amended

complaint strongly resembles the original complaint and that the parties in this round have re-fought many of the battles they joined in the prior round.

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 MemoryGel, a breast implant made of silicone gel. Doc. 37 at ¶¶ 1, 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, including information derived from investigations other than those proposed in the application from commercial marketing experience." Doc. 37 at ¶ 17(g); *see* 21 U.S.C. § 360e.

In a letter dated November 17, 2006 (the "November 2006 letter"), the FDA granted PMA to Mentor for the use of MemoryGel as a breast augmentation device. Doc. 37 at ¶ 20; Doc. 39 at 20-24. In connection with the 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. 37 at ¶ 21; Doc. 39 at 21-23. 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 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 format 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 the use of such implants on new patients. Doc. 37 at ¶ 21; Doc. 39 at 21-23. Pertinent here, and in connection with the first two of those studies, 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. 39 at 21. Mentor was also required to

"update [its] patient and physician labeling" after five and ten years to reflect the core and large post-approval studies' findings. *Ibid*. The FDA cautioned Mentor that "[f]ailure to comply with any postapproval requirement constitutes a ground for [PMA] withdrawal." Doc. 37 at ¶ 32.

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. *Id*. at ¶ 30(a)(2). Mentor reported study results for only six years rather than the required ten, and the study's reported findings lacked statistical reliability within the subgroups (or cohorts) into which Mentor broke down the data. *Id*. at ¶ 30(a)(3). Without explanation, Mentor reported the reasons for re-operation for only 36 percent of those members of the primary augmentation cohort who underwent 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 "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 required by the November 2006 letter. *Id*. at ¶ 30(b)(2); Doc. 39 at 21. Mentor omitted material information for 113 of the 41,451 patients. Doc. 37 at ¶ 30(b)(2). 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. *Id*. at ¶¶ 30(b)(2)-(3). Mentor's "skeletal" 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)-(3). 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, some of whom expressed concerns about Mentor's informational materials and proposed recommendations for labeling changes that Mentor ultimately ignored. *Id*. at ¶¶ 30(d)(2)-(3). 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, FDA 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, 820.100, 820.198). 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." *Id*. at ¶ 36. Mentor also underreported both the likelihood that the type of silicone used in MemoryGel implants would leak and the danger posed by the platinum used in the implants. *Ibid*. Despite "kn[owing] of these risks," Mentor nevertheless "covered up the information by terminating

studies, sponsoring only self-serving research … and misrepresenting the risks presented by its products." *Ibid*.

Moreover, Mentor failed "to revise its product labeling after becoming aware of otherwise undisclosed dangers in its MemoryGel products." *Id*. at ¶ 27. Ordinarily, such adverse events are reported to the FDA, which maintains a publicly searchable and regularly updated database known as "MAUDE." *Id*. at ¶ 29. 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 ¶¶ 37-38. Thus, Mentor's "Product Insert Data Sheet" for MemoryGel—which stated that "[t]he overall body of available evidence supposes that the extremely low level of gel bleed is of no clinical consequence"—was materially and knowingly false when published. *Id*. at ¶ 43. Mentor's "Directions for Use" for MemoryGel, and its consumer labeling more generally, similarly failed to disclose the true risk associated with MemoryGel implants. *Id*. at ¶ 47.

Mentor's MemoryGel manufacturing process was also deficient, leading the FDA to cite the company for compliance failures six times from May 2000 to December 2007. *Id*. at ¶¶ 40-42. 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 ¶ 49. Catherine initially underwent saline breast implantation surgery. *Id*. at ¶ 50. After a series of complications, she underwent revision, or curative, implantation surgery, during which MemoryGel implants were implanted. *Id.* at ¶ 51. At that time, Catherine did not know, nor did

her physicians advise her, of the true risk that her MemoryGel implants would rupture or leak or of the consequences of their doing so. *Id*. at ¶ 52. Had Mentor disclosed that risk, Catherine's physicians would not have recommended MemoryGel implants, nor would Catherine have consented to their implantation. *Id*. at ¶¶ 53-54.

Since the implantation of her MemoryGel implants, Catherine has experienced symptoms causing her "extreme suffering," including severe skin rashes and acne, blackouts and periods of disorientation, significant memory loss, muscle soreness, extreme fatigue, abnormal thyroid levels, drowsiness, and anxiety and depression. *Id*. at ¶ 55. 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 ¶¶ 59-60. By 2016, Catherine's condition had substantially worsened. *Id*. at ¶ 61. 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 ¶¶ 63-64. Earlier medical tests also showed elevated levels of bromine and other toxins in her blood stream. *Id*. at ¶ 57.

Ultimately, Catherine underwent a third round of surgery—this time, to remove the MemoryGel implants. *Id*. at ¶ 66. Surgeons also removed some of Catherine's lymph nodes, which were contaminated with silicone. *Ibid*. Catherine's breast region and armpits have since been very swollen and painful, and later tests suggested that additional lymph nodes had been contaminated. *Id*. at ¶ 67. Further surgeries have been determined to be life-threatening, and so Catherine must live with any remaining discomfort. *Id*. at ¶ 67. As a result of Catherine's health

problems, Travis has taken full responsibility for supporting and managing the household and has, in consequence, lost wages and income. *Id*. at ¶¶ 125, 127.

Discussion

Plaintiffs' claims arise under Illinois tort law. *Id*. at ¶¶ 72-128. 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 ¶¶ 72-86, 105-123. 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 ¶¶ 87-104. Count IV alleges that Mentor's actions resulted in Travis's loss of consortium. *Id*. at ¶¶ 124-128.

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.

"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" *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), and *Ashcroft v. Iqbal*, 556 U.S. 662 (2009). *Bausch v. Stryker Corp.*, 630 F.3d 546, 558 (7th Cir. 2010). "'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.'" *Ibid*. (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 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, 315-16 (2008). The MDA contains an express preemption provision, codified at 21 U.S.C. § 360k(a), which states, 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). As the Seventh Circuit explained, *Lohr* "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 are "expressly preempted to the extent [they are] based on alleged 'methodological defects' in the post-approval studies." Doc. 39 at 8. To determine whether Mentor is correct, it is instructive to examine the

Seventh Circuit's decision in *Bausch*, which held the plaintiff's claim there to fall outside the preemptive scope of § 360k(a).

The complaint in *Bausch* alleged that the hip-replacement device at issue—known by its brand name, Trident—"was implanted in [the plaintiff's] 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* complaint further alleged that, by the time the Trident system was implanted into the plaintiff's 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 alleged "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)).

Here, as was true of Plaintiffs' original complaint, the amended complaint's allegations are largely of a different kind. The complaint alleges 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 and the nature of the data reported. As noted, the

complaint alleges that Mentor failed to make certain disclosures regarding possible reasons why women in the core study underwent re-operation, Doc. 37 at ¶¶ 30(a)(4)-(7), and that the core study's findings lacked within-cohort statistical reliability, *id*. at ¶ 30(a)(3). The complaint does 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, Doc. 37 at ¶¶ 30(a)(4)-(7); *see* Doc. 39 at 21-22, or that the November 2006 letter or any other federal law set forth a test for statistical reliability that Mentor failed to satisfy, Doc. 37 at ¶ 30(a)(3); *see* Doc. 39 at 21-22. In fact, the complaint provides no detail at all explaining how or why Mentor's within-cohort findings were statistically unreliable.

The same is true of other studies required by the November 2006 letter. The complaint alleges, 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. 37 at ¶¶ 30(b)(2)-(3). But the 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. 39 at 21. The complaint similarly alleges that Mentor omitted relevant information for certain study participants, but points to no federal law governing the information on participants that must be disclosed in a post-PMA study. Doc. 37 at ¶ 30(b)(2).

Likewise, although the complaint alleges that Mentor's summaries of findings for the device failure and informed decision studies had certain limitations, it does not allege that those limitations violated any terms of the November 2006 letter or other requirement of federal law. Doc. 37 at ¶¶ 30(c)(2), (e)(2); *see* Doc. 39 at 22. While the November 2006 letter requires that the informed decision study involve 50 randomly selected physicians, the complaint does not allege that Mentor failed to recruit this number of participants; rather, it alleges only that

Mentor's summary of findings did not list the study's sample size. Doc. 37 at ¶ 30(e)(2). The complaint similarly alleges 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. 37 at ¶ 30(f)(2); *see* Doc. 39 at 23. And while the complaint implies that Mentor's enrollment of only 35 women in its focus group study was inadequate, nowhere does it 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. 37 at ¶ 30(d)(2); *see* Doc. 39 at 22. Although the complaint alleges that some focus group participants were critical of Mentor's labeling practices, it does not suggest that this invalidates Mentor's methodology (or any conclusions it might have drawn) in conducting the focus group. Doc. 37 at ¶ 30(d)(2).

It is true that the complaint alleges that each such deficiency in Mentor's post-PMA studies amounts to an independent "failure to comply with [the FDA's] postapproval requirement[s]," and thus that each "constituted a ground for withdrawal of the PMA." *Id*. at ¶¶ 32-33. But putting aside that the FDA did not withdraw PMA for MemoryGel, Plaintiffs simply assume, without legal or other support, that those deficiencies amount to violations of the FDA's conditions for PMA. Such an assumption may not ground a viable claim. *See Diedrich v. Ocwen Loan Servicing, LLC*, 839 F.3d 583, 589 (7th Cir. 2016) (holding that "[l]egal conclusions or bare and conclusory allegations … are insufficient to state a claim").

Nonetheless, the complaint plausibly alleges that Mentor violated federal law as 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. 37 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. 39 at 21 (emphasis added); (2) that Mentor reported results for the core study for only six years, rather than the ten required by the November 2006 letter, Doc. 37 at ¶ 30(a)(3); Doc. 39 at 21, and thus that Mentor failed to comply with the PMA approval condition that it "update its patient and physician labeling" based on the core study's results after five and ten years, Doc. 37 at ¶¶ 30(a)(1), (3); *see* Doc. 39 at 21; (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. 37 at ¶ 30(b)(2); Doc. 39 at 21; and (4) that, as to the large post-approval study, "Mentor did not collect about 80% of the available data in the later years and collected none of the available data in year ten," and so did not "accurately update[] its patient and physician labeling at the 10-year mark" as the FDA required in granting PMA, Doc. 37 at ¶ 30(b)(3); Doc. 39 at 21. The complaint also plausibly 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. 37 at ¶¶ 36-38, 43, 46-47. Finally, the complaint plausibly 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. 37 at ¶¶ 24(d)-(f) (citing 21 C.F.R. § 820), 40-41.

Because Plaintiffs plausibly allege that those shortcomings in Mentor's post-PMA testing and manufacturing processes violated federal law, § 360k(a) does not preempt those claims. *See Bausch*, 630 F.3d at 556; *Laverty v. Smith & Nephew, Inc.*, 197 F. Supp. 3d 1026, 1033 (N.D. Ill. 2016); *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," as distinct "from claims based on state law tort principles." 630 F.3d at 557. Thus, under *Buckman*, federal law preempts 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 those claims, *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 the 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, meaning that "the existence of [the relevant] federal enactments is a critical element" of those claims. 531 U.S. at 353; s*ee also 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.").

It is true that the complaint alleges that had Mentor more "substantially complied with the PMA, rather than flagrantly underperforming the post-approval requirements … [its] disclosures would have led to much wider knowledge of the risks associated with [its] products." Doc. 37 at ¶ 35. But the *Buckman* analysis centers on the nature of the asserted claim and the source of the violation, not on the violation's effects. As the Supreme Court cautioned, "were plaintiffs to maintain their fraud-on-the-agency claims … they would not be *relying on* traditional state tort law" in pursuing them. 531 U.S. at 353 (emphasis added); *see also Bausch*, 630 F.3d at 557-58 ("The plaintiff must be suing for conduct that *violates* the [FDCA] … , but the plaintiff must not be suing *because* the conduct violates the [FDCA] … ."") (internal quotation marks omitted); *Vincent*, 221 F. Supp. 3d at 1009 ("'Fraud-on-the-agency' claims rooted in violations of federal administrative and reporting requirements … are impliedly preempted [under *Buckman*]."). That caution applies here. Regardless of the consequences of Mentor's flawed implementation of the required post-PMA follow-up studies, the FDA, not traditional state tort law, establishes the requirements for conducting those studies. *See Buckman*, 531 U.S. at 347 ("[T]he relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law."). A claim arising entirely out of a violation of Mentor's compliance with the FDA's requirements in granting PMA is, in consequence, not "independent of the [PMA] process," *Stengel*, 704 F.3d at 1233, and so is preempted under *Buckman*. *See Buckman*, 531 U.S. at 353; *Bausch*, 630 F.3d at 557; *Vincent*, 221 F. Supp. 3d at 1011.

In addition, although *Bausch* recognized the informational disadvantages faced by plaintiffs in product liability suits like this one, 630 F.3d at 561, Plaintiffs' assertion that more robust compliance with the FDA's requirements for post-PMA studies would have "led to much wider knowledge of the risks associated with" MemoryGel, Doc. 37 at ¶ 35, is implausible given the complaint's other allegations. As noted, the complaint alleges that Mentor was aware of the true risk associated with MemoryGel implants, but nevertheless concealed that risk from the public, in part by "terminating studies [and] sponsoring only self-serving research Mentor could control." *Id*. at ¶¶ 36-38, 43, 48. Assuming, as the court must at this stage, that this allegation is true, it is implausible that Mentor's conducting the required studies with higher follow-up rates, or larger numbers of participants, would have led it to be appropriately forthcoming about MemoryGel's risks. *See Bell v. City of Country Club Hills*, 841 F.3d 713, 716 (7th Cir. 2016) ("[T]he complaint's factual allegations must raise the claim above a mere 'speculative level.'") (quoting *Twombly*, 550 U.S. at 555).

In any event, the FDA was aware of some of these alleged deficiencies, referencing them in published materials concerning MemoryGel. At least as of 2011, for instance, the FDA noted that after three years of following participants in the large post-approval study, Mentor had collected data on only "21% of participants," cautioning that "[l]ow follow-up rates and other study limitations may limit interpretation of the data" Mentor had compiled in conducting its post-PMA studies and "preclude the detection of very rare complications." Doc. 39 at 27-28. To the extent the agency was concerned about those gaps but "did not take … action against" Mentor, that decision "rest[s] within the enforcement authority of the FDA, not this [c]ourt." *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013); *see also Brooks v. Howmedica, Inc.*, 273 F.3d 785, 798 (8th Cir. 2001) ("The FDA was deeply involved in drafting and editing the

warnings on the Simplex label and package label, beginning with the product's approval in 1971 and continuing on through the period in which Brooks was exposed to it. Through its approval of the PMA application for Simplex and its continuing series of directives, the agency imposed specific federal requirements on Howmedica. The failure to warn claim Brooks seeks to assert could impose state requirements which conflict or interfere with these federal directives.").

C. Remaining Claims

That leaves two sets of claims: (1) 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. 37 at ¶¶ 40-41; and (2) 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 true risk of MemoryGel implants bleeding, "from the FDA and the public," in part by failing to update its product labeling, *id*. at ¶¶ 36-38, 43, 46-47.

As to Mentor's manufacturing processes, the complaint alleges that Mentor's "deviations" from FDA requirements "contributed to faulty manufacture of MemoryGel," Doc. 37 at ¶ 42, and thus that Mentor violated a traditional state law duty, *see Bausch*, 630 F.3d at 557. But the complaint alleges only that MemoryGel implants were, *as a category*, unlawfully "prone to rupture," and therefore that Catherine's specific implants were representative of the product's broader failings rather than outliers in an otherwise well-functioning industrial process. Doc. 37 at ¶¶ 42-46; *see also* Doc. 42 at 4 ("As a result of manufacturing failures, MemoryGel implants were defective and adulterated in that they were prone to rupture and gel bleeding."). This is significant because, under Illinois law, "[a] manufacturing defect differs from a design defect in that the former occurs in only a small percentage of units in a product line, whereas the

latter arises when the specific unit conforms to the intended design but the intended design itself, or its sale without adequate instructions or warnings, renders the product not reasonably safe." *Blue v. Envtl. Eng'g, Inc.*, 828 N.E.2d 1128, 1137 (Ill. 2005); *see also Salerno v. Innovative Surveillance Tech., Inc.*, 932 N.E.2d 101, 108 (Ill. App. 2010) ("A manufacturing defect occurs when one unit in a product line is defective, whereas a design defect occurs when the specific unit conforms to the intended design but the intended design itself renders the product unreasonably dangerous.").

Here, even acknowledging *Bausch*'s caution that a product liability plaintiff "may not be able to determine without discovery and further investigation whether the problem is a design problem or a manufacturing problem," 630 F.3d at 560, the core premise of Plaintiffs' suit is that the risks associated with MemoryGel implants as a class were higher than what Mentor publicly disclosed. *E.g.*, Doc. 37 at ¶¶ 46, 78, 85, 112-113, 120. The complaint—Plaintiffs' second—thus does not allege, nor is it reasonable to infer, that the particular MemoryGel implant Catherine received was defectively manufactured; it therefore does not state a true manufacturing defect claim. *See Blue*, 828 N.E.2d at 1137; *Salerno*, 932 N.E.2d at 108. In any event, because Mentor contended in its opening brief that Plaintiffs did not raise a plausible manufacturing defect claim (as distinct from their design defect and failure to warn claims), Doc. 39 at 12 n.4, and Plaintiffs did not address the matter in their opposition brief, Plaintiffs have forfeited their claims regarding MemoryGel's manufacturing process to the extent they concern defects in Mentor's manufacturing the particular implants that Catherine received. *See Firestone Fin. Corp. v. Meyer*, 796 F.3d 822, 825 (7th Cir. 2015) ("[A] party generally forfeits an argument or issue not raised in response to a motion to dismiss."); *Alioto v. Town of Lisbon*, 651 F.3d 715, 721 (7th Cir. 2011) ("Our system of justice is adversarial, and our judges are busy people. If

they are given plausible reasons for dismissing a complaint, they are not going to do the plaintiff's research and try to discover whether there might be something to say against the defendants' reasoning.") (internal quotation marks omitted).

As to the allegations concerning Mentor's concealing MemoryGel's true risks, including the actual likelihood of rupture—of which the allegations about Mentor's overall manufacturing process form a part, Doc. 37 at ¶¶ 44, 75, 85, 88-90, 100, 106, 108, 118, 120—they, like those at issue in *Bausch*, concern a violation of federal law. 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*, those allegations are distinct from the allegations 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 558, Mentor's alleged underreporting MemoryGel's tendency to rupture implicates 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 553 (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 predicated on a product manufacturer's failure to disclose known defects.") (citing cases); *Rosenstern v. Allergan, Inc.*, 987 F. Supp. 2d 795, 801-04 (N.D. Ill. 2013) (denying dismissal of 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).

To be sure, Plaintiffs' claim that Mentor underreported the frequency of MemoryGel ruptures is less developed than the allegations in *Bausch* of adulteration and lack of compliance. *See* 630 F.3d at 549, 558-59. Still, as noted, 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 product 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 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 thus cannot form the basis for "a dismissal under Rule 12(b)(6)." *Id*. at 560. And 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*.

Mentor contends that *Buckman* nevertheless preempts any claim based on these allegations because they are grounded in a report made to the FDA by a Mentor chemist before the FDA granted PMA for MemoryGel. Doc. 39 at 16. Because the FDA was already aware of the chemist's concerns, Mentor adds, Plaintiffs seek to have a jury "second-guess the FDA's decision to approve Mentor's labeling notwithstanding its knowledge of the company's alleged reporting violations." *Ibid*. This mischaracterizes Plaintiffs' allegations. As noted, Plaintiffs allege broadly that Mentor underreported the risks associated with MemoryGel. *E.g.*, Doc. 37 at ¶ 46. Thus, even accepting for present purposes that the Mentor chemist made the report before Mentor received PMA for MemoryGel, the allegation of earlier underreporting tends to make it more plausible that Mentor continued to underreport MemoryGel's risks even after receiving PMA. And crossing "the line from conceivable to plausible" is all Plaintiffs must do at this stage

of a lawsuit. *Twombly*, 550 U.S. at 570; *see also Al Haj v. Pfizer*, 2018 WL 1784126, at *7 (N.D. Ill. Apr. 13, 2018) (citing cases).

In sum, 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. 37 at ¶¶ 76-77, 92-96, 110-114; *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 had she known the true risk of device rupture and that her physicians, were they informed that the risks of MemoryGel implants were higher than disclosed, would not have recommended that she undergo the MemoryGel implant procedure.

Doc. 37 at ¶¶ 35, 46-48, 53-54, 82, 97-98, 103, 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). Mentor contends that Plaintiffs "do[] not allege that *her* physicians even relied on information in the FDA database when making their treating decisions." Doc. 39 at 15. But, as noted, Plaintiffs at this stage need only "plead a plausible claim, after which [they] receive[] the benefit of imagination, so long as the hypotheses are consistent with the complaint." *Chapman v. Yellow Cab Coop.*, 875 F.3d 846, 848 (7th Cir. 2017) (internal quotation marks omitted); *see also Swanson v. Citibank, N.A.*, 614 F.3d 400, 404 (7th Cir. 2010) ("[T]he plaintiff must give enough details about the subject-matter of the case to present a story that holds together. In other words, the court will ask itself *could* these things have happened, not *did* they happen.") (emphasis in original). And it is at least plausible that had Mentor reported the true risks of MemoryGel, that information would have reached Catherine's physicians, whether through the FDA's MAUDE database, Doc. 37 at ¶ 29, or through some other professional channel, and that they would have advised her accordingly.

Finally, because the court concludes that Catherine's claims are viable to this extent, 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. The other claims are dismissed. Given the substantial overlap between the claims the court dismissed in its earlier opinion and those brought in the amended complaint, the dismissal is with prejudice. *See Bausch*, 630 F.3d at 562 ("Generally, if

a district court dismisses for failure to state a claim, the court should give the party one opportunity to try to cure the problem … .").

June 12, 2018

United States District Judge