



to treat her pelvic organ prolapse. Cutter alleges that the Prolift implant caused various physical injuries and resulting emotional damages.<sup>1</sup>

On January 9, 2020, the Court entered summary judgment in favor of the defendants on fourteen of the eighteen counts asserted in the operative Second Amended Short Form Complaint. [Record Nos. 27 and 148] The Court found that the negligence claims were barred by the statute of limitations but determined that the NIED claim was subject to a different and longer limitations period. [*Id.* at pp. 8-14, 22-23] Cutter's failure to warn products liability claim was dismissed on statute of limitations grounds, but the Court also found that it failed because the plaintiff could not demonstrate that any inadequate warning about the Prolift was the proximate cause of her alleged injuries. [*Id.* at pp. 8-17] After the initial summary judgment motion was resolved, the plaintiff maintained claims for NIED, fraud by omission, "violation of consumer protection laws," and unjust enrichment. [*Id.*] The Court subsequently issued an April 29, 2020, opinion regarding certain *Daubert* motions that were not resolved prior to the case's remand from the MDL. [Record No. 155]

The parties thereafter filed a joint motion for a continuance of trial and entry of a briefing schedule for a supplementary summary judgment motion. [Record No. 161] In this motion, the plaintiff indicated that she would not pursue her consumer protection and unjust enrichment claims. [*Id.*] On June 10, 2020, the Court granted the motion, dismissed those two claims, and set a briefing schedule for the supplementary summary judgment motion. [Record No. 164] The defendants subsequently filed the pending motion arguing that they are entitled

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<sup>1</sup> The Court's initial January 9, 2020, Summary Judgment Memorandum Opinion and Order provides a comprehensive recitation of the material facts underlying Cutter's claims. [Record No. 148] Additionally, the analysis portion of that opinion will include citations to evidence in the record.

to judgment as a matter of law on the remaining NIED and fraud by omission claims. [Record No. 165] The matter is now ripe for consideration.

## **II. Standard of Review**

“Summary judgment is appropriate when no genuine dispute of material fact exists and the moving party is entitled to judgment as a matter of law.” *I.L. by and through Taylor v. Tenn. Dep’t of Educ.*, 739 Fed. App’x 319, 321 (6th Cir. 2018) (citing Fed. R. Civ. P. 56(a)). The moving party initially bears the burden of “pointing out” that “there is an absence of evidence to support the nonmoving party’s case.” *Celotex Corp. v. Catrett*, 477 U.S. 317, 325 (1986). “Once the movant meets the initial burden, the opposing party must set forth specific facts showing that there is a genuine issue for trial.” *McLaughlin v. Fifth Third Bank, Inc.*, 772 F. App’x 300, 302 (6th Cir. 2019) (citing Fed. R. Civ. P. 56(e)). “The mere existence of a scintilla of evidence in support of the [nonmovant’s] position will be insufficient; there must be evidence on which the jury could reasonably find for the [nonmovant].” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 252 (1986). The Court views all evidence in the light most favorable to the nonmoving party. *McLaughlin*, 772 F. App’x at 302 (citing *Anderson*, 477 U.S. at 252).

## **III. Analysis**

### **A. Negligent Infliction of Emotional Distress**

#### **i. The *Osborne* Standard and *Demetre*’s Parasitic Claim Exception**

The defendants first contend that summary judgment is appropriate on the NIED claim. Ethicon generally argues that, in Kentucky, NIED claims require expert testimony regarding a plaintiff’s sustained emotional injuries and that the plaintiff lacks such evidence. [Record No. 165, pp. 4-6] In *Osborne v. Keeney*, 399 S.W.3d 1, 17 (Ky. 2012), the Supreme Court of Kentucky held that in addition to producing evidence of the elements of a common law

negligence claim, a plaintiff asserting a claim for emotional distress must prove that her injury is “severe” or “serious.” “A ‘serious’ or ‘severe’ emotional injury occurs where a reasonable person, normally constituted, would not be expected to endure the mental stress engendered by the circumstances of the case.” *Id.* (citation omitted). The court further held that “a plaintiff claiming emotional distress damages must present expert medical or scientific proof to support the claimed injury or impairment.” *Id.* at 17-18 (citation omitted).

Later, in *Indiana Ins. Co. v. Demetre*, 527 S.W.3d 12 (Ky. 2017), the Supreme Court of Kentucky held that *Osborne’s* expert testimony requirement “is limited to *claims* of intentional infliction of emotional distress or negligent infliction of emotional distress.” *Id.* at 39 (emphasis added). The court continued:

Our conclusion is due in part to the recognition that claims for emotional damages grounded in breach of contract or violation of statute, such as those alleged by Demetre in the case at bar, are less likely to be fraudulent than those advanced under a free-standing claim of intentional or negligent infliction of emotional distress. To evaluate whether emotional damages are appropriate in those cases that do not allege the free-standing torts of intentional or negligent infliction of emotional distress, we have historically relied on our trial courts and the jury system to evaluate the evidence and determine the merits of the alleged claims . . . . We see no compelling reason to depart from this view.

*Id.* (internal citations omitted). In other words, *Osborne’s* heightened expert testimony standard applies only where a plaintiff asserts a free-standing negligent (or intentional) infliction of emotional distress *claim* and not a different cause of action through which a plaintiff alleges emotional *damages*. *Id.*; see also *Hall v. Rag-O-Rama, LLC*, No. 18-12-DLB-CJS, 2020 WL 2134121, at \*20 n. 28 (explaining *Demetre’s* holding).

Cutter argues that she does not assert a free-standing NIED claim that is subject to the heightened standard under *Osborne* and *Demetre*, but rather a claim for emotional damages that are parasitic consequences of Ethicon’s otherwise tortious behavior. [Record No. 167, pp.

4-5] The plaintiff bases her argument on *Osborne* and *Demetre*'s reliance on a line of Tennessee cases that explain the circumstances in which a heightened standard should be applied. See *Estate of Amos v. Vanderbilt Univ.*, 62 S.W.3d 133 (Tenn. 2001); *Camper v. Minor*, 915 S.W.2d 437 (Tenn. 1996). Specifically, Cutter emphasizes that the *Demetre* court was persuaded by *Amos*'s conclusion that “[w]hen emotional damages are a ‘parasitic’ consequence of negligent conduct that results in multiple types of damages, there is no need to impose special pleading or proof requirements that apply to ‘stand-alone’ emotional distress claims.” *Demetre*, 527 S.W.3d at 38 (quoting *Amos*, 62 S.W.3d at 137). Cutter insists that the same parasitic claim exception to *Osborne* applies in this case.<sup>2</sup>

To accept the plaintiff's argument regarding the heightened standard would be to ignore the realities of this case. The operative Second Amended Short Form Complaint pleads a separate NIED count in addition to, *inter alia*, various counts of negligence, gross negligence, and products liability claims. [Record No. 27] Unlike her claim for punitive damages, the pleading does not indicate that the NIED claim pertained only to *damages* parasitic on her other claims. [*Id.*]

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<sup>2</sup> Cutter notes that *Demetre* involved a bad faith insurance claim and notes that the Supreme Court of Kentucky has not yet applied this parasitic claim exception to the circumstances of this case. [Record No. 167, p. 5] The plaintiff requests that the Court certify the question of whether the parasitic claim exception applies here if the Court is not convinced that it does. [*Id.*] “[A] district court should not certify a question of state law if it has ‘a reasonably clear and principled course’ to follow . . . because federal courts ‘generally will not trouble . . . sister state courts every time an arguably unsettled question of state law comes across [their] desks.’” *Ellis v. Arrowood Indem. Co.*, No. 12-140-ART, 2014 WL 12650948, at \*1 (E.D. Ky. Sept. 23, 2014) (quoting *Pennington v. State Farm Mut. Auto. Ins. Co.*, 553 F.3d 447, 450 (6th Cir. 2009)). Because the posture of this case and the nature of Cutter's claim indicate that the heightened standard applies, there is no need to certify the question.

And importantly, the NIED claim's survival of the initial summary judgment motion was premised on the idea that it was pleaded as a free-standing claim with a different limitations period than the other negligence-based claims that were dismissed on statute of limitations grounds. [Record No. 148, pp. 22-23] If the Court had merely construed it as a parasitic request for damages, it would no longer exist as a separate cause of action on which relief could be granted, and the plaintiff would now only maintain a fraud by omission claim. The plaintiff does not acknowledge this point. Instead, she essentially asks that the Court not apply the heightened standard reserved for free-standing NIED claims but treat the NIED claim as a separate ground for relief in all other regards.

Relatedly, *Demetre* assumes that its exception will apply when a plaintiff asserts a different free-standing claim stemming from the same specific conduct that caused the alleged emotional injuries – this is why an otherwise separate NIED claim can be construed as a parasitic claim for emotional damages. Here, the plaintiff does not identify any other specific claim on which an award of emotional damages would be parasitic if the Court did not consider it a free-standing count. As *Ethicon* notes, *Cutter* does not explain how it would be parasitic on the remaining fraud by omission claim. [Record No. 168, pp. 2-3, n. 1] And as the defendants also point out, the other negligence-based claims have been dismissed on summary judgment. [Record Nos. 148 and 168, pp. 2-3 n. 1] The plaintiff's position regarding the exception to *Osborne's* heightened standard might be persuasive if she provided some argument justifying how an emotional damages allegation is parasitic on another specific claim, but the Court declines to consider it parasitic on some other amorphous (likely negligent) allegation of tortious conduct.

Thus, the Court concludes that *Osborne*'s heightened evidentiary standard applies to the free-standing NIED claim that remains in this case. The analysis will proceed with the understanding that Cutter must provide expert medical or scientific evidence of a severe or serious emotional injury.

**ii. Application of *Osborne*: Failure to Provide the Requisite Expert Testimony**

The defendants assert that the plaintiff lacks the evidence required under *Osborne* to prove a NIED claim, contending, *inter alia*, that Cutter cannot provide the requisite expert testimony that her alleged emotional injuries are sufficiently severe or serious. [Record Nos. 165, pp. 4-6 and 168, pp. 3-6] Cutter primarily asserts that the caselaw on Kentucky NIED claims indicates “medical records, particularly evidence of a prescription drug to treat emotional damages, [are] sufficient to support a claim of NIED” and that her medical records demonstrate that the implanted Prolift device caused her severe emotional injuries. [Record No. 167, p. 7] The plaintiff also states that her retained and non-retained experts can discuss the severity of her emotional injuries and satisfy *Osborne*'s requirements. [*Id.* at p. 8]

At the onset, there appears to be some confusion over whether *Osborne* always requires expert testimony or merely some significant medical or scientific evidence of severe emotional injury. To be sure, *Osborne* itself is not particularly clear on this issue. At various points, the opinion states: (1) “a plaintiff will not be allowed to recover without showing, by expert *or* scientific proof, that the claimed emotional injury is severe or serious;” (2) “[p]ut simply, a plaintiff must show that the defendant was negligent and that the plaintiff suffered mental stress or an emotional injury, *acknowledged by medical or scientific experts*, that is greater than a reasonable person could be expected to endure given the circumstances;” (3) “a plaintiff claiming emotional distress damages must present *expert medical or scientific proof*

to support the claimed injury or impairment;” and (4) “[a] plaintiff claiming emotional distress must satisfy the elements of a general negligence claim, as well as show a severe or serious emotional injury, *supported by expert evidence.*” *Osborne*, 399 S.W.3d at 6, 17-18, 23 (emphasis added). The first phrase indicates that expert or scientific proof is sufficient, the second and fourth phrases indicate that expert evidence (either medical or scientific in nature) is required, and the third phrase is ambiguous.

Against this backdrop, the United States Court of Appeals for the Sixth Circuit has broadly interpreted *Osborne* to require expert testimony for NIED claims. *Gregory v. Burnett*, 577 F. App’x 512, 520 (6th Cir. 2014) (“Gregory did not present expert testimony supporting his claimed emotional damages as Kentucky law requires, and therefore his [negligent] infliction-of-emotional-distress claim was properly dismissed.”). And more significantly, the Supreme Court of Kentucky interprets the rule the same way. In its 2017 *Demetre* decision, the court variably refers to the rule as “*Osborne*’s heightened proof requirement – expert testimony regarding severe emotional distress,” “*Osborne*’s heightened requirement of expert testimony,” “the expert-testimony requirement,” “the requirement of expert testimony,” “*Osborne*’s expert proof requirement,” and “*Osborne*’s expert requirement.” *Demetre*, 527 S.W.3d at 35, 36, 36 n. 26, 37 n. 28, 37-38. Thus, the Court will proceed with the understanding that the plaintiff must produce expert evidence regarding severe emotional injuries to maintain her NIED claim.<sup>3</sup>

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<sup>3</sup> The plaintiff’s argument that her medical records alone may be sufficient to prove a NIED claim without expert testimony relies primarily on the Court’s decision in *Mitchell v. Mike*, No. 5: 14-301-DCR, 2015 WL 6675549, at \*4-5 (E.D. Ky. Oct. 30, 2015). On this point, the Court makes an important observation. That case was decided prior to the 2017 decision in *Demetre*, the only other opinion from the Supreme Court of Kentucky to squarely discuss the application of *Osborne*’s rule. As noted above, the rule was ambiguous prior to *Demetre*,



Ethicon argues that the experts who have been disclosed cannot provide the requisite testimony regarding severe emotional conditions. Specifically, the defendants state that the retained case-specific experts Dr. Bruce Rosenzweig and Dr. Vladimir Iakovlev do not opine in their reports that the plaintiff suffered sufficiently severe or serious emotional distress as a result of Ethicon's negligence. [Record No. 165, p. 5]

Rosenzweig's report includes a summary of Cutter's medical history and notes the following: (1) Cutter complained of depression in 2004 (prior to the implant procedure); (2) Guiler diagnosed her with depression in 2008; and (3) APRN Cheryl Lewis diagnosed her with situational mixed anxiety and depressive disorder in 2014 and 2015. [Record No. 165-2, pp. 5, 7, 19] Rosenzweig conducted a physical examination of the plaintiff but did not note or diagnose her with any emotional or psychological disorders. [*Id.* at pp. 20-24] The opinions contained in Rosenzweig's report include conclusions regarding: (1) the Prolift device's role in causing various physical injuries; (2) the prognoses of these physical injuries; and (3) the plaintiff's ability to offer informed consent to the Prolift. [*Id.* at pp. 23-28]

Iakovlev's report nondescriptly mentions that Cutter had depression and anxiety in her medical history. [Record No. 165-3, p. 3] The opinions contained in this report include pathological findings relating to samples of the Prolift implanted in Cutter and clinicopathological findings regarding the Prolift's effect on the plaintiff's physical condition. [*Id.* at pp. 11-17]

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in no small part due to the language of the *Osborne* opinion itself. However, it is now evident that a plaintiff may only successfully maintain a NIED claim under Kentucky law if she produces expert testimony (either medical or scientific in nature) about the severity of her emotional injuries.

The Court agrees that these retained medical experts cannot opine on the severity of the alleged emotional injuries. While these reports make fleeting mentions of the plaintiff's mental health history, they do not offer any opinions regarding the severity of Cutter's alleged emotional injuries. And if these retained experts were intended to opine about such issues, they should have disclosed such opinions under Rule 26(a)(2)(B)(i) of the Federal Rules of Civil Procedure. They cannot simply, as the plaintiff vaguely contends, take the stand to testify about the physical impairment issues they were actually retained to discuss and tangentially opine about alleged emotional injuries. *See* Fed. R. Civ. P. 37(c)(1).

The defendants also dispute the plaintiff's claim that non-retained treating provider experts can testify about the severity of Cutter's emotional condition. [Record Nos. 165, pp. 5-6 and 168, pp. 4-5] They point to the plaintiff's non-retained expert disclosures [Record No. 165-1, pp. 5-7] and argue that the barebones descriptions of these treating providers do not contain any information about the substance of their testimony as required by Rule 26(a)(2)(C) of the Federal Rules of Civil Procedure, let alone indications that these experts would opine about Cutter's allegedly severe emotional distress. [Record Nos. 165, pp. 5-6 and 168, pp. 4-5] Ethicon contends that because the testimony of these non-retained treating provider experts would be excluded from trial, Cutter cannot provide the expert testimony required of a NIED claim. [Record No. 165, pp. 5-6]

Again, the Court agrees with Ethicon. When expert witnesses are not required to provide a written report, the party disclosing them must nonetheless "state the subject matter, facts, and opinions to which the expert witness is expected to testify." *Blair v. GEICO Gen. Ins. Co.*, 917 F. Supp. 2d 647, 655 (E.D. Ky. 2013) (citing Fed. R. Civ. P. 26(a)(2)(C)). The "automatic and mandatory" sanction for failing to do so is exclusion of such testimony under

Rule 37(c)(1) unless the sanctioned party demonstrates that the failure to do so was either “justified or harmless.” *Id.* (citing *Roberts v. Galen of Va., Inc.*, 325 F.3d 776, 782 (6th Cir. 2003)).

Guiler and Lewis (and potentially other treating healthcare providers) are non-retained expert witnesses who could, conceivably, testify about the severity of the alleged emotional injuries suffered by the plaintiff because they have documented her conditions while treating her. But while they are listed on the May 5, 2016 disclosure of expert witnesses, that disclosure offers no information about their testimony apart from their names, addresses, and general medical specialties. [Record No. 165-1, pp. 5-7] There is no information in this disclosure about the subject matter, facts, or opinions to which these witnesses are expected to testify. Ethicon placed the plaintiff on notice of the deficiency of the non-retained expert disclosure in the pending motion, and Cutter has not offered any explanation for the disclosure’s deficiency other than the conclusory statement that treating healthcare providers will testify about their treatment of Cutter and the contents of her medical records. The plaintiff has made no actual attempt to establish that the failure to disclose information about the substance of the expert testimony was substantially justified or harmless, and the Court agrees with the defendants that any non-retained experts could not testify regarding the severity of alleged emotional or psychological injuries.

As *Osborne*’s heightened expert testimony standard applies to the free-standing claim and Cutter has ostensibly failed to offer any experts who could testify about the severity of the alleged emotional injuries, she cannot obtain relief on her Kentucky law NIED claim. Accordingly, the defendants are entitled to summary judgment on this count.

## **B. Fraud by Omission**

To succeed on a fraud by omission claim in Kentucky, “a plaintiff must prove: ‘(1) the defendant had a duty to disclose the material fact at issue; (2) the defendant failed to disclose the fact; (3) the defendant’s failure to disclose the material fact induced the plaintiff to act; and (4) the plaintiff suffered actual damages as a consequence.’” *Republic Bank & Trust Co. v. Bear Stearns & Co., Inc.*, 683 F.3d 239, 255 (6th Cir. 2012) (quoting *Giddings & Lewis, Inc. v. Indus. Risk Insurers*, 348 S.W.3d 729, 747 (Ky. 2011)). Ethicon argues that the plaintiff has failed to establish a duty to disclose and causation, *i.e.*, the inducement element. [Record No. 165, pp. 6-9] The Court will address these arguments in turn.

### **i. The Duty to Disclose**

Ethicon argues that the fraud by omission claim fails because, *inter alia*, the plaintiff has failed to establish the existence of a duty to disclose a material fact. [Record No. 165, pp. 6-8] The plaintiff, *inter alia*, contends that the defendants have failed to bear the initial summary judgment burden. [Record No. 167, p. 10]

Ethicon’s motion correctly states the four circumstances which may give rise to a duty to disclose: (1) the existence of a fiduciary relationship between parties; (2) a statute provides a duty; (3) a partial disclosure of facts by one party who has created the impression of full disclosure; and (4) “where one party to a contract has superior knowledge and is relied upon to disclose” it. [Record No. 165, pp. 6-7 (citing *Giddings*, 348 S.W.3d at 747).] Ethicon proceeds to discuss the four categories, citing various cases to demonstrate its point that the relationship between Cutter and Ethicon did not establish a duty in this case. [*Id.* at pp. 6-7]

“The moving party need not support its motion with evidence disproving the nonmoving party’s claim, but need only show – that is, point out to the district court – that

there is an absence of evidence to support the nonmoving party's case.” *Hartsel v. Keys*, 87 F.3d 795, 799 (6th Cir. 1996) (quoting *Celotex*, 477 U.S. at 325) (internal quotation marks omitted); see also *Harvey v. Campbell Cty.*, 453 F. App'x 557, 560 (6th Cir. 2011) (“[T]here is ‘no express or implied requirement in Rule 56 that the moving party support its motion with affidavits or other similar materials negating the opponent’s claim.’”) (quoting *Celotex*, 477 U.S. at 323).

Here, Ethicon did not need to offer specific evidence in support of its motion – that is the responsibility on the nonmoving party. *E.g.*, *Harvey*, 453 F. App'x at 560. But it did need to make some showing that there is an absence of evidence regarding a duty of disclosure, and the movant's argument mistakenly relies on specific caselaw to show that a “partial disclosure” duty does not apply in this case. Ethicon cites to *Morris Aviation, LLC v. Diamond Aircraft Industries, Inc.*, 3:09-CV644-S, 2012 WL 3684760, at \*5 (W.D. Ky. Aug. 27, 2012), noting that it held that there is no cause of action for partial disclosure where a plaintiff and a defendant “were not parties to a contract or transaction.” [Record No. 165, p. 7] This initially appears to be a valid assertion, as the case did contain that holding. *Morris Aviation, LLC*, 2012 WL 3684760, at \*5. However, the Sixth Circuit found this analysis erroneous on appeal and determined that, under Kentucky law, a partial disclosure duty could arise from a non-contractual relationship. *Morris Aviation, LLC v. Diamond Aircraft Industries, Inc.*, 536 F. App'x 558, 569 (6th Cir. 2013). Thus, the Court finds that the defendants have not carried the initial burden of showing that the plaintiff lacks support for a duty of disclosure.

Further, Cutter has sufficiently provided evidence of a partial disclosure. Cutter states that the defendants had “a duty to disclose information about the risks of their mesh devices . . . because they partially disclosed material facts and created the impression of full disclosure

...” [Record No. 167, p. 11] She proceeds to cite evidence from retained expert Dr. Daniel Elliott’s report (which was not excluded by this Court’s April 29, 2020 Order) documenting that the Prolift’s Instructions for Use (“IFU”), Surgical Guide, and patient information brochure failed to disclose certain known risks of the device:

[N]either the original Prolift IFU nor the Surgical Guide adequately warned of the risk of mesh contraction . . . the Prolift IFU did not report the negative consequences of mesh contraction, which were known by Ethicon, such as “vaginal anatomic distortion,” pelvic pain, vaginal pain, “negative impact on sexual function,” “difficult treatment” and “stiffness of the vagina that further impacts sexual function in a negative manner.” Instead of properly warning of these potential problems, the Prolift IFU misleadingly claimed was that “the mesh remains soft and pliable, and normal wound healing is not noticeably impaired.” The Prolift patient information brochure misleadingly stated: “[Prolift] allows for the restoration of sexual function by restoring vaginal anatomy.” Given the known high rates and amounts of shrinkage, such statements were false and misleading.

[*Id.* (citing Record No. 149-1, p. 31).] The plaintiff also makes other partial disclosure arguments about that are not particularly relevant to the existence of a duty of disclosure, but the Court finds that the Elliott-based argument sufficiently proves a duty to disclose.<sup>4</sup> [*Id.* at pp. 11-18]

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<sup>4</sup> These pieces of evidence primarily pertain to questions posed to Guiler in his depositions for this case as well as *Burton v. Ethicon, Inc.*, No. 5: 20-cv-280-DCR (E.D. Ky. 2020). At first glance, some of these deposition excerpts look like they may relate to the issue of whether Ethicon withheld material facts from doctors and/or implant patients. For example, the plaintiff includes the following question:

Is that information, the fact that the French doctors who helped develop this project as early – or this product as early as 2003 were telling Ethicon they were concerned about erosions and contraction, is that information that you would have liked to know prior to determining whether to implant the Prolift device in [Plaintiff]?

[Record No. 167, p. 14 (citing Record No. 167-4, p. 5).] However, the deposition transcript excerpts do not actually provide evidence that Ethicon partially disclosed certain material facts.

Because the Court finds that Ethicon has failed to sufficiently point out that the plaintiff cannot demonstrate a duty of disclosure and Cutter has offered support for her assertion that a partial disclosure occurred, it concludes that the plaintiff has sufficiently demonstrated a duty to disclose. Accordingly, the fraud by omission claim will not be dismissed on this basis.

## **ii. Inducement**

Finally, Ethicon contends that the fraud by omission claim should be dismissed because Cutter has failed to offer sufficient evidence of causation, *i.e.*, that the failure to disclose material facts about the Prolift device induced the plaintiff to agree to the implant. The defendants claim that: (1) the learned intermediary doctrine applies, and the plaintiff cannot demonstrate that the omission of any material fact to Guiler induced him to implant the Prolift; and (2) even if the learned intermediary rule does not rigidly apply to a fraud by omission claim, the plaintiff has nonetheless testified that she based her decision on Guiler's recommendation which would not have changed with the allegedly undisclosed facts. [Record Nos. 165, pp. 8-9 and 168, pp. 7-11] The plaintiff agrees that the learned intermediary rule applies, asserts that the warnings given to Guiler did not disclose all material facts about the risks of the Prolift, contends that Guiler has stated in the depositions that knowledge of the risks known to Ethicon in 2006 would have influenced his decision to recommend the Prolift, and states that the plaintiff testified that she would have declined the implant if she herself had known about these risks. [Record No. 167, pp. 11-20]

The learned intermediary rule is “an exception to the general rule that a manufacturer’s duty to warn of any risks or dangers inherent in the product runs to the ultimate consumer,”

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They merely serve to elicit Guiler’s testimony concerning how he would have weighed the risks of Prolift implantation had he known of what the deposing attorney claims Ethicon did.

and shifts a prescription drug or medical device manufacturer's duty to warn in products liability cases from the consumer/patient to the prescribing or implanting physician. *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 762 (Ky. 2004) (citations omitted). Its application to fraud by omission claims is not entirely clear. No Kentucky state court has ever applied it in the fraud by omission context. However, at least two federal courts have tacitly endorsed its use. *See Corder v. Ethicon*, No. 6: 19-CV-273-REW, 2020 WL 4194986, at \*7 n. 15 (E.D. Ky. July 21, 2020) ("For fraud theories premised on a duty of disclosure, the Court sees no reason why a manufacturer could not endeavor to assert the [learned intermediary] rule as a challenge to that element."); *Prather v. Abbott Labs*, 960 F. Supp. 2d 700, 716 (W.D. Ky. 2013) (granting summary judgment on, *inter alia*, a fraudulent concealment claim where the plaintiff's doctor did not rely on representations by the defendant).

And as noted, the Sixth Circuit has concluded that a contractual buyer-seller relationship is not necessary to establish a partial disclosure duty. *Morris Aviation, LLC*, 536 F. App'x at 569 (noting that "*Giddings* put no limitation on the partial-disclosure duty."). Therefore, a partial disclosure fraud by omission claim may be compatible with the learned intermediary rule because the rule presumes that plaintiffs do not negotiate with manufacturers to buy and use medical devices. *See Larkin*, 153 S.W.3d at 763. But regardless, the third element of a fraud by omission claim is inducement. *Giddings*, 348 S.W.3d at 747. And here, the record is clear that any omission of a material fact did not induce the plaintiff to agree to the Prolift implant.

The plaintiff testified that her decision to undergo the Prolift implant was based solely on the recommendation of Guiler. [Record No. 82-3, p. 20] Cutter argues that Guiler indicated in this case as well as the *Burton* case that he would have considered various undisclosed facts



about the Prolift when weighing the risks and benefits of using the device. [Record No. 167, pp. 11-21 (citing Record Nos. 167-3 and 167-4).] However, as the defendants point out, the fact that Guiler would have liked to know such information and considered it when making a recommendation is insufficient to create a dispute of material facts. [Record No. 168, p. 10] Guiler testified *in this case* that he believed the Prolift device “was safe and effective for the treatment of pelvic organ prolapse in women” even with the knowledge of alleged defects he had obtained by the time of his 2016 deposition. [Record No. 82-7, p. 1] He agreed that the Prolift had produced good clinical results for his patients prior to Cutter’s 2006 implant surgery and generally agreed that the device had improved the quality of life of his patients. [*Id.*] Further, he testified that the Prolift’s benefits outweighed its risks in 2006 despite subsequent knowledge of its alleged defects. [*Id.*]

The plaintiff does not account for this testimony, which unequivocally demonstrates that any omission or partial disclosure would not, as the plaintiff contends, materially alter Guiler’s analysis of the Prolift’s risks and benefits. There is no evidence that he would have changed his recommendation that Cutter use the Prolift with additional information, and because she relied entirely on Guiler’s professional analysis, there is similarly no evidence to support the claim that any omission induced the plaintiff to use the Prolift implant.

The plaintiff also asserts that she “testified that [the d]efendants’ failure to disclose [] risks induced her to act, in that she would not have consented to the Prolift implant had she known about these risks.” [Record No. 167, p. 11] This is not an accurate characterization of the deposition transcript excerpt Cutter cites. [Record No. 167-1, p. 51] The plaintiff actually testified that she would not have consented to the Prolift implant in 2006 “if [she] knew that [she] would experience all of the injuries that [she had] talked about [during the deposition],

the pain, the pain with sex . . . .” [*Id.*] And as the Court stated in its prior summary judgment Opinion, this statement does not change the analysis because it does not actually suggest that the plaintiff would have changed her mind with knowledge of additional undisclosed *risks*. [Record No. 148, p. 17] It merely demonstrates that she would not consent to the Prolift if she had known that she would suffer the *injuries* she has allegedly sustained since its implant. [*Id.*] The record clearly indicates that Cutter decided to undergo the implant surgery based on Guiler’s professional opinion of the risks and benefits of the device, and the actual statement cited by the plaintiff does not suggest that she would have changed her mind if she had known of all the risks herself.

In short, there is no dispute of material facts concerning the inducement element of the fraud by omission claim. Ethicon is entitled to judgment as a matter of law, and this claim will be dismissed.

#### **IV. Conclusion**

Based on the foregoing analysis and discussion, it is hereby

**ORDERED** as follows:

1. Defendants Ethicon, Inc. and Johnson & Johnson’s supplementary summary judgment motion [Record No. 165] is **GRANTED**.
2. Plaintiff Jenesta Cutter’s remaining claims are **DISMISSED**, with prejudice.
3. The trial of this action, previously scheduled to begin on **Monday, September 28, 2020**, is **CANCELED**.

Dated: August 14, 2020.



A handwritten signature in black ink, appearing to read "Danny C. Reeves".

Danny C. Reeves, Chief Judge  
United States District Court  
Eastern District of Kentucky