Gravitt et al v. Mentor Worldwide, LLC Doc. 382


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

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

**MEMORANDUM OPINION AND ORDER**

Catherine and Travis Gravitt, a married couple, brought this suit in state court against Mentor Worldwide, LLC, the manufacturer of a silicone breast implant called MemoryGel. Doc. 1. Mentor removed the suit to federal court, *ibid*., and the court granted in part Mentor's motion to dismiss, Doc. 38, leaving Catherine with a state law failure to warn claim and Travis with a loss of consortium claim. Docs. 32-33 (reported at 289 F. Supp. 3d 877 (N.D. Ill. 2018)); Docs. 70-71 (reported at 2018 WL 2933609 (N.D. Ill. June 12, 2018)). With discovery completed, Mentor moves for summary judgment. Doc. 338. The motion is granted.

**Background**

The court recites the facts as favorably to Plaintiffs as the record and Local Rule 56.1 allow. *See Johnson v. Advoc. Health & Hosps. Corp.*, 892 F.3d 887, 893 (7th Cir. 2018). At this juncture, the court must assume the truth of those facts, but does not vouch for them. *See Gates v. Bd. of Educ. of Chi.*, 916 F.3d 631, 633 (7th Cir. 2019).

Mentor manufactures MemoryGel, a breast implant made of silicone gel. Doc. 362-18 at p. 5, ¶ 3. The Food and Drug Administration ("FDA") classifies breast implants as Class III medical devices, a designation that requires a manufacturer to obtain premarket approval before



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marketing the device to the public. *See* 21 U.S.C. § 360e(a); 21 C.F.R. § 878.3530. In 2003, Mentor applied to the FDA for premarket approval of its MemoryGel implants. Doc. 362-18 at p. 20, ¶ 1. In November 2006, the FDA approved MemoryGel as a Class III medical device. *Id*. at p. 20, ¶ 2.

Both before and after receiving premarket approval, Mentor was required to report to the FDA complaints of certain adverse health outcomes associated with MemoryGel. *Id*. at pp. 20-21, ¶¶ 4-6. Before premarket approval, the agency permitted Mentor to make those reports through the Alternative Summary Reporting ("ASR") program. *Id*. at p. 20, ¶ 4; Doc. 339 at 7; Doc. 340-21 at 2. After premarket approval, the FDA designed the Postmarket Spreadsheet Reporting ("PSR") program, Doc. 362-18 at p. 21, ¶ 5, and, in March 2007, the agency gave Mentor permission to report certain adverse events through the PSR program, *id*. at p. 21, ¶ 6. But even after premarket approval, certain adverse health outcomes associated with devices implanted prior to approval remained subject to ASR reporting. *Ibid*.

The ASR and PSR reporting programs were exemptions from the standard FDA adverse health outcome reporting requirement imposed by 21 C.F.R. § 803.50(a). *Id*. at p. 21, ¶¶ 5-6. Under § 803.50(a), reports are made monthly and (apparently) become public immediately. Doc. 240-8 at ¶ 28; Doc. 340 at ¶ 6. The ASR and PSR reports, by contrast, were made quarterly, and the FDA did not make Mentor's MemoryGel reports publicly available until 2019. Doc. 362-18 at pp. 21-22, ¶¶ 6-7.

In December 2009, Catherine received MemoryGel implants in a surgery performed by Dr. Sami Bittar. *Id*. at p. 27, ¶ 19. Dr. Bittar received with the implants a product insert data sheet summarizing the risks associated therewith, including the risk of rupture and gel bleed. *Id*. at p. 28, ¶¶ 22-23; Doc. 340-25 at 13-16, 23. The data sheet noted some literature that, though

inconclusive, supported a link between silicone breast implants and connective tissue disease and symptoms, including fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Doc. 340-25 at 20-21. The data sheet further explained that some women with breast implants have complained of neurological symptoms such as weakening muscle strength and difficulty thinking or remembering things, though it noted that a scientific expert panel had found insufficient evidence of a causal connection. *Id*. at 22. Catherine concedes that Dr. Bittar warned her prior to surgery of the risk of rupture, though she does not recall if the doctor warned her of all the risks associated with MemoryGel implants. Doc. 362-18 at p. 27, ¶¶ 20-21.

After receiving her implants, Catherine began experiencing new or worsening autoimmune type symptoms, including thyroid conditions, celiac disease type intolerance to foods, rashes, pain, swelling, discomfort, worsening anxiety and depression, muscle soreness, memory loss, and declining memory function. *Id*. at p. 19, ¶ 39. In 2016, an ultrasound and MRI revealed that one of the implants had ruptured. *Id*. at p. 29, ¶ 24. In October of that year, Catherine's implants were removed in a surgery performed by Dr. Florence Mussat. *Ibid*.

**Discussion**

As the court explained in its opinion granting in part Mentor's motion to dismiss, federal law limits the state law claims that a plaintiff may pursue for injuries allegedly caused by a Class III medical device. 2018 WL 2933609, at *4. Under 21 U.S.C. § 360k(a)(1), state law claims are expressly preempted "to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (quoting 21 U.S.C. § 360k(a)(1)); *see also Bausch v. Stryker Corp.*, 630 F.3d 546, 550 (7th Cir. 2010) ("[L]awsuits brought under state law against medical device manufacturers who obtain the

full federal 'premarket approval' are preempted by section 360k(a) when liability is premised on violations of state law requirements that are in addition to or different from federal requirements regulating the devices."). And as the Supreme Court held in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), state law claims are impliedly preempted to the extent that they are "fraud-on-the-FDA" claims rather than traditional state law torts. *See Bausch*, 630 F.3d at 556-57.

The upshot of these preemption principles is that a plaintiff may sue under state law for an injury caused by a Class III medical device only when the injury results from the violation of a federal requirement that is parallel to the pertinent state law requirement. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495 (1996) ("Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."); *Bausch*, 630 F.3d at 550 (holding that state law is not preempted "where the [plaintiff] can prove that she was hurt by the manufacturer's violation of federal law") (emphasis removed). Here, preemption left Catherine with only the claim that Mentor violated its state law duty to warn by concealing MemoryGel's true risk of rupture or gel bleed. 2018 WL 2933609, at *8, *11. As the court explained, that claim "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." *Id*. at *9. And, as noted, that claim requires Catherine to show that Mentor violated a parallel federal requirement, causing her injuries. *See Medtronic*, 518 U.S. at 495; *Bausch*, 630 F.3d at 550.

To forestall summary judgment, Catherine must offer evidence that Mentor violated a federal requirement by underreporting to the FDA MemoryGel's risk of rupture or gel bleed and that the violation caused her injuries. She has not done so. During discovery, Mentor produced

the quarterly ASR and PSR summary reports regarding implant rupture and gel bleed that it had submitted to the FDA. Doc. 339 at 8; Doc. 362-18 at pp. 23-24, ¶¶ 10-12. Catherine also requested, and Mentor produced, all individual files for complaints involving rupture or gel bleed that it had received in 2009. Doc. 362-18 at p. 23, ¶ 11; *see* Doc. 162 at 1-2 (noting the parties' agreement to the court's proposal that Catherine select a calendar year; that Mentor produce all individual complaint files from that year; and that if Catherine showed that Mentor's aggregate data and summary reports for that year inaccurately reflected in a material way the underlying data from the individual complaint files, Catherine could seek additional years of individual complaint reports); Doc. 299 (reported at 2021 WL 5564862 (N.D. Ill. Nov. 29, 2021)) (addressing the history of Mentor's production of aggregate rupture, leakage, and gel bleed data from several years and the individual complaint files from 2009).

An analysis of the individual complaint files performed by Catherine's expert showed that Mentor reported 98.6% of the complaints therein to the FDA via the ASR and PSR reporting programs. Doc. 240 at 4; Doc. 240-8 at ¶ 29; Doc. 339 at 8. Mentor maintains, and Catherine does not dispute, that this is insufficient to show that any underreporting of rupture or gel bleed caused her injuries. Doc. 339 at 8, 15; Doc. 369 at 3-4. Catherine thereby forfeited any argument that Mentor materially underreported MemoryGel's rate of rupture or gel bleed, or that any such underreporting caused her injuries. *See Bonte v. U.S. Bank, N.A.*, 624 F.3d 461, 466 (7th Cir. 2010) ("Failure to respond to an argument … results in waiver."). For that reason alone, Catherine's claim cannot survive summary judgment.

An argument that Catherine does press is that Mentor underreported the adverse health *consequences*—such as the autoimmune symptoms she suffered—associated with gel bleed or rupture. Doc. 362-17 at 8. And she further argued at the motion hearing, Doc. 380, that

underreporting such events is tantamount to underreporting instances of gel bleed itself because complaints of autoimmune symptoms may indicate gel bleed even if a patient is not aware of it. (As to this argument, Catherine distinguishes gel bleed from rupture.)

Catherine's submissions lack merit. Her position conflates gel bleed, on the one hand, with health consequences that may follow from gel bleed, on the other. Yet the rate at which MemoryGel may release toxins into the body—due to gel bleed or otherwise—is not the same as the potential health consequences that may follow. The court's opinion granting in part Mentor's motion to dismiss made clear that Catherine's surviving claim relates to alleged underreporting of rupture or gel bleed, not the health consequences thereof. 2018 WL 2933609, at *8-11. To be sure, the claim allows Catherine to argue that such consequences are injuries that result from Mentor's alleged underreporting, but, as far as Mentor's reporting obligations go, the claim concerns rupture and gel bleed. Discovery proceeded accordingly, centering on Mentor's reporting of complaints of gel bleed or rupture. *E.g.*, Doc. 162 at 1-2; Doc. 299.

Even if Catherine's claim were broad enough to encompass the allegation that Mentor underreported the adverse health consequences of gel bleed, it still would not survive summary judgment. The reason rests on the timing of Catherine's surgeries relative to the FDA's public release of Mentor's ASR and PSR reporting. As noted, it was not until 2019 that the FDA made public the ASR and PSR reports that Mentor submitted to the agency. Doc. 362-18 at p. 22, ¶ 7. Catherine received her MemoryGel implants in 2009, *id*. at p. 18, ¶ 38, and she had them removed in 2016, *id*. at p. 29, ¶ 24. Because the ASR and PSR reporting was not made public until well after both surgeries, any underreporting by Mentor of adverse health consequences associated with gel bleed could not have affected her healthcare decisions as to the implants.

Seeking to undermine this line of reasoning, Catherine contends that the ASR and PSR exemptions from the FDA's ordinary reporting requirements under 21 C.F.R. § 803.50(a) did not cover reporting of autoimmune symptoms like those she experienced. Catherine maintains that the ASR exemption was limited to certain product codes—"FTR," "FWM," and "LCJ," according to the document she cites—that she says do not include MemoryGel. Doc. 362-17 at 6; Doc. 340-21 at 5. Catherine further maintains that the PSR exemption did not apply to the autoimmune symptoms that she suffered. Doc. 362-17 at 6-7. Without the ASR and PSR exemptions, the argument continues, Mentor's duty to report such symptoms was subject to § 803.50(a), which requires a medical device manufacturer to report to the FDA information "that reasonably suggests that a device that [it] market[s] … [m]ay have caused or contributed to a death or serious injury." 21 C.F.R. § 803.50(a). And reports made under § 803.50(a), unlike Mentor's ASR or PSR reports, apparently would have been made public immediately. (Catherine also argues that Mentor had additional reporting duties under 21 U.S.C. § 360i(a). Doc. 362-17 at 5. But that statute merely provides in relevant part that the Secretary of Health and Human Services may prescribe regulations like § 803.50(a).)

Catherine's view that the ASR and PSR exemptions did not cover Mentor's pertinent reporting obligations lacks support. The record indicates that MemoryGel is coded as "FTR," Doc. 340-2 at 2, which, as noted, was among the codes covered by the ASR exemption, Doc. 340-21 at 5. The record also shows that the FDA letter approving MemoryGel for the PSR exemption included four exceptions for which reporting remained subject to § 803.50(a). Doc. 340-23 at 2, 4. Catherine, however, does not explain how those exceptions might include the autoimmune symptoms she suffered, nor can the court discern how that might be so. *Id*. at 4. Accordingly, because the ASR and PSR exemptions governed Mentor's duty to report

autoimmune symptoms, and because the FDA did not make public those reports until 2019, any underreporting of those symptoms could not have caused Catherine's injuries. (The FDA approved MemoryGel in November 2006 and did not approve the product for the PSR exemption until March 2007, Doc. 362-18 at pp. 20-21, ¶¶ 2, 6, but Catherine does not submit that any underreporting in that four-month gap caused her injuries.)

It is theoretically possible that the FDA would have earlier made public the ASR and PSR reports had Mentor reported autoimmune symptoms at higher rates. That is, a greater number of reports from Mentor may have alerted the FDA to a higher risk of autoimmune symptoms, thereby prompting the agency to publicly release those reports more quickly. But Catherine does not make that argument, thereby forfeiting it. *See Nichols v. Mich. City Plant Plan. Dep't*, 755 F.3d 594, 600 (7th Cir. 2014) ("The non-moving party waives any arguments that were not raised in its response to the moving party's motion for summary judgment.").

Even putting aside forfeiture, the argument would fail. To prove that Mentor violated a federal reporting requirement—whether set forth in the ASR program, the PSR program, or 21 C.F.R. § 803.50(a)—Catherine points chiefly to evidence that Mentor repeatedly revised its internal policies regarding when to report autoimmune symptom events to the FDA. Doc. 362-17 at 7, 11. For example, for at least some time between 2015 and 2017, Mentor did not report certain autoimmune symptoms unless they were first confirmed by a medical provider. *Id*. at 11; Doc. 362-18 at p. 15, ¶ 33. That Mentor changed its reporting *policies*, however, is not itself evidence of actual *underreporting*, nor does it reasonably support an inference of actual underreporting.

Catherine also points to a Mentor internal presentation from July 2017 indicating that the company's reporting had been "inconsistent" over the preceding two years. Doc. 362-15 at 5-6;

Doc. 362-17 at 11. Due to Mentor's reporting policies, including its policy that complaints be confirmed by a physician, only 81 of 195 autoimmune-related complaints had been reported to the FDA in that two-year period. Doc. 362-15 at 5-6. According to Mentor's presentation, the 114 previously unreported complaints would be included retroactively in Mentor's next ASR and PSR reports. *Ibid*. That evidence likewise fails to establish a violation of Mentor's reporting obligations. The record reveals no details about the unreported complaints, so there is no basis to conclude that they rose to the level of "death or serious injury," or whether the information available to Mentor "reasonably suggest[ed]" that MemoryGel was the cause of the injuries, for purposes of the reporting obligation imposed by § 803.50(a). In short, the fact that Mentor made some reports retroactively does not permit the conclusion that failing to make those reports earlier in fact violated any federal requirement.

Even presupposing a federal violation, there is insufficient evidence to prove that the violation caused Catherine's injuries. Illinois law adopts the learned intermediary doctrine, under which a medical device manufacturer has a duty to warn a patient's healthcare professional, rather than the patient herself, of risks associated with the device. *See Walton v. Bayer Corp.*, 643 F.3d 994, 999-1000 (7th Cir. 2011) ("[T]he [learned intermediary] doctrine excuses the manufacturer of a prescription drug from having to warn consumers of the drug's adverse side effects; it need warn only physicians, so that armed with the warning they can make a medical decision to prescribe or not to prescribe the drug for a particular patient."); *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002) ("The duty to warn the health-care professional, rather than the ultimate consumer or patient, is an expression of the 'learned intermediary' doctrine."); *Aquino v. C.R. Bard, Inc.*, 413 F. Supp. 3d 770, 789 (N.D. Ill. 2019) ("[U]nder the learned-intermediary doctrine, a manufacturer has no duty to warn patients directly

of the risks of prescription medical products so long as it provides sufficient warnings to the physician."). To prove causation, then, Catherine must adduce evidence that Mentor's (supposed) underreporting to the FDA deprived her physicians of information that they would have used to prevent or mitigate her injuries. *See In re Zimmer, NexGen Knee Implant Prods. Liab. Litig.*, 884 F.3d 746, 753-54 (7th Cir. 2018) (Wisconsin law) (holding that the learned intermediary doctrine demands evidence that an adequate warning would have been read and heeded by a physician).

The record does not include such evidence. For one thing, there is no basis to conclude that the FDA would have more quickly made public the ASR and PSR reports had Mentor disclosed the 114 previously unreported complaints earlier. Indeed, although it appears that Mentor retroactively made those 114 reports in 2017, the FDA did not publicly release them until 2019.

Additionally, Catherine does not dispute that the MemoryGel product insert data sheet made available to Dr. Bittar, the surgeon who performed the implant surgery, noted some literature supporting the possibility that silicone implants could cause autoimmune symptoms like those she suffered. And Catherine argues affirmatively that publicly available research predating her implant surgery supported a link between silicone implants and those symptoms. Doc. 362-17 at 10; Doc. 362-18 at p. 2-4, ¶¶ 1-2. Given the information available to Dr. Bittar and Catherine's other physicians, to find that increased, earlier reporting by Mentor would have prevented or mitigated her injuries would require an unrealistically speculative causal chain. A jury would need to find that: (1) increased, earlier reporting by Mentor would have caused the FDA to more quickly make public the ASR and PSR reports; (2) such data, if made public more quickly, would have reached Catherine's physicians; and (3) those physicians would have

mitigated Catherine's injuries by advising her to remove the implants prior to October 2016, when she ultimately had them removed. A theory of causation based on such a speculative series of events is insufficient to preclude summary judgment. *See Jokich v. Rush Univ. Med. Ctr.*, 42 F.4th 626, 635 (7th Cir. 2022) (rejecting a theory of causation at summary judgment resting on an "improbable series of events").

The causation analysis could stop there, but it bears mention that Catherine offers no evidence from her physicians—in the form of an affidavit, deposition, or otherwise—as to what they would have recommended had they been made aware earlier of Mentor's ASR and PSR reports. Catherine's failure in this respect underscores the lack of evidence supporting any feasible causal chain between Mentor's alleged underreporting and her injuries. *See Blackwell v. C.R. Bard, Inc.*, 2021 WL 2355393, at *5 (N.D. Tex. June 9, 2021) (rejecting a failure to warn claim where there was no evidence from the plaintiff's physician regarding whether he actually encountered allegedly inadequate warnings); *May v. Ethicon, Inc.*, 2020 WL 674357, at *4 (N.D. Ga. Feb. 11, 2020) ("The Plaintiffs cannot establish the necessary elements of their failure to warn claim without any evidence indicating how the implanting physician—to whom the duty to warn was owed—responded to the Defendants' warning or how he might have responded to some different, more comprehensive warning."); *Contreras v. Bos. Sci. Corp.*, 2016 WL 1436682, at *3-4 (S.D. W. Va. Apr. 11, 2016) (rejecting a failure to warn claim where there was no evidence from the plaintiff's physician as to the course she would have taken had she been given an adequate warning); *Thompson v. Zimmer Inc.*, 2013 WL 5406628, at *3 (D. Minn. Sept. 25, 2013) (similar).

That leaves Travis's loss of consortium claim. That claim cannot survive summary judgment because it is entirely derivative of Catherine's claim. *See McCreary v. Libbey-Owens-*

*Ford Co.*, 132 F.3d 1159, 1167 (7th Cir. 1997) ("[A] claim for loss of consortium is derivative in nature and its viability depends upon the validity of the injured spouse's claims.") (Indiana law) (internal quotation marks omitted); *Allender v. Guardian Life Ins. Co. of Am.*, 592 F. Supp. 541, 544 (N.D. Ill. 1984) (granting summary judgment on a loss of consortium claim "[b]ecause loss of consortium claims are derivative in nature and require that the defendant be liable for the injuries to the person whose spouse brings the action").

**Conclusion**

Mentor's summary judgment motion is granted. Both sides' motions under Evidence Rule 702 to exclude each other's experts, Docs. 337, 341-345, 347, 349, 351-352, are denied as moot, as none implicates the grounds on which summary judgment is granted. Mentor's motion to strike portions of Plaintiffs' Local Rule 56.1(b)(3) statement, Doc. 368, and Plaintiffs' motion for leave to reply to Mentor's Local Rule 56.1(c)(2) response, Doc. 378, likewise do not bear on the summary judgment analysis, and they are denied as moot as well. Judgment will be entered in favor of Mentor and against Plaintiffs.

December 14, 2022

United States District Judge