UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF KENTUCKY
CENTRAL DIVISION at LEXINGTON

CONNIE J. THACKER	)	
	)	
Plaintiff,	)	
	)	Case No.:
v.	)	5:20-cv-0050-JMH-MAS
	)	
ETHICON, INC., et al.,	)	
	)	
Defendants.	)	

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This matter is before the Court on Defendants' Motion for Summary Judgment [DE 159]. Plaintiff Connie J. Thacker filed suit against Defendants, Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon"), for claims arising out of the surgical implantation of Pelvic Mesh Products manufactured by Ethicon. For the reasons set forth below, Defendants' motion will be granted in full.

I. BACKGROUND

On May 8, 2009, Dr. Michael Guiler surgically implanted the TVT-Secur (TVT-S) mesh sling and Prolift posterior mesh for Ms. Thacker to treat her stress urinary incontinence and rectocele. [Second A. Short Form Complaint, DE 19 at ¶ 10-12]. After experiencing continued problems, Ms. Thacker attempted to have the devices removed. [Defendants' Separate Statement of Undisputed Facts in Support of Motion for Summary Judgment, DE 159-10 at ¶¶ 3 & 8-9, undisputed by Plaintiffs, DE 225 at 2].

Ms. Thacker alleges the TVT-Secur and Prolift devices caused pain, voiding dysfunction and urge incontinence, fecal incontinence (only a "couple" of times), and painful intercourse. [Connie J. Thacker Dep., DE 159-8 at 111:25-112:13; 115:2-18; 116:24-117:16]. Ms. Thacker brought suit in 2012 against Ethicon, the maker and seller of the device in question, alleging several counts related to the surgical implantation of the devices: Negligence (Count I), Strict Liability - Manufacturing Defect (Count II), Strict Liability - Failure to Warn (Count III), Strict Liability - Defective Product (Count IV), Strict Liability – Design Defect (Count V), Fraud (Count VI), Fraudulent Concealment (Count VII), Constructive Fraud (Count VIII), Negligent Misrepresentation (Count IX), Negligent Infliction of Emotional Distress (Count X), Breach of Express Warranty (County XI), Breach of Implied Warranty (Count XII), Violation of the Kentucky Consumer Protection Act (Count XIII), Gross Negligence (Count XIV), Unjust Enrichment (Count XV), Punitive Damages (Count XVII), Discovery Rule/ Tolling (Count XVIII).

II. DISCUSSION

A. SUMMARY JUDGMENT

"The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A "genuine dispute" exists when "a reasonable jury could return a

verdict for the non-moving party." *Olinger v. Corporation of the President of the Church*, 521 F. Supp. 2d 577, 582 (E.D. Ky. 2007) (quoting *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986)); *Smith v. Perkins Bd. Of Educ.*, 708 F. 3d 821, 825 (6th Cir. 2013). In the Court's analysis, "the evidence should be viewed in the light most favorable to the non-moving party." *Ahlers v. Schebil*, 188 F. 3d 365, 369 (6th Cir. 1999) (citing *Anderson*, 477 U.S. at 255).

The initial burden falls on the moving party, who must identify portions of the record establishing the absence of a genuine issue of material fact. *Chao v. Hall Holding Co.*, 285 F. 3d 415, 424 (6th Cir. 2002) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986)). If established, the non-moving party "must go beyond the pleadings and come forward with specific facts to demonstrate that there is a genuine issue for trial." *Id.* The nonmoving party will not overcome a motion for summary judgment by simply showing "some metaphysical doubt as to the material facts." *Id.* (citing *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986)). In other words, "the respondent must adduce more than a scintilla of evidence to overcome the motion." *Street v. J.C. Bradford & Co.*, 886 F. 2d 1472, 1479 (6th Cir. 1989). As a "mere scintilla of evidence" is insufficient, the non-movant must show the existence of "evidence on which the jury could reasonably find for the non-moving party." *Sutherland v. Mich. Dept. of*

Treasury, 344 F. 3d 603, 613 (6th Cir. 2003) (citing *Anderson*, 477 U.S. at 251). Instead, the non-moving party is required to "present significant probative evidence in support of its opposition." *Chao*, 285 F. 3d at 424.

"As a federal court exercising diversity jurisdiction, the choice-of-law rules of the forum state, Kentucky, determine what substantive law to apply." *State Farm Mut. Auto. Ins. Co. v. Norcold, Inc.*, 849 F.3d 328, 331 (6th Cir. 2017)(citing *NILAC Int'l Mktg. Grp. v. Ameritech Servs., Inc.*, 362 F.3d 354, 358 (6th Cir. 2004)). "When applying Kentucky's choice of law rules, 'a strong preference exists in Kentucky for applying Kentucky law.'" *Brass Reminders Co. v. RT Eng'g Corp.*, 462 F. Supp. 3d 707, 716 (E.D. Ky. 2020), aff'd, 844 F. App'x 813 (6th Cir. 2021)(citing *Asher v. Unarco Material Handling, Inc.*, 737 F. Supp. 2d 662, 667 (E.D. Ky. 2010)). For tort claims, Kentucky law will apply if there is significant contact. *Foster v. Leggett*, 484 S.W.2d 827, 829 (Ky. 1972); *Bell v. Kokosing Indus., Inc.*, No. CV 19-53-DLB-CJS, 2020 WL 4210701, at *11 (E.D. Ky. July 22, 2020). Because Plaintiff, a Kentucky resident, had her implantation surgery in Kentucky, the state with the most significant relationship is Kentucky. Additionally, Plaintiff does not dispute that Kentucky substantive law applies. [*See* Plaintiff's Response In Opposition to Summary Judgment, DE 225 at 7].

1. VOLUNTARILY DISMISSED CLAIMS

Plaintiff agrees this Court's recent case involving Ethicon's Pelvic Mesh Products, *Chasity Sexton v. Ethicon, Inc.*, 2021 WL 4138399 (E.D. Ky. Sept. 10, 2021), should be adopted where applicable. [DE 225 at 1]. Therefore, Ms. Thacker voluntarily dismisses the following causes of action: Manufacturing Defect (Count II), Defective Product (Count IV), Fraud (Count VI), Fraudulent Concealment (Count VII), Constructive Fraud (Count VIII), Negligent Misrepresentation (Count IX), Negligent Infliction of Emotional Distress (Count X), Breach of Express Warranty (County XI), Breach of Implied Warranty (Count XII), Violation of the Kentucky Consumer Protection Act (Count XIII), and Unjust Enrichment (Count XV). However, several claims remain.

2. FAILURE TO WARN (COUNT III)

To maintain her claim for failure to warn, Ms. Thacker must show Ethicon (1) had a duty to warn, (2) Ethicon provided inadequate warnings, and (3) the inadequate warnings were the proximate cause of her injuries. *See Manuel v. Traditional Sporting Goods, Inc.*, No. 5:09-cv-406, 2011 WL 6091710, at *6 (E.D. Ky. Dec. 7, 2011) (citing *Stewart v. General Motors*, 102 F. App'x 961, 964 (6th Cir. 2004)). Under Kentucky law, which applies the learned intermediary doctrine, the manufacturer is relieved of its duty to warn the patient if the manufacturer provides an adequate warning to the prescribing physician "regardless of how or if the physician warns

the patient." *Larkin v. Pfizer, Inc.*, 153 S.W. 3d 758, 765 (Ky. 2004).

Defendants assert that Ms. Thacker's claim must fail because she cannot establish proximate causation for three independent reasons. [DE 159-1, at 4]. Kentucky law applies the substantial factor test for proximate causation where the Court asks, "was the defendant's conduct a substantial factor in bringing about plaintiff's harm?" *Cutter v. Ethicon, Inc.*, No. CV 5:19-443-DCR, 2020 WL 109809, at *7 (E.D. Ky. Jan. 9, 2020)(citing *Morales v. American Honda Motor Co., Inc.*, 71 F.3d 531, 537 (6th Cir. 1995)). Circumstantial evidence may be used to prove causation, but "in that situation the evidence must be sufficient to tilt the balance from possibility to probability." *Id.*

First, Defendants argue proximate cause is not met because Plaintiff cannot show Dr. Guiler relied upon Ethicon's warnings via the Instructions for Use ("IFU") in making his treatment decision for Ms. Thacker. Instead, Defendants claim Dr. Guiler became aware of the risks involving the TVT-Secur and Prolift through his own experience and research. [James Michael Guiler, M.D. Deposition, DE 159-2 at 70:16-71:10]. Defendants further refute reliance on the IFU because even though Dr. Guiler "probably" reviewed the IFUs at his initial training [*Id.* at 7:25-8:18; 114:21-115:1], he does not review the IFU before every surgery [*Id.* at 114:16-20], does not remember the last time he

reviewed the IFU [*Id.* at 115:7-9], did not review the IFU with Ms. Thacker as a part of her risk analysis because he was already aware of the listed complications [*Id.* at 115:15-116:1], and he did not rely on the words in the IFU in making his recommendations. [*Id.* at 116:25-117:12].

Under Kentucky law to prove the causation element in a failure-to-warn claim, the doctor must have relied on the manufacturer's warning in accessing risks and making treatment decisions. At the summary judgment stage, failure-to-warn claims have survived as long as some reliance on the IFU is shown, even if it is not the main consideration. *Sexton*, 2021 WL 4138399, at *3. Precedent illustrates that if the doctor never reviewed the IFU, reliance is impossible and proximate cause cannot be established requiring summary judgment to be granted. *Cutter v. Ethicon, Inc.*, 2020 U.S. Dist. LEXIS 4016, at *23.

In *Cutter*, the failure to warn claim was dismissed at the summary judgment stage because it was "clear that any inadequate warning in the instructions for use...was not the proximate cause of the alleged injuries." *Id.* at *20. The doctor testified that "he did not consult these materials [the IFUs] to obtain information about the risks of implanting...and, in fact, has never relied on them for such information." *Id.* The doctor not only did not rely on the IFUs, he did not read them at all. *Id.* at *23. The doctor clarified that "he relied on personal surgical experience and demonstrations

by preceptors to inform his knowledge of risks involved in similar surgeries." *Id.* at *20.

In *Sexton*, the failure to warn claim survived a motion for summary judgment. The implanting physician, Dr. Voss, read the IFU and relied on it in part. *Sexton*, 2021 WL 4138399, at *3. Even though Dr. Voss did not rely upon the IFU as "the sole source of information when learning or the risks," the Court found the "relevant inquiry is whether Dr. Voss relied on the IFU" and concluded there was sufficient evidence to show Dr. Voss did rely on the IFU. *Id.*

In *Huskey*, the failure to warn claim survived summary judgment in part because there was sufficient evidence that the prescribing doctor, Dr. Byrkit, did rely on the IFU. *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 742 (S.D.W. Va. 2014), at *742. Even though the moving party argued there was no reliance because Dr. Byrkit could not "recall the last time" she reviewed the IFU, the court iterated that Dr. Byrkit had "read the IFU before implanting the TVT-O" and used the "'the same' implantation procedure described in the IFU on every patient." *Id.* The court distinguishes the case from *Lewis v. Johnson & Johnson*, where the failure to warn claim was dismissed. *Id.* at n.2 (citing I*n re Ethicon, Inc., Pelvic Repair Sys. Products Liab. Litig.*, No. 2:12-cv-2327, 2014 WL 186869, at *4 (S.D.W.Va. Jan. 15, 2014)(reversed on other grounds). In *Lewis*, "the treating physician affirmatively testified that she

did not rely on the IFU when prescribing the device" but "relied on a number of other factors. *Id.* at n.2. Since, there was no similar testimony from Dr. Byrkit denouncing reliance, the *Huskey* court found there was "sufficient evidence that Dr. Byrkit relied on the IFU." *Id.* at *742.

Unlike *Cutter*, where the court granted summary judgment, it is clear or at least genuinely disputed that Dr. Guiler did actually read the IFUs. [*See* DE 159-2 at 7:17-8:18]. While the doctor in *Cutter* testified that he did not consult or rely on the IFUs to obtain information about the risks, Dr. Guiler testifies that he "probably" reviewed and read the IFUs when training, received materials from Ethicon that were associated with the products, and received information at Ethicon summits and trainings. Therefore, this Court is unable to use *Cutter* to immediately grant summary judgment as there is evidence Dr. Guiler read the IFU.

However, as *Sexton* makes clear, the question is not whether the doctor read the warning, but whether the doctor relied on the warning. *Sexton*, 2021 WL 4138399, at *3. While Plaintiff points to parts of Dr. Guiler's deposition that show Dr. Guiler had *read* the IFU [DE 159-2, 7:25-8:18] and *received information* related to the products [*Id.* at 22:7-23:3], there is contradicting evidence regarding whether Dr. Guiler actually relied on the IFU in accessing risks for Ms. Thacker. Defendants point to parts of Dr. Guiler's testimony where he specifically said he did not rely on

the words in the IFU in making his recommendations [*Id.* at 116:25–117:12] (Q. (BY MS. HAMMOND) Okay. At – at the time of Ms. Thacker's surgery, did you rely on the actual words in the IFU when you made your recommendation to Ms. Thacker to have Prolift and TV – TVT-Secur implanted? A. No. Q. At the time of Ms. Thacker's surgery in May of 2009, did you rely on the actual words in the IFU to inform you about the risks of the TVT-Secur and Prolift procedures? A. No.). However, in support of reliance, Ms. Thacker identifies portions of Dr. Guiler's testimony indicating that he did rely on the IFU for his risk/ benefit analysis [*Id.* at 22:2-6] ("Q. So you mentioned the training. Then it would be fair to say that the instructions for use for the device would have been a part of your risk/ benefit analysis, correct? A. I suppose so, yes."). Although Dr. Guiler directly states that he did not rely on the IFU for Ms. Thacker's surgery, he later stated that he did rely on the IFU in forming his risk/ benefit analysis related to using the device. The conflicting testimony creates a genuine issue of material fact regarding whether Dr. Guiler *relied* on the IFU.

Two final points are worth mentioning. First, that Dr. Guiler cannot remember the last time he reviewed the IFU is not detrimental to proving reliance. The doctor in *Huskey* similarly could not "recall the last time" she reviewed the IFU, but the court allowed the claim to survive partially because it was clear that the doctor had read the IFU in the past. *Huskey*, 29 F. Supp.

3d at 742. Similarly, here, Dr. Guiler read the IFU in the past and, therefore, the lack of recent reliance is not fatal to the claim. Second, Dr. Giuler's testimony that he did not review the IFU as part of his discussion of risks with Ms. Thacker because he was already aware of all the risk does not makes it "illogical to say that he relied on the IFU for *her* surgery" as Defendants claim. [DE 251 at 5]. That Dr. Guiler did not sit down and go through the IFU immediately prior to discussing the risks with Ms. Thacker, does equate to the absence of any reliance on the IFUs. Defendants' first argument against the finding of proximate causation fails.

Second, Defendants argue proximate cause is not met because Dr. Guiler independently knew the risks of using the TVT-Secur and Prolift devices, therefore, there was no duty to warn. [DE 159-1 at 5]. However, Defendants cite to *Cutter*, which this Court has already factually distinguished from the case at hand. Additionally, this Court finds the argument to simply be a combination of the other two theories and generally unpersuasive.

Third, Defendants argue proximate cause cannot be established because even if Dr. Guiler had read the IFU, Plaintiff cannot establish that additional warnings would have altered Dr. Gueiler's treatment decisions. [DE 159-1 at 6]. Ms. Thacker's response does not deny that Dr. Guiler's actions would have changed, but rather she argues the plaintiff is not required to prove supplemental warnings would have changed the doctor's mind

to establish the causation element in a failure to warn claim. [DE 225 at 15]. Many of the moving parties in the aforementioned precedential cases also presented this argument. However, courts in the Sixth Circuit have conjured an irresolute response, claiming there is no "bright-line rule" in Kentucky regarding the necessity of proving the doctor would have changed his mind with the additional warning. *Mitchell v. Ethicon Inc.*, No. CV 5:20-157-DCR, 2020 WL 4550898, at *6 (E.D. Ky. Aug. 6, 2020). While many courts have at least discussed or engaged in an application of the rule, in the end they have been able to avoid ruling on whether it is a required element of causation because the case could be decided via alternative means.

Ms. Thacker cites *Corder* to support her argument that showing the doctor would have changed their course of action is not a required element. *Corder v. Ethicon, Inc.*, 473 F. Supp. 3d 749, 759 (E.D. Ky. 2020). In *Corder*, the failure-to-warn claim survived summary judgment as the court found a genuine issue of material fact remained regarding whether the failure to warn was the proximate cause of the plaintiff's injuries. *Id.* at 761. Defendants claimed the failure of the plaintiff to elicit testimony from the implanting physician, Dr. Bush, stating that an adequate warning would have led to a different course of treatment meant no causation could be proven. *Id.* at 758. However, the court was wary to make such direct evidence a "mandatory predicate to prove

causation." *Id.* "The Court is not convinced that here Corder must prove that supplemented warnings would have changed Dr. Bush's recommendation to establish the necessary causal nexus." *Id.* at 759. While neither the plaintiff nor the defendants deposed Dr. Bush, the court held the lack of testimony is not detrimental as a reasonable juror could infer from the silent record that either Dr. Bush, knowing all the information, would have continued on the same treatment plan or that he would have changed his course. *Id.*

Corder, obviously factually distinct from this case, cannot be used to support Ms. Thacker's notion that establishing the doctor would have acted differently is *never* required. Unlike *Corder*, where the doctor was never deposed so there was no testimonial evidence, here Dr. Guiler was deposed and clearly indicated even if he knew at the time of implantation what he knows now, he still believed the devices to be safe and effective with the benefits outweighing the costs. [DE 159-2 at 119:10-120:8 ("Q. Putting yourself back at the time you implanted TVT-Secur and Prolift into Ms. Thacker in May of 2009, but with the knowledge you have today, do you agree that TVT-Secur and Prolift were safe and effective treatments for – A. Yes. Q. – SUI and POP [pelvic organ prolapse] in women? A. Yes)]. While in *Corder* the lack of evidence one way or the other created a genuine issue of material fact concerning the matter, here there is direct evidence and Ms. Thacker has been unable, nor does she even attempt, to present any evidence to the

contrary. *Corder* thus stands for the proposition that at the summary judgment stage where there is no direct testimony from the doctor, the Court will allow the case to proceed because circumstantial evidence might prove the doctor would have changed his course. *Corder* is not meant to be used by plaintiffs to escape summary judgment when there is direct testamentary evidence proving the doctor's decision would be the same even with the additional information and the plaintiff is unable to present refuting evidence.

Other decisions relied upon by the parties do not affirmatively renounces the element, but rather the courts are able to skirt the question because they found the plaintiffs had presented sufficient evidence showing the doctor might have changed their mind if given a proper warning so as to make it a genuine issue of material fact. The court in *Huskey*, rejected defendant's argument that that proximate cause could not be established because "Dr. Byrkit would not have changed her decision to prescribe the TVT-O if she had received a better warning" since Dr. Byrkit's testimony was inconsistent when asked about the matter, thus presenting a genuine issue of material fact. *Huskey*, 29 F. Supp. 3d 736 at 743. While the court questioned whether as a part of causation plaintiffs are required to show the doctor would have acted differently if she had received a better warning, ultimately the court left the issue unresolved because the

plaintiffs presented refuting evidence that the doctor would have acted differently. *Id.* at n.3. The *Sexton* court also avoided deciding on the issue because the plaintiff was able to point to areas of Dr. Voss' testimony that "at minimum" created a genuine dispute of material fact. *Sexton*, 2021 WL 4138399, at *4 (Despite testimony from Dr. Voss that he would still have used the device even with a revision of the wording in the IFU, Plaintiff presented other testimony from Dr. Voss' "showing that he was under the assumption the information Ethicon provided him was accurate, that he identified additional risks found in Ethicon's IFU after Plaintiff's procedure that were not present in the IFU prior to the procedure, that the additional risks may have been helpful to know, and that if he, in fact, received misleading information from Ethicon, that would have influenced his decision to use their product.").

Sexton and *Huskey* do not apply when the plaintiff is unable to put forward any evidence indicating that the doctor would have acted differently if given a different warning. Unlike *Huskey* and *Sexton*, here there is no inconsistent testimony.[1] Plaintiff is

[1] While Plaintiff points to Dr. Guiler's deposition where he agrees that information that the device causes chronic pain would have been considered in his risk/ benefit analysis as "all information would be important in that decision" [DE 159-2 at 36:19-27:10; 44:21-45:], Dr. Guiler goes on to testify that the benefits nonetheless outweighed the risks [*Id.* at 119:10-120:8]. That Dr. Guiler would have considered that information as he considered all relevant information does not create a factual dispute because Dr. Guiler is clear that even if he knew then what he knows now, he would not have changed his mind. [*Id.*]. Thus, even if the additional warning had been given and Dr. Guiler would

unable to present any evidence contradicting Dr. Guiler's clear declaration that even with the knowledge he has today he considers the procedure are safe, effective, and the benefits outweigh the risks. [DE 159-2 at 119:10-120:8]. In fact, Plaintiff seems to admit that Dr. Guiler "stands by his decision to use the Prolift and TVT-Secur devices," so her only argument to refute Defendants' point is that plaintiffs do not need to prove this element, that additional warning would have changed the prescribing doctor's recommendations, to survive summary judgment. [DE 225 at 15]. However, other courts dealing with more similar cases, have denied summary judgment where defendants show that that an additional warning would not have altered the doctor's course of action and plaintiff is unable to present refuting evidence.

In *Cutter*, even though the claim was barred by the statute of limitations, the court further declared that proximate cause could not be satisfied because after gaining knowledge of the implantation risks, the doctor "continued to believe that the benefits outweighed the risks", so "further information" about the risks "would not have affected his decision." *Cutter*, 2020 WL 109809, at *8.

In *Mitchell*, the court held the failure to warn claim was unable to survive summary judgment partially because the plaintiffs

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have considered the information in the analysis, he still would not have changed his decision.

"failed to come forward with sufficient evidence indicating that a deficient warning was the proximate cause of their harm." *Mitchell*, 2020 WL 4550898, at *5. The defendants focused their argument for lack of causation on the idea that an adequate warning would not have changed the implanting doctor's decision to use the product. The court speculated whether proof of the treating physician standing by their decision in the face of additional information is required. "While it does not appear that any Kentucky court has issued a bright-line rule for causation in this scenario, many others have required the plaintiff to produce evidence that an additional warning would have changed the treating physician's prescribing decision." *Id.* at *6. The court goes on to weigh the evidence of whether additional information would have changed the doctor's mind. The implanting doctor testified that "she did not recall reviewing the IFU prior to [the plaintiff's surgery] and did not rely on it to learn the risks associated with the procedure" because "she learned the potential complications" about the procedure "during her medical education a decade prior to [the plaintiff's] surgery." *Id.* Additionally, the doctor testified that "she stands by her decision to use" the device in question. Ultimately, the court concluded that causation could not be proven because the element was not met. *Id.*

While Ms. Thacker was able to present sufficient evidence to create a genuine issue of fact regarding consultation of the IFU,

she, like the plaintiff in *Cutter*, was unable to do the same for proof of the doctor changing his mind. Very similar to *Mitchell* where the doctor directly testified that she stood by her decision to use the devise in question, Dr. Guiler stays committed to his choice even with the additional knowledge he has gained since the implantation in 2009. [DE 159-2 at 119:10-120:8]. Dr. Guiler goes on to affirm his belief that benefits of using the devices outweigh the risks. [*Id.* (Q. Do you agree that the potential benefits of using TVT-Secur and Prolift to treat stress urinary incontinence and pelvic organ prolapse outweighed the potential risks? A. Yes, I believe that to be a fact. Q. Do you agree that TVT-Secur was an appropriate treatment option for Ms. Thacker's stress urinary incontinence? A. I do. Q. Do you agree that Prolift was an appropriate treatment option for Ms. Thacker's pelvic organ prolapse? A. I do."). Ms. Thacker offers no conflicting testimony. Therefore, it is undisputed that Dr. Guiler would not have changed his mind with the additional warning.

In conclusion, under Kentucky law a plaintiff does not have to present evidence showing the doctor would have changed his mind when the defendant also has not presented evidence that the doctor would not have changed their mind. *Corder*, 473 F. Supp. 3d 749. However, when the defendant does present affirmative testamentary evidence that the doctor would not have changed his course of action with the additional warning, the plaintiff must present

evidence to the contrary in order to show a genuine issue of material fact exists. *Sexton*, 2021 WL 4138399, at *4; *Huskey*, 29 F. Supp. 3d 736 at 743. If the plaintiff is unable to come forward with such evidence, then causation, a necessary element in a failure-to-warn claim, cannot be proven and the moving party is entitled to judgment as a matter of law. Since here Defendants have presented clear testimony from Dr. Guiler that he stands by his decision even with the additional information [DE 159-2 at 119:10-120:8], and Plaintiff has not presented refuting testimony, Ms. Thacker will be unable to prove the element of causation. Even though there is likely a genuine issue of material fact regarding whether Dr. Guiler relied on the IFU, Ms. Thacker must still present evidence contradicting the defendants' proof that Dr. Guiler would not have changed his mind even with the additional warning in order to establish causation. In this situation, it is a necessary element. Since Ms. Thacker has not presented conflicting evidence, she is unable to prove causation exists and her failure to warn claim must fail as a matter of law.

3. DESIGN DEFECT CLAIM (COUNT V)

Under Kentucky law, a risk-utility test is used in design defect cases. *Burgett v. Troy-Bilt LLC*, 579 F. App'x 372, 378 (6th Cir. 2014) (referencing *Toyota Motor Corp. v. Gregory*, 136 S.W.3d 35, 42 (Ky. 2004)). The applicable test is "whether an ordinarily prudent company being fully aware of the risk, would not have put

the product on the market." *Id.* For there to be liability in a design defect claim, there must be proof of a safer and feasible alternative design. *Owens v. Ethicon*, Inc., No. 3:19-cv-00080-GFVT, 2020 U.S. Dist. LEXIS 72587, at *7-8 (E.D. Ky. Apr. 24, 2020).

Ms. Thacker, through a case-specific report by Dr. Rosenzweig, puts forward four alternatives to the mesh products:

(1) the use of sutures, including delayed absorbable sutures like PDS, in a colposuspension procedure like the Burch or a native tissue rectocele repair with absorbable suture;

(2) autologous fascia sling or rectocele repair;

(3) an allograft sling or rectocele repair using a product such as Repliform; and

(4) a sling or rectocele repair using a product with less polypropylene such as Ultrapro.

[Rosenzweig Report, DE 159-6 at 81-82]

In order to qualify as a proper alternative and thus withstand summary judgment, the alternative must be properly analogous to the product at issue. In *Burton*, the court found the techniques of two alternatives proposed by the case-specific expert, sutures and Fascia POP repair with Biologics, not to be alternative designs to Prolift because they were "entirely different procedures." *Burton v. Ethicon Inc.*, No. CV 5:20-280-DCR, 2021 WL 1725514, at *2 (E.D. Ky. Apr. 30, 2021). "[E]vidence of surgical procedures not

involving mesh has no bearing on the existence of a safer alternative design for the defendant's Prolift product." *Id.* at *2 (referencing *Owens*, 2020 WL 1976642, at *3).

The first three listed alternatives do not qualify as proper alternatives because they are not appropriately analogous to the mesh products actually used. First, similar alternatives were rejected in *Burton*. Second, the first three proposed alternatives are "entirely different procedures" because they do not involve mesh. *Id.* at *2. Third, Ms. Thacker does not dispute that "courts have concluded that alternative procedures are not sufficient to prove an alternative safer design for a design defect claim as they are not a product" [DE 225 at 13] nor does she argue that the three proposed alternatives should not fall into this rejected category. Instead, Plaintiff requests the court "reserve ruling on this evidence until the time of trial because the procedure may be relevant for other issues." [*Id.*]. While it is possible the first three proposed alternatives may be relevant down the road, that is immaterial to the current issue of whether they constitute proper alternative designs, which Plaintiff is required to put forward to survive summary judgment on a design defect claim. As noted above, the first three alternatives do not constitute proper alternative designs, and therefore, cannot be relied upon to defeat summary judgment.

This leaves the fourth proposed alternative—the use of a mesh with less polypropylene, like Ultrapro—as the only possible alternative. This Court holds that the fourth proposal cannot constitute a proper alternative because Plaintiff has failed to show there is a genuine issue of material fact regarding feasibility.[2]

Specifically at issue is whether Ms. Thacker has met her burden of showing feasibility. The Federal Rules of Civil Procedure require the nonmoving party to present specific facts showing that a genuine factual issue exists by "citing to particular parts of materials in the record" or by "showing that the materials cited do not establish the absence ... of a genuine dispute[.]" Fed. R. Civ. P. 56(c)(1)). "Rule 56(c) mandates the entry of summary judgment ... against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex Corp.*, 106 S. Ct. at 2552.

Kentucky law is clear that a valid alternative design must be feasible. *Low v. Lowe's Home Ctrs., Inc.*, 771 F. Supp. 2d 739, 741 (E.D. Ky. 2011)(citing *Toyota Motor Corp.*, 136 S.W.3d at 42)("To

[2] Since this Court grants summary judgment based off lack of proof of feasibility, the Court does not need to address the merits of Defendants' other two arguments. Defendants assert that Ultrapro cannot be considered a proper alternative because (1) they claim Dr. Rosenzweig admits that a sling or posterior repair using Ultrapro would not have prevented Ms. Thacker's injuries, which they claim is a mandatory prerequisite and (2) absent FDA clearance, Ultrapro was not feasible.

prove a design defect, he must show that the defendants could have used a safer, and still feasible, design."). To prove feasibility, a plaintiff must provide "proof of an alternative, safer design that is practicable under the circumstances." *Owens v. Ethicon, Inc.*, No. 3:19-cv-00080-GFVT, 2020 U.S. Dist. LEXIS 72587, at *7-8 (E.D. Ky. Apr. 24, 2020)(citing *Bosch v. Bayer Healthcare Pharm., Inc.*, 13 F. Supp. 3d 730, 742 (W.D. Ky. 2014)); *see also Jackson v. E-Z-GO Div. of Textron, Inc.*, 326 F. Supp. 3d 375, 395 (W.D. Ky. 2018)(quoting *Johnson v. Manitowoc Boom Trucks, Inc.*, 484 F.3d 426, 433 (6th Cir. 2007)(Kentucky law requires that expert testimony establish the alternative design "could have been practically adopted at the time of sale."). Kentucky courts have defined feasibility as "[t]he possibility that something can be made, done, or achieved, or that it is reasonable; practicability." *Smith v. Ethicon, Inc.*, No. 6:20-CV-222-REW-HAI, 2021 WL 4098408, at *4 (citing Feasibility, BLACK'S LAW DICTIONARY (11th ed. 2019)).

"[T]he onus is on Plaintiffs to provide expert testimony setting forth 'competent evidence of some practicable, feasible, safer, alternative design.'" *Estate of Bigham v. DaimlerChrysler Corp.*, 462 F. Supp. 2d 766, 773 (E.D. Ky. 2006)(citing *Gray v. General Motors Corp.*, 133 F. Supp. 2d 530, 535 (E.D. Ky. 2001)). In a design defect claim, because the subject is outside the scope of lay knowledge, a plaintiff must offer "sufficiently detailed expert testimony to establish that a reasonable alternative design

could have been practically adopted at the time of the sale." *Burton*, 2021 WL 1725514, at *4 (granting summary judgment on the design defect claim because the plaintiff did not offer specific evidence of an alternative feasible design); *Smith*, 2021 WL 4098408, at *4 (granting summary judgment on the design defect claim because the expert's "statement, lacking any indication of or probativeness regarding contemporaneous feasibility, is insufficient for a juror to reasonably find Smith's burden met"); *see also Lambert v. G.A. Braun Int'l, Ltd.*, No. 3:14-CV-00390-JHM, 2016 WL 3406155, at *1 (W.D. Ky. June 17, 2016)(granting summary judgment where "Plaintiff has failed to show that a feasible alternative or safer design existed" by offering no specific evidence). "It is well-settled that Plaintiffs are required, by way of expert testimony, to provide proof of an alternative design through 'competent evidence' that there was available to Defendant a 'practicable, feasible, safer, alternative design' at the time of manufacturing...the lack of evidence establishing an alternative design proves fatal to Plaintiffs' claims." *Est. of Bigham v. DaimlerChrysler Corp.*, 462 F. Supp. 2d 766, 776 (E.D. Ky. 2006)(citing *Gray*, 133 F.Supp.2d at 535)(granting summary judgment where the plaintiff was "under the mistaken belief that the mere mention that alternative possibilities exist [was] sufficient" and, therefore, failed to put forward evidence establishing an alternative design). "A failure to offer 'the

required proof of a feasible, alternative design' dooms the claim." *Smith*, 2021 WL 4098408, at *5 (citing *Gray*, 133 F.Supp.2d at 242).

The Plaintiff has not presented sufficient evidence to create a genuine issue of material fact regarding the feasibility of the fourth alternative. In her Response to Defendants' Motion for Summary Judgment, Plaintiff argues that lack of FDA approval does not warrant summary judgment and then simply declares:

> In sum, Plaintiff has provided evidence of a safer alternative feasible design product that is "more than that it was theoretically probable." *Brock v. Caterpillar, Inc.*, 94 F.3d 220, 224 (6th Cir. 1996). Dr. Rosenzweig's opinions explain how the Ultrapro device is a "practicable, safer, alternative design" that not only was feasible, but actually existed, at the time Plaintiff had the Prolift and TVT-Secur devices implanted in 2009. *See Gray v. Gen. Motors Corp.*, 133 F. Supp. 2d 530, 535 (E.D. Ky. 2001). This evidence is more than sufficient to defeat summary judgment.

[DE 225 at 11-12]. Yet Plaintiff cites no portion of the record, does not provide evidence proving such feasibility, nor attempt to explain how the device was feasible. Compare this lack of evidence to that produced by the plaintiff in *Sexton*, where the court found there to be a genuine issue of material fact regarding feasibility:

> Ultrapro is a lightweight, large-pore mesh that was originally developed for hernia treatment. (*Id.* at 37). As early as 1997, Ethicon knew that its Prolene mesh was not ideal for vaginal tissues, but it never used Ultrapro or another larger-pore material for treatment of SUI because it wanted to be able to rely on studies done to support the

original TVT, using the old-construction Prolene mesh. (*Id.*; *see also* Brigitte Hellhammer Dep., Sept. 11/12, 2013, portions attached as Exhibit B, at 119:24-121:11, 754:12-20).

Ethicon's primary argument is that Plaintiffs cannot establish that it was feasible to use Ultrapro to treat SUI in 2014, when Ms. Sexton had her implant. Ethicon is incorrect. Ethicon began using lighter-weight, larger pore meshes for hernia treatment in the late 1990s. (General Report, Ex. A-Ex. 2, at 14-15). In 2004, Ethicon obtained clearance for use of Ultrapro mesh from the FDA. [citation omitted]. From 2005-07, there was a clinical trial in which Ultrapro mesh was used in a sling to treat SUI. The trial was ultimately successful, and the results were published in 2013. (Okulu, et al., *Use of three types of synthetic mesh material in sling surgery: A prospective randomized clinical trial evaluating effectiveness and complications*, Scandinavian J. of Urology, 2013:47:217-224, at p. 223, attached as Exhibit C ("Ultrapro mesh...can be reliably and effectively used in sling surgery.").[citation omitted]. Nonetheless, Ethicon claims that its own failure involving a different product should shield it from liability. Ethicon asserts that because the FDA rejected a mesh that was supposedly "similar to Ultrapro," this somehow establishes that it was impossible to gain clearance for a mesh actually using Ultrapro. (See Dkt. No. 69-1 at 9). Ethicon makes this remarkable argument even though the FDA did approve the use of Ultrapro in a pelvic floor device—specifically the Prolift +M, an Ethicon device used to treat pelvic organ prolapse. [citation omitted]. Thus, Ethicon claims it was impossible to gain clearance for a material that had been cleared by the FDA six years earlier, based on a failed attempt to gain clearance for a different material. The Court should reject this absurd argument

Response in Opposition to Motion for Summary Judgment at 10-11, *Sexton*, 2021 WL 4138399 (No. 70). The plaintiff in *Sexton* cited to specific parts of the record and explained how the evidence shows it was at least possible for the alternative to be practically adopted at the time. Ms. Thacker has not.

As Defendants met their initial burden of establishing the absence of a genuine issue of material fact, Plaintiff was required to "go beyond the pleadings and come forward with specific facts to demonstrate there is a genuine issue for trial." *Chao*, 285 F. 3d 415 at 424. Plaintiff has failed to do so. Ms. Thacker cites to no particular parts of the record that establish feasibility nor does she offer sufficiently detailed expert testimony to establish that a reasonable alternative design could have been practically adopted at the time of the sale. Since Plaintiff fails to make a showing sufficient to establish the existence of feasibility, an element essential to that party's case and on which that party will bear the burden of proof at trial, the Federal Rules require the Court to grant summary judgment.

Giving Plaintiff the benefit of the doubt, the Court completed a generous review of the record looking for evidence of feasibility since Plaintiff provided none. First, in Dr. Rosenzweig's case-specific expert report, Dr. Rosenzweig states the four alternative designs were "safer and feasible." [DE 159-6 at 81]. However, this is a mere declaration with no support. This is not sufficiently

detailed specific evidence of how the design was practicable under the circumstances. *Burton*, 2021 WL 1725514, at *4. Second, the Court notes portions of the Expert Report of Bruce Rosenzweig, M.D, that suggest Ultrapro existed and was being used for the treatment of organ prolapse.[3] However, even if the product existed at the time of Ms. Thacker's surgery, Plaintiff has not shown nor attempted to explain how Ultrapro "could have been practically adopted at the time of sale" simply because it existed. *Jackson*, 326 F. Supp. 3d 375, 394–96. Instead, Plaintiff simply says lack of FDA approval does not doom the claim. Whether FDA approval is or is not required for feasibility is immaterial now because Plaintiff has failed to argue feasibility in the first place.[4] In

[3] "Ethicon did not change the Prolene mesh in its TVT device despite having better and safer options available for economic reasons. Ethicon believed that continued use of the TVT mesh gave the company an economic and competitive advantage in marketing the product because they could continue to use the existing clinical data on the product to market the device, even though because the mesh was changed, the existing clinical data would be obsolete. Dr. Brigitte Hellhammer testified that despite having incorporated the use of the lightweight, large pore Ultrapro mesh in vaginal tissues for the treatment of pelvic organ prolapse, the Ultrapro was never used by Ethicon in a device used for the treatment of stress urinary incontinence largely because the company wanted to continue to rely on the Ulmsten/Nilsson series of studies on 130 patients performed with the TVT device. Dr. Arnaud also confirmed that the company did not want to change anything with the mesh because of the existing clinical data on the product. It is my opinion to a reasonable degree of medical certainty that Ethicon was negligent in failing to correct the defects in the TVT mesh as the company had knowledge of the defects and failed to correct the defects with products and solutions that were already available to the company because it valued its economic interests above patient safety." [DE 225-9 at 390-91].

[4] Whether FDA approval is necessary for an alternative design to be feasible remains uncertain in Kentucky. Several courts have addressed feasibility as related to relevance, but not feasibility. However, it seems to be implied that for a design to be feasible it must "comply with federal, state, or local regulations." *See Jones v. IC Bus*, LLC, 626 S.W.3d 661, 678 (Ky. Ct. App. 2020). While the Kentucky case, *Sexton*, briefly addresses the issue finding lack of FDA approval "unavailing" to defeat feasibility, they based part of their conclusion on defendants' failure to "cite any authority requiring FDA approval

conclusion, Ms. Thacker cannot survive summary judgment on the design defect claim as she fails to provide any evidence showing the alternative was feasible, a required element of the claim.

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for a product to be a feasible, safer alternative." *Sexton*, 2021 WL 4138399. However, Defendants now offer two Texas cases to support their argument.

A Texas case from 2020 granted summary judgment on the defective design claim because the alternative design was not technologically feasible as it had not been approved by the FDA. *Pizzitola v. Ethicon, Inc.*, No. 4:20-CV-2256, 2020 WL 6365545, at *4 (S.D. Tex. Aug. 31, 2020) ("FDA regulates the sale of medical devices...[b]efore a medical device can be used in a hospital, the device must have FDA clearance."). The second case, decided after *Sexton*, also granted summary judgment finding that Ultrapro was not a viable alternative because it lacked FDA approval. *Labiche v. Johnson & Johnson*, No. H-20-4249, 2021 U.S. Dist. LEXIS 161087, at *5 (S.D. Tex. Aug. 19, 2021) ("The mere existence of alternative mesh designs is inadequate alone to be a safer alternative design. The alternative design must have been legally available at the time for proper use. Ultrapro was not approved by the Food & Drug Administration at the time, so it could not have been used.").

The Texas cases are not binding on this Court and Texas law requires the alternative be "economically and technologically feasible," while Kentucky does not have this standard. *Meindertsma v. Ethicon Inc.*, No. 1:20-CV-00708-RP, 2021 WL 2010355, at *2 (W.D. Tex. May 17, 2021); *Moore v. Lowe's Cos.*, No. 1:13-CV-00005-GNS-HBB, 2016 U.S. Dist. LEXIS 39137, at *20 (W.D. Ky. Mar. 25, 2016) (noting that Kentucky does not "impose this two-pronged requirement for feasibility). However, Kentucky does require that expert testimony establish the alternative design "could have been practically adopted at the time of sale." *Jackson*, 326 F. Supp. 3d 375, 394-96 (W.D. Ky. 2018). Because "practically adopted" and "technologically feasible" are far more alike than they are different, it is likely that Kentucky courts would side with Texas courts.

However, this Court also acknowledges a New York court, which held differently. Applying New York law, which also requires an alternative design be "economically and technologically feasible," the Court denied summary judgment finding that Ultrapro was a proper alternative regardless of FDA approval. *Baccaro v. Coloplast Corp.*, No. 1:19-CV-1088, 2021 U.S. Dist. LEXIS 136476, at *43 (N.D.N.Y. July 22, 2021) "Accordingly, the Court is satisfied that the appropriate standard under New York law is the feasibility of a hypothetical alternative design, not whether an alternative design has been actively approved by the FDA for a manufacturer to use for a specific purpose." *Id.* Yet, New York law explicitly allows alternative designs to be hypothetical opposed to Kentucky law. *Estate of Bigham*, 462 F. Supp. 2d at 776 (quoting *Brock v. Caterpillar, Inc.*, 94 F.3d 220, 224 (6th Cir. 1996))("Plaintiffs must show 'something more than that it was 'theoretically probable that a different design would have been feasible.'"). Nonetheless, the court's reasoning for not requiring FDA approval is compelling. The court notes how requiring FDA approval would change the design defect inquiry to more of a medical malpractice claim because instead of the plaintiff needing "to present evidence of a hypothetical alternative product that would improve on the manufacturer's...the question would have to be whether the physician selected the proper, approved drug or device among those available." *Id.*

4. NEGLIGENCE (COUNT I) AND GROSS NEGLIGENCE (COUNT II)

In Kentucky, "[a] party injured by a product can bring suit for that injury under three different theories: (1) breach of warranty under the Uniform Commercial Code, (2) negligence, or (3) strict liability in tort." *Ostendorf v. Clark Equip. Co.*, 122 S.W.3d 530, 535 (Ky. 2003). Defendants sought product liability claims under both strict liability and negligence. As described above, Plaintiff's failure-to-warn claim failed due to lack of causation and the design defect claim failed due to lack of feasibility. Because a negligence theory under the two claims requires the same, the negligence claim must fail as well. *Snawder v. Cohen*, 749 F. Supp. 1473, 1476 (W.D. Ky. 1990) (citing *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A.2d 374, 386 (1984) ("Thus, theories of negligence and strict liability in failure to warn cases have been deemed to be 'functional equivalents.'"); *Duff v. C.R. Bard*, No. 5:20-CV-00060-GNS-CHL, 2021 U.S. Dist. LEXIS 41658, at *5 (W.D. Ky. Mar. 4, 2021) (citing *Holbrook v. Rose*, 458 S.W.2d 155, 157 (Ky. 1970))("To be clear, '[a] plaintiff's...claims of negligence...and strict liability...have [a] common denominator which is that causation must be established.'"); *Red Hed Oil, Inc. v. H.T. Hackney Co.*, 292 F. Supp. 3d 764, 773 (E.D. Ky. 2017)(citing *Halsey v. Agco Corp.*, No. 16-cv-461-JMH, 2017 U.S. Dist. LEXIS 174075, 2017 WL 4767679, at *1 (E.D. Ky. Oct. 20, 2017)("The causation analysis 'is the same under a negligence

theory in a products liability case as...under a strict liability theory.'"); *Jackson*, 326 F. Supp. 3d at 391 (citing *Toyota Motor Corp.*, 136 S.W.3d at 42)("Under Kentucky law, a plaintiff can bring a defective design claim under a theory of strict liability or negligence, the foundation of both theories being that the product is unreasonably dangerous...Regardless of which theory a plaintiff chooses, design defect liability requires proof of a feasible alternative design.")(internal quotations omitted); *Smith*, 2021 WL 4098408, at *4 (noting that although in product liability design defect cases the "distinction between strict liability and negligence is of no practical significance" they are "not interchangeable" but, nonetheless, dismissing the negligence claim alongside the strict liability design claim because the "deficits" were the same); *Burton*, 2021 WL 1725514, at *4 (citing *Estate of Bigham*, 426 F. Supp. 2d 766, 773)("Whether the claim is based in negligence or strict liability, the plaintiff in a design defect case must provide expert testimony 'setting forth competent evidence of some practicable, feasible, safer, alternative design.'"). Ms. Thacker's inability to demonstrate negligence also precludes a finding of gross negligence.

5. PUNITIVE DAMAGES (COUNT XVII) AND TOLLING (COUNT XVIII)

First, while Defendants seek dismissal of Punitive Damages (Count XVII) and Tolling (count XVIII), Plaintiff is clear that they are not attempting to assert these as causes of action. [DE

225 at 17]. Therefore, there is no claim to grant or deny summary judgment upon. Second, since the Court has granted summary judgment on all claims for the defendants, there can be no punitive damages.

B. OTHER PENDING MOTIONS

With the Motion for Summary Judgment [DE 159], both Plaintiff and Defendants filed several related Motions *in Limine* and Motions to Exclude [DE 112-58, 160-66]. Because the Court finds Defendants are entitled to summary judgment even if all their motions to exclude are denied and all expert testimony permitted, there is no need to address the merits of the motions. Additionally, in granting the Motion for Summary Judgment [DE 159], the Court does not rely on any evidence that Plaintiff wished to have excluded. For these reasons, all pending motions to exclude and motions *in limine* are denied as moot.

III. Conclusion

Having considered the matter fully, and being otherwise sufficiently advised,

It is ordered as follows:

(1) Defendants' Motion for Summary Judgment [DE 159] is **GRANTED IN FULL.**

(2) Defendants' and Plaintiff's pending Motions *in Limine* and Motions to Exclude [DE 112-158, 160-166] are **DENIED AS MOOT.**

This the 17th day of November, 2021.

Signed By:
Joseph M. Hood
Senior U.S. District Judge