Kenneth A. Murphy
kenneth.murphy@dbr.com
Attorney Identification No. 58162
Melissa A. Merk
melissa.merk@dbr.com
Attorney Identification No. 90363
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
Telephone: (215) 988-2700
Facsimile: (215) 988-2757

Julie A. Callsen
julie.callsen@tuckerellis.com
Attorney Identification No. 323883
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, OH 44113
Telephone: (216) 592-5000
Facsimile: (216) 592-5009

Attorneys for Defendants Ethicon, Inc. and Johnson & Johnson

Nils Burton Snell
burt.snell@butlersnow.com
Attorney Identification No. 89455
BUTLER SNOW LLP
500 Office Center Drive, Suite 400
Fort Washington, PA 19034
Telephone: (267) 513-1884
Facsimile: (267) 513-1701

Kimberly Gustafson Bueno
(admitted pro hac vice)
kbueno@scottdoug.com
SCOTT DOUGLASS & MCCONNICO LLP
303 Colorado Street, Suite 2400
Austin, TX 78701
Telephone: (512) 495-6300
Facsimile: (512) 495-6399

James M. Campbell (admitted *pro hac vice*)
jmcampbell@campbell-trial-lawyers.com
CAMPBELL, CAMPBELL, EDWARDS & CONROY
Constitution Center, 3rd Floor
Boston, MA 02129
Telephone: (617) 241-3000
Facsimile: (617) 241-5115

IN RE: PELVIC MESH LITIGATION
Patricia K. Blockus, et al., Plaintiffs, v. Ethicon, Inc., et al., Defendants.

PHILADELPHIA COUNTY
COURT OF COMMON PLEAS
TRIAL DIVISION - CIVIL

JULY TERM 2013
No. 707

DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON'S REPLY BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

Opposing Counsel:
Lee Balefsky
Christopher Gomez
Christine Clark
Kline & Specter, P.C.
1525 Locust St., 19th Flr.
Philadelphia, PA 19102
Attorneys for Plaintiffs

DrinkerBiddle&Reath LLP

Melissa A. Merk
215-988-3343 Direct
215-988-2757 Fax
melissa.merk@dbr.com

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Law Offices
One Logan Square, Ste. 2000
Philadelphia, PA
19103-6996

(215) 988-2700 phone
(215) 988-27
57 fax
www.drinkerbiddle.com

CALIFORNIA
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WASHINGTON D.C.
WISCONSIN

VIA ELECTRONIC FILING AND HAND DELIVERY

The Honorable Arnold New
Court of Common Pleas of
Philadelphia County
Complex Litigation Center
City Hall, Room 602
Philadelphia, PA 19107

Re: *In re: Pelvic Mesh Litig.*, Feb. Term 2014, No. 829
***Blockus, et al. v. Ethicon, Inc., et al.*, July Term 2013, No. 0707**

Dear Judge New:

Per the Case Management Orders governing all Ethicon Pelvic Mesh cases and Mass Tort Procedure, please accept the following Reply Brief in Support of Motion for Summary Judgment filed by Defendants Ethicon, Inc. and Johnson & Johnson (collectively "Ethicon").

EXECUTIVE SUMMARY

In their Response, Plaintiffs concede certain claims and fail to respond to Ethicon's arguments as to other claims. They attempt to defeat summary judgment Plaintiffs misconstrue Pennsylvania law and ignore key, undisputed testimony and evidence. In sum, Plaintiffs' Response fails to demonstrate any genuine issue of material fact on this record. For the reasons stated in its opening brief and below, summary judgment in Ethicon's favor is warranted.

A. Ethicon Is Entitled to Summary Judgment on the Claims that Plaintiffs Have Abandoned.

Plaintiffs either have expressly abandoned or implicitly abandoned (by not responding to Ethicon's summary judgment arguments) the following claims:

- Strict Liability – Manufacturing Defect (Count II);
- Strict Liability – Defective Product (Count IV);
- Negligent Infliction of Emotional Distress (Count X);
- Breach of Express and Implied Warranties (Counts XI-XII);
- Gross Negligence (Count XIV); and
- Unjust Enrichment (Count XV).

Pls.' Resp. at 23. Ethicon is entitled to summary judgment on those claims. *See, e.g.*, *McCarrell v. Cumberland Cty. Emps.' Retirement Bd.*, 44 Pa. D. & C. 3d 219, 222, 228 (Pa. Ct. Com. Pl., Cumberland Cty. 1987) (granting summary judgment on a particular claim because "Plaintiffs concede that a summary judgment should be entered on the claim"); *see also* Pa. R.C.P. 1035.3(d) (stating that "[s]ummary judgment may be entered against a party who does not respond").

Accordingly, the remaining claims that Plaintiffs continue to assert are Negligence (Count I), Strict Liability – Failure to Warn (Count III), Strict Liability – Design Defect (Count V), Common Law Fraud (Count VI), Fraudulent Concealment (Count VII), Constructive Fraud (Count VIII), Negligent Misrepresentation (Count IX), Violation of Consumer Protection Laws (Count XIII), Loss of Consortium (Count XVI), and Punitive Damages (Count XVII).

B. Ethicon Is Entitled to Summary Judgment on Plaintiffs' Remaining Claims Because They Are Time-Barred.

This is as clear a case for summary judgment on limitations grounds as there can be: Ms. Blockus testified that she was told by her doctors—*twice*—during the limitations period that her mesh device was the cause of her injuries. That fact is undisputed, and it is dispositive. Accordingly, as Ethicon established in its Motion, Plaintiffs' negligence, strict liability, and fraud claims are time-barred because, by no later than July 2008, Ms. Blockus possessed the "salient" facts concerning her claimed injuries and those products. *See* Defs.' Mot. at 11-18; *Ingenito v. AC & S, Inc.*, 633 A.2d 1172, 1175 (Pa. Super. Ct. 1993).[1]

The parties agree that the limitations period is triggered when the plaintiff either has a subjective awareness of her claim or when it is objectively reasonable that she should have been aware of her claim. Pls.' Resp. at 25 ("the discovery rule operates 'to toll the statute of limitations until the plaintiff discovers, or reasonably should discovery, that she has been injured and that her injury has been caused by another party's conduct.'") (quoting *Wilson v. El-Daief*, 964 A.2d 354, 364 (Pa. 2009). On this record, there is no factual dispute that Ms. Blockus 1) possessed a subjective awareness that her mesh caused her injury in July 2008 and then again in October 2010; and 2) reasonably should have discovered that Prolift was the cause of her alleged injuries no later than November 2011.

[1] Plaintiffs imply that Ethicon should be precluded from arguing the statute of limitations in this case because this Court has allowed a jury to determine the issue in *other* cases. *See* Pls.' Resp. at 24-25. As each case has distinct facts, there is no merit to Plaintiffs' implication.

1. Ms. Blockus Knew in 2008 (and again in 2010) the Mesh Had Caused Her Alleged Injuries.

Plaintiffs' incantation that Ms. Blockus "was never once told by any treating physician that Ethicon's mesh products were defective," and so summary judgment is not warranted spans for 20 pages. *See* Pls.' Resp. at 32. The argument's length betrays its weakness. Mrs. Blockus herself testified that her treating physicians told her twice that her mesh was the cause of her injuries.

To the extent Plaintiffs' argument hinges on the proposition that Mrs. Blockus had to be told that her mesh was *defective*, it is wrong as a matter of law. Pennsylvania does not require that a potential plaintiff know of a product's "defect" before the limitations period begins running. *See Wilson*, 964 A.2d at 364 n.10 ("[T]he following are correct statements: the plaintiff need not know the precise medical cause of her injury, . . . the plaintiff need not apprehend that her physician was negligent, . . . and the plaintiff need not understand she has a cause of action." (internal citations omitted)). This Court has expressly rejected the argument that the statute of limitations does not begin to run until a doctor informs a plaintiff of the cause of her injury, although in this case no fewer than *two* doctors, according to Mrs. Blockus, told her that the mesh was the cause of her injury. *See Winter v. Janssen Pharms., Inc. (In re Risperdal® Litig.)*, 2015 Phila. Ct. Com. Pl. LEXIS 315, *21 (Pa. C.P. 2015) (attached as Exhibit HH).

Here, Plaintiffs fail their own test. Even if the Court were to apply the precise discovery rule Plaintiffs advance, Ms. Blockus's testimony definitively established that she knew as early as 2008 that mesh caused her injuries because two treating physicians told her something was wrong with her mesh. Plaintiffs' Response ignores this testimony and sets forth arguments

untethered to the evidence in the case. For example, on the issue of when she learned that mesh was causing her problems, Ms. Blockus testified:

> Q. Any other doctor tell you that mesh was causing you problems?
>
> A. Dr. Mitesh Parekh.
>
> Q. And when did Dr. Parekh tell you that?
>
> A. Before he did his revision, and I believe that revision was in 2009.
>
> Q. So your implant surgery was in March of 2007?
>
> A. Correct.
>
> Q. And then Dr. Parekh performed a procedure to move some of the mesh, correct?
>
> A. Right.
>
> Q. And that was in 2008, right?
>
> A. Correct.

Id. at 33:13-34:2. *Compare* Pls.' Resp. at 38 ("It is clear: not one of Mrs. Blockus's treaters informed her that her problems she was having were issues resulting from the mesh material.")[2].

She continued:

[2] The record fails to support Plaintiffs' unsubstantiated argument that, "Mrs. Blockus was left believing that these problems were normal complications following her surgery." Indeed, Ms. Blockus testified she does not remember anything about her implant surgery, including any risk discussion with Dr. Plucknett, the fact Dr. Plucknett planned to implant mesh, or going to the hospital for the procedure. Ex. S, Blockus Dep. 86:9-89:16. If Ms. Blockus had no memory of what the potential risks of the surgery where, she certainly could not determine whether later complications were "normal" or otherwise.

> Q. Did any doctor ever tell you that there was something wrong with the mesh?
>
> A. Yes.
>
> Q. Okay. And which doctor was that?
>
> A. Dr. Parekh.
>
> ***
>
> Q. And that was a conversation that you had before your procedure?
>
> A. Right the first revision.
>
> Q. So sometime before July 2008?
>
> A. Right.

Id. at 36:11-37:1. *Compare* Pls.' Resp. at 38 ("There is no testimony or evidence that anyone told her or even suggested that the mesh was defective").

It is undisputed that Mrs. Blockus was subjectively aware that the mesh was the cause of her injury as early as 2008. Dr. Parekh's testimony that he could not recall that conversation with Mrs. Blockus—*not*, as Plaintiffs characterize it, that he never told her that—neither changes that conclusion nor affects the analysis. Dr. Parekh only testified that he did not remember whether he told Ms. Blockus the mesh was defective, and that he "probably had some discussion." Pls.' Resp. at 34. Thus, there is no conflict whatsoever between Dr. Parekh's testimony and Ms. Blockus's on this issue, and thus the only relevant testimony on this point is Mrs. Blockus's.

Even if Dr. Parekh's testimony were equivocal, there is no conflict in testimony regarding the fact that a separate doctor, Dr. Adam, also told her in 2010 that the mesh was the cause of her injury:

> Q. [H]ave you ever been told by a doctor that the mesh was causing your problems?
>
> A. Yes.
>
> Q. Which doctor?
>
> A. Dr. Rony Adam
>
> Q. What did Dr. Adam say to you?
>
> A. That the mesh was causing the problems.
>
> Q. When did you have that conversation?
>
> A. 2010, 2011.

Id. at 32:21-33:9. Plaintiffs simply state that "[a]t no point . . . did Dr. Adams tell her that her transvaginal mesh was defective or the cause of her complications." Pls.' Resp. at 5; *see also id.* at 36. But Plaintiffs cite no deposition testimony to that effect. That is because there is none. The only testimony in the entire summary judgment record on this point is from Mrs. Blockus and it is undisputed: Dr. Adam told her in 2010 that the mesh was the cause of her injuries. Summary judgment is therefore warranted, because the undisputed testimony establishes that her claim is time-barred.

2. Ms. Blockus Reasonably Should Have Known the Cause of Her Injuries Before November 2011.

Even if Mrs. Blockus was not subjectively aware of the causal link between her implant and her injuries, her claim is time-barred because a reasonable person in her position would have

investigated and discovered that there was a causal link, well before Mrs. Blockus filed suit. Specifically, the record here demonstrates that by November 2011, Ms. Blockus "reasonably should [have] discover[ed]" that Prolift was the cause of her injuries. *Wilson*, 964 A.2d at 364. As Plaintiffs' acknowledge, "atypical and lasting post-surgical symptoms, such as those experienced by plaintiff, may trigger the limitations period." Pls.' Resp. at 29 (citing *Wilson*, 600 Pa. at 180). **Between March 2007 and November 2011, Ms. Blockus alleges she experienced over four years of ongoing pain and urinary symptoms, experienced four erosions, underwent four surgical procedures to correct the erosions, and had an additional prolapse device implanted.** *See* Defs.' Mot. at 12-13. This is not a case where Mrs. Blockus's symptoms "could be understood as a temporary consequence of a surgical procedure," Pls.' Resp. at 26; no one—let alone someone who works in the medical field—could plausibly think that a condition that lasted four years after surgery was but a mere "temporary" consequence. *See also id.*, at 27 (Plaintiffs' claiming that this case falls within the exception for symptoms that "could reasonably be understood as *transient* effects of a procedure, versus a physical injury" (emphasis added)). In other words, it is objectively unreasonable for Mrs. Blockus to have waited four years through the limitations period without conducting even the most basic of inquiries. No reasonable jury could conclude otherwise.

Plaintiffs' argument is also illogical. They assert that their claims are timley because "Mrs. Blockus had no reason to consider herself permanently injured," until she saw "a television commercial regarding mesh litigation in March 2013." *Id.* But Plaintiffs never explain why—after *six years of alleged debilitating and life-altering pain*—seeing a commercial

would alert Mrs. Blockus to the *permanency* of her injury.[3] The permanency of her injury should have been apparent from the passage of time. Rather, if anything, the commercial would have alerted her to the defectiveness of the product but that knowledge, as established above, is irrelevant to the limitations inquiry. That is why courts in Pennsylvania routinely hold that the limitations period does not run only on knowledge of a defect or on first seeing an attorney advertisement. Defs.' Mot. at 10-11.

In any case, had she undertaken any sort of reasonable investigation following her July 2008 revision procedure, Ms. Blockus would have discovered the 2008 and 2011 FDA Public Health Notices. Defs.' Mot. at 16-17.[4] Plaintiffs rely heavily on *Simon v. Wyeth Pharms., Inc.*, 989 A.2d 356 (Pa. Super. Ct. 2009) but that case merely proves that Mrs. Blockus's claim is barred as a matter of law. In *Simon*, the court held that the jury reasonably found that the plaintiff's claims did not accrue until the National Institutes of Health's Women's Health Initiative study reporting a causal link between hormone replacement therapy and breast cancer was published. *Id.*at 367. The 2008 FDA notification is no different than the WHI study in *Simon* that the court held triggered the limitations period: It would have alerted a reasonable

[3] Plaintiffs urge the Court to apply *Marinari v. Asbestos Corp.*, 612 A.2d 1021, 1022 (Pa. Super. Ct. 1992), but this case is inapposite. As an initial matter, there is no evidence that Ms. Blockus ever received trigger point injections for pelvic pain following her March 2007 surgery, which would have delayed her discovery of permanent pain. Ms. Blockus also testified that, at the time she saw the television commercial, her injuries were identical to those she was experiencing in 2008. Indeed, her testimony demonstrates injuries were impacting her daily life. Nothing about the alleged injuries "lay dormant" or "creeped" as in the case of an asbestos plaintiff's cancer. Ms. Blockus simply sat on the knowledge that her mesh caused her injuries for five years after her discussion with Dr. Parekh.

[4] Plaintiffs do not dispute that the Notification was publicly-available, could have been discovered by Ms. Blockus, and reported complications associated with surgical mesh device that she is claiming. In fact, Plaintiffs do not respond to the impact of the Notification at all.

person—and it should have alerted Mrs. Blockus—to the fact that transvaginal mesh devices including Prolift are linked with her precise injuries, and that actual inquiry was needed. Under *Simon*, a plaintiff cannot just sit back and wait to see a lawyer television advertisement before filing suit when there is similar, if not more detailed, information from a government source regarding a potential causal connection between a product and certain symptoms that has been accessible and available to the public for 5 years.

Courts around the country routinely find as a matter of law certain events trigger a reasonable person's duty to investigate her potential claims. When analyzing similar factual records as that presented here, courts have found that a mesh revision surgery is enough to begin the limitations clock running. *See Adams v American Medical System, Inc.*, NO. 14-4057, 2017 WL 3668930, at * 2 (10th Cir. Aug. 25, 2017) (holding plaintiff "knew or should have known" that she had been harmed by the mesh after undergoing a revision procedure). *See also Brawley v. Bos. Sci. Corp.*, No. 2:13-cv-23832, 2015 WL 1481837, at *5 (S.D. W. Va. Mar. 31, 2015) (granting summary judgment where when physician informed plaintiff that her symptoms were a result of mesh device and that he would need to remove the portion of the sling that was inside the bladder") (Arkansas law); *Hay-Rewalt v. Bos. Sci, Corp.*, No. 2:12-cv-9912, 2015 WL 1405504, at *6 (S.D. W. Va. Mar. 26, 2015), *aff'd* 623 F. App'x 92 (4th Cir. 2015) ("I FIND that a reasonable person, upon being told that the removal of the Advantage could alleviate that person's symptoms, would discover through the exercise of reasonable diligence that she has a possible cause of action") (citations omitted) (Michigan law)

Other courts have found that the FDA Public Health Notifications start the statute of limitations running. *See Adam*, 2017 WL 3668930, at * 2 (affirming grant of summary judgment

when 2008 FDA notification should have provided link between mesh product and injury to trigger inquiry notice); *Timothy v. Bos. Sci. Corp.*, 665 F. App'x 295, 298 (4th Cir. 2016) (noting that had the plaintiff performed "the most basic inquiry" she would have discovered the Notice and been able to link her injuries to her mesh). The New Jersey Supreme Court found that the formation of a FDA Advisory Panel should have put a person exercising reasonable diligence on notice of a potential claim. *Cornett v. Johnson & Johnson*, 211 N.J. 362 (N.J. 2012). This Court's precedent is in accord. *See Winter*, 2015 Phila. Ct. Com. Pl. LEXIS 315, *21 (publically-available information "should have awakened" plaintiffs' inquiry so that they could begin investigating their claims.).

Ms. Blockus failed to conduct any investigation into her potential claims, even though she alleges she experienced years of pain and other injuries. Her failure to do so is objectively unreasonable, and her claim is thus untimely as a matter of Pennsylvania law. Had Ms. Blockus undertaken any investigation of the cause of her injuries, she would have discovered the October 2008 FDA Public Health Notification, the July 2011 FDA Public Health Notification, and the September 2011 FDA Advisory Panel. Each of these publically-available Notices would have provided her sufficient information to begin investigating a potential claim. Pursuant to the persuasive authority of *Timothy*, *Adams*, *Cornett*, and this Court's decision in *Winter*, Ms. Blockus should have been aware of the link between her mesh and her alleged injuries before November 2011—two years before she filed her Complaint. [5] The Court should find, as a matter

[5] Nothing in Plaintiffs' Response warrants the applicable of fraudulent concealment to toll Plaintiffs' claims. Plaintiffs point to no evidence that Ethicon actively concealed information, or that they relied upon that concealment. *See, e.g.*, *Baselice v. Franciscan Friars Assumption BVM Province, Inc.*, 879 A.2d 270, 279 (Pa. Super. Ct. 2005) (declining to apply the doctrine where the

of law, that Ms. Blockus should have discovered her injuries and their cause before November 2011, and enter judgement for Ethicon on Plaintiffs' negligence, strict liability, and fraud claims.

C. Ethicon Is Entitled to Summary Judgment on Plaintiffs' Strict Liability Claims Because Pennsylvania Law Does Not Recognize These Claim for Medical Devices.

Plaintiffs' argument that they should be allowed to pursue their strict liability claims has no basis under the precedent consistently followed by Pennsylvania courts that strict liability is not a viable theory in cases involving prescription products. Plaintiffs have identified no cases in which a Pennsylvania court, directly presented with the issue, has held that a plaintiff may pursue a strict liability claim involving her prescription medical device or drug. Plaintiffs point to *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), as support for their contention that they should be allowed to proceed under a theory of strict liability. Pls.' Resp. at 56-57. Yet, *Lance* did nothing to change or limit the application of comment k to medical devices. In fact, the plaintiff in *Lance* argued she should be able to pursue a negligence claim, therefore the case did not even address strict liability. *See* 85 A.3d at 448. The *Lance* court explicitly acknowledged that *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996), and its progeny were still good law in Pennsylvania. *See* 85 A.3d at 452 n.21 ("We emphasize that we are not revisiting *Hahn*. . . .").

Ethicon's Motion includes a non-exhaustive list of *eleven* cases, nine of which are from the last three years alone, in which Pennsylvania state and federal courts squarely rejected the argument that Plaintiffs assert here. *See* Defs.' Mot. at 23-24. This precedent has been so consistently applied that Pennsylvania's model jury instructions expressly exclude pharmaceutical

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plaintiff failed to prove either that the defendant had actively misled him or lied to him in such a manner that caused him to suspend pursuit of his claims).

products and medical devices from strict liability treatment. "Pennsylvania courts have declined to apply strict liability in cases involving prescription drugs *and medical devices*, in accordance with comment k." Pa. Suggested Standard Civil Jury Instructions § 23.00 Subcommittee Note (2016) (emphasis added). Instead, "it is well settled law in Pennsylvania that" pharmaceutical and medical device manufacturers are subject to a "reasonable care" or negligence standard. *Id.*

Plaintiffs' attempt to distinguish *Hahn* on the grounds that it involved a prescription drug and not a medical device falls flat. Pls' Resp. at 55-56. The court's analysis, relying on comments j and k to the Restatement (Second) of Torts § 402A, applies equally to any medical product that is available only by prescription. *See Creazzo*, 903 A.2d at 31 ("stating that Pennsylvania courts "find no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices") (citing *Hahn*, 673 A.2d at 890-91). As the *Hahn* court noted: "Comment k, titled 'Unavoidably unsafe products,' denies application of strict liability to products *such as* prescription drugs, which, although dangerous in that they are not without medical risks, are not deemed defective and unreasonably dangerous when marketed with proper warnings." 673 A.2d at 889-90 (quoting comment k) (emphasis added). The court's wording specifically identifies prescription drugs as only one subset of "unavoidably unsafe products" that are "dangerous" because they are "not without medical risks." *Id.* The Pennsylvania courts in the cases cited by Ethicon in its Motion and additional courts nationwide have all recognized that this language applies equally to prescription implanted medical devices. *See, e.g., Transue v. Aesthetech Corp.*, 341 F.3d 911, 915-16 (9th Cir. 2003) (applying Washington law); *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 19-20 (analogizing implanted medical devices to prescription drugs, as opposed to products such as wheelchairs, and concluding under California law by "draw[ing] a bright line within which

the comment k test is applied to all implanted medical devices"); *Breen v. Synthes-Stratec, Inc.*, 947 A.2d 383, 388 (Conn. App. 2008) ("comment (k) is not limited to prescription drugs but also is applicable to medical devices").

Plaintiffs' assertion that the Court should disregard *Hahn* and the other cases that apply a bright-line rule to all prescription drugs and implanted medical devices, and instead, apply comment k on a case-by-case basis is unsupported by Pennsylvania law. *See* Pls.' Resp. at 57-58. The argument derives from a misreading of *Creazzo*. The *Creazzo* court did no preliminary risk-utility balancing in deciding whether to apply comment k. It held unequivocally that *Hahn*'s rule applies fully to medical devices and, under *Hahn*, Pennsylvania takes a blanket approach to "unavoidably unsafe" products. *See Lance v. Wyeth*, 85 A.3d 434, 442 n.11 ("Others, however, including Pennsylvania, have taken a blanket approach applying comment k to preclude strict-liability design-defect claims for all prescription drugs.");*Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 410 (E.D. Pa. 2012) ("Even assuming that Plaintiff's argument that a case-by-case analysis is a 'better course of action,' this is not the law in Pennsylvania.").

Because Pennsylvania courts take a blanket approach to comment k, Plaintiffs' assertion that Prolift "are not the products envisioned by comment k" because they are "'lifestyle,'" not "'life-saving'" products,'" has no basis in law, *see* Pls.' Resp. at 58, and in fact conflicts with the myriad cases above applying comment k to "lifestyle" products. Comment k draws no distinction between the severity of the conditions that prescription products are designed to treat so long as those products are associated with unavoidable medical risks. And a device that must be surgically implanted and carries with it a known list of potential complications is a device that cannot be made completely safe. As Prolift is a medical device available only by a surgeon's prescription,

they fall squarely within comment k, and thus are exempt from strict liability claims. Ethicon is thus entitled to summary judgment on Plaintiffs' Strict Liability – Failure to Warn claim (Count III).Strict Liability – Design Defect claim (Count V).[6]

D. Ethicon Is Entitled To Summary Judgment on Plaintiffs' Negligence-Based Failure-to-Warn Claims

As Plaintiffs' response illustrates, Ethicon is entitled to summary judgment on Plaintiffs' warning claims for two independent reasons: (1) Ethicon did not, as a matter of law, breach a duty to warn; and (2) Plaintiffs lack the testimony necessary to establish proximate causation.

1. Ethicon Did Not Breach Its Duty To Warn

Tellingly, Plaintiffs do not dispute that it was common knowledge in the medical community generally, and that Dr. Plucknett knew specifically, of all the risks of injury sustained by Mrs. Blockus. *See* Defs.' Mot. at 20-23. Under ordinary legal principles, that tacit

[6] Even under Plaintiffs' proposed reading of *Creazzo* their strict-liability claim would be barred. Plaintiffs argue *Creazzo* requires a preliminary assessment of whether the device has "potential utility," Pls.' Resp. at 57, before applying comment k to bar the claim. That preliminary assessment obviously must be fairly lax; otherwise, it would be redundant with the risk-utility balancing that strict liability prescribes (in other words, a preliminary assessment cannot logically involve the same analysis as the ultimate merits test). And the assessment must be made by the Court, not the jury, because it would make no sense to have the jury determine whether to submit the strict liability claim to itself. *See Creazzo*, 903 A.2d at 26 (the "trial court" noted the device's "potential utility"). Here, Plaintiffs cannot dispute that the device helps (i.e., has "utility" for) the vast majority of patients, especially those with severe cases of prolapse or those with particularly weak native tissues for whom native tissue repair would not work. Indeed, Plaintiffs claim the complication rate is as high as 33.6 %, which Ethicon disputes, but even so, that means that 66.4% receive the device and are likely helped. As set forth by Defense experts Drs. Toglia and Kavaler in their General Expert Reports, Prolift is safe and effective with cure rates generally between 80-95% as reported in the high level data, meaning the device works for an overwhelming number of patients. *See* Ex. FF, Toglia General Report at 12-19; Ex. GG, Kavaler General Report at 17-19. Even Plaintiffs' experts concede that some patients with Prolift have demonstrated improvements in symptomatic results and improved quality of life. *See* Ex. II, *Beltz v. Ethicon, Inc.*, June Term 2013, No. 3835, Clip Rep. Daniel Elliott, M.D. at 182:22-183:7, 236:3-238:8.

concession would be fatal to Plaintiffs' warning-based claims. A manufacturer has no duty to warn of risks that are commonly known to users of the product (here pelvic-floor surgeons) and cannot be deemed the cause of an injury under the learned-intermediary doctrine where the prescribing physician was aware of risks but prescribed the device anyway. *Id*.

Plaintiffs instead try to change the applicable legal principles, stating (over and over) that summary judgment is unwarranted because there is a fact dispute as to whether Ethicon breached its duty to warn Dr. Plucknett "of the severity, frequency, and permanency" of the risks posed by Prolift. Defs.' Mot. at 43; *see also id*. at 53 ("Dr. Plucknett did not receive adequate warnings about the frequency, se[ver]ity and permanency of risks associated with the Prolift); *id*. (arguing that common surgical knowledge does not defeat their claim because risks associated with Prolift are "more frequent, severe, and permanent" than those attending other pelvic-floor surgeries).

But whether Ethicon has a duty to warn of a risk's frequency, severity, and permanency, in the first place is a "question of law for the trial court to decide, not a question of fact for the jury, and is therefore a proper basis for summary judgment." *Stephens v. Paris Cleaners, Inc.*, 885 A.2d 59, 67 (Pa. Super. 2005); *see Althaus ex rel. Althaus v. Cohen*, 756 A.2d 1166, 1169-70 (2000) (duty is a legal question for the court). That is, this Court must decide on summary judgment whether Pennsylvania law—not Plaintiffs' expert testimony, which is irrelevant to the inquiry—establishes that a prescription-only device manufacturer has a duty to warn of a risk frequency, severity, and permanency before it may submit the claim to the jury. If Ethicon has no such duty, summary judgment must be granted in its favor. *Stephens*, 885 A.2d at 67.

Prescription-only device manufacturers like Ethicon have no duty to warn of the frequency, severity, or permanency of the risks presented by their products. This is especially

true where the risks depend on the surgeon's skill, training and experience and will vary with the level of skill training and experience. Plaintiffs identify no case—not one—holding otherwise. That is because "the manufacturer of an ethical drug [or device] is only required to warn the prescribing physician of the potential harmful reactions" and contraindications associated with the product, i.e., the risks of injury that attend its use. *Smith v. Wyeth Labs.*, 1986 WL 720792, at *8 (S.D.W.Va. Aug. 21, 1986) (collecting cases); *accord* PA Suggested Standard Civil Jury Instruction 23.10 (A "medical device manufacturer only has a duty to warn the implanting physician about the dangers of its medical devices." (alterations omitted)). A manufacturer does *not*, by contrast, have a duty to warn of the frequency, severity, and permanency of those risks, as the cases below illustrate.

Even in prescription drug cases, courts have thus declined to impose a duty to warn physicians of a given risk's specific frequency. *See McDowell v. Eli Lilly & Co.*, 58 F.Supp.3d 391, 405 (S.D.N.Y. 2014) ("courts have refused to graft onto the adequacy standard a requirement that a package insert must include specific adverse event frequencies"); *Ames*, 431 F.Supp.2d at 573 ("[P]laintiffs were unable to cite a single case in which a court has found a label to be defective because the incidence rate was not described."); *see also, e.g.*, *Alston v. Caraco Pharm.,Inc.*, 670 F. Supp. 2d 279, 286-87 (S.D.N.Y. 2009); *Percival v. Am. Cyanamid Co.*, 689 F. Supp. 1060, 1063-64 (W.D. Okla. 1987); *Calabrese v. Trenton State Coll.*, 392 A.2d 600, 604 (N.J. App. Div. 1978).

The reason for the absence of a duty to warn of risk frequency is straightforward: Frequency or incidence rates are a constant and regular subject of study and debate sorted out by the peer-reviewed medical literature and physicians' independent medical judgment. Studies of

complication rates vary in their sample size, duration, methodology, definitions, controls, quality, and outcomes (to name but a few examples). Debate over the merits and quality of a study can be enduring, and reasonable doctors may reach different conclusions.

For all these reasons, one court explained, "[i]t would require an extended discussion, in the nature of a medical journal article, to lay out the debate" over risk frequency. *Ames*, 431 F.Supp.2d at 573. But that prolonged discussion could never be included in a product label or warning—doing so would only dilute the strength of the warnings that absolutely must be given and potentially dissuade doctors from using a drug or device with a patient that really should receive it. *See, e.g.*, *id*. ("[W]arnings must be brief and focused to be effective."); *Finn v. G.D. Searle & Co.*, 677 P.2d 1147, 1153 (Cal. 1984) (overwarning an important consideration in determining duty to warn).

There is similarly no authority for a duty to elaborate on an otherwise-clear warning to explain that the identified complications could be severe—which, again, Dr. Plucknett specifically knew, and easily could know from the literature, continuing education, and her colleagues. *See, e.g.*, *Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 813 (N.D. Ohio 2004) ("[T]he proffered warning does not detail the scope of the danger. However, because it is directed at physicians, it need not. Physicians are well aware of the scope of the risks associated with increased blood pressure and do not need specifics regarding the possible consequences of blood pressure increases."); *Upjohn Co. v. MacMurdo*, 562 So. 2d 680, 683 (Fla. 1990) ("[T]he insert warned of the possibility of abnormal bleeding. It would be unreasonable to hold Upjohn liable for not characterizing the bleeding as excessive, continuous, or prolonged.").

As to the permanency of risks, Ethicon had no duty to warn because the possibility of

permanent injury obviously inheres in the nature of a permanent implant—any trained physician would know that, especially the trained pelvic-floor surgeons to whom the Prolift IFU restricted the device. *See* Defs.' Mot. at 20-21. Dr. Plucknett testified she understood that Prolift was intended to be permanently implanted in the body. *See* Ex. T, Plucknett Dep. 25:9-11.

Medical professionals apprise themselves of these characteristics of a given risk from developments in the medical literature, their colleagues, and their own experience. *See, e.g.*, Ex. O, Prolift Instructions for Use, at ETH.MESH.02341527 (IFU restrict Prolift device to trained pelvic-floor surgeons); *see also* T, Plucknett Dep. 191:7-192:22 (testifying she relied on medical literature, communications with her colleagues, and medical conferences to learn of the risks of a product). And their own training and experience not only gives them knowledge, but it influences the frequency and severity of the risks their patients will face.

After all, "the warnings are intended to be read by learned intermediaries who are presumed to have considerable medical training as well as the ability to access the medical literature if they require additional information." *Ames v. Apothecon, Inc.*, 431 F. Supp. 2d 566, 573 (D. Md. 2006).

2. Plaintiffs lack the testimony necessary to establish proximate causation.

Plaintiffs argue that, if given different information, Dr. Plucknett would have "altered her counseling of Mrs. Blockus." Pls.' Resp. 53. . They assert, without citation, that Dr. Plucknett's testimony on this point allows them to withstand summary judgment. Pennsylvania law requires more exacting testimony from an implanting physician to establish causation. *Lineberger v. Wyeth*, 894 A.2d 141 (Pa. Super. Ct. 2006). In *Lineberger*, the court was faced with an appeal from the lower court's grant of summary judgment in favor of defendant as to the issue of proximate

causation. In that case, the court rejected the plaintiff's argument that summary judgment was not appropriate because her prescribing physician testified that he would have "passed information about the material risk of valvular heart disease to" her and "she would not have taken the drugs if she had known about the risk of valvular heart disease." *Lineberger*, 894 A.2d at 147.

Plaintiffs argue that it is "very clear that [Dr. Plucknett] would have affirmatively changed her prescribing decision and/or patient counseling." *See* Pls.' Resp. at 52. The only testimony Plaintiffs cite demonstrates Dr. Plucknett would have changed her patient counseling; the record is devoid of testimony that Dr. Plucknett would have changed her decision to implant Prolift. ,.

E. Plaintiffs' Negligent Design Defect Claims Fail as a Matter of Law.

Plaintiffs allege a cause of action for negligent design, essentially asserting that the risks associated with Prolift so outweighed the benefits that Ethicon should have ceased marketing and selling the device. *See* Pls.' Resp. at 54 (stating that Prolift's risks "outweigh any potential benefits"). The summary judgment record conclusively shows that Plaintiffs cannot establish this negligent design claim under Pennsylvania law.

In *Lance*, the Pennsylvania Supreme Court stated that the duty of a prescription-product manufacturer under negligence "can be viewed on a continuum from the requirements of: a warning of dangers, through a stronger warning if justified by the known risks, through non-marketing or discontinuance of marketing when it becomes or should become known that the product simply should not be used in light of relative risks." 85 A.3d at 459-60.

Where a plaintiff's negligence theory of the case is that the product's design is so unsafe that the product should not be used, she must prove that the manufacturer has "introduce[d] [the product] into the marketplace, or continue[d] a previous tender, with actual or constructive

knowledge that the [product] is too harmful to be used by anyone." *Id.* at 461. While the court in *Lance* may have called into question the general requirement that a plaintiff establish a design defect through proof of a reasonable alternative design, the court noted that the negligence standard it adopted had limited applicability to prescription products that remain on the market:

> We recognize that the application of Appellee's theory of liability would present more difficult questions in a circumstance in which a prescription drug maintained its FDA approval, it remained on the market, and U.S. doctors continued to prescribe it. The assertion that no reasonable physician would prescribe the drug (knowing what the manufacturer knew or should have known) is capable of gaining greater traction when, as here, the inquiry is more in the nature of a post-mortem.

Id. at 457 n.33.

The court in *Lance* relied upon the Restatement (Third) of Torts: Products Liability § 6(c), which provides:

> A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.

See Lance, 85 A.3d at 459. The comment to the Restatement provides that under this provision:

> [A] drug is defectively designed only when it provides no net benefit to any class of patients. Courts have concluded so long as a . . . medical device provides net benefits to some persons under some circumstances, the . . . device manufacturer should be required to instruct and warn health-care providers of the foreseeable risks and benefits.

Restatement (Third) of Torts: Products Liability § 6 cmt. B. "Thus, a . . . medical device that has usefulness to any class of patients is not defective in design even if it is harmful to other patients." *Id.*

In their Response, Plaintiffs have not offered any evidence of a safe and effective way for the Prolift to have been designed. Instead, they have chosen to pursue their negligence claim under *Lance's* "too harmful to be used by anyone" standard. Pls.' Resp. at 53-54. Plaintiffs cannot prevail under this standard.

Plaintiffs have failed to establish that at the time Dr. Plucknett implanted Prolift in March 2007, Ethicon knew or should have known that the alleged risks associated with the device were so significant that it should have discontinued its marketing and selling as it should not have been implanted in any class of patients, as required by the *Lance* standard. *See* 85 A.3d at 459-60. The evidence cited by Plaintiffs in their Response does not demonstrate the level of constructive knowledge in 2007 required to state a claim under *Lance*. In fact, even today, the FDA has not banned or recalled devices like Prolift because it believes they can be needed for some patients.

Dr. Plucknett testified that in March 2007, she was independently aware of the risk of all injuries Ms. Blockus claims to have experienced as a result of her Prolift. Defs.' Mot. at 23. This testimony alone shows that Plaintiffs cannot demonstrate that in March 2007, a reasonable health-care provider, knowing the foreseeable risks and benefits of Prolift, would not have prescribed the device in any class of patients. *See* Restatement (Third) of Torts § 6(c). Because Plaintiffs have failed to present any evidence establishing that Prolift was unsafe for any patient at the time of Ms. Blockus's implant surgery, their negligent design claim fails. 85 A.3d at 459-60.[7]

[7] To the extent Plaintiffs assert that under *Lance*, they can state a claim for Ethicon's failure to stop selling Prolift, that argument has been rejected by the United States Supreme Court. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2477-78 (2013). The Court in *Bartlett* stated:

> We reject this "stop-selling" rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not

F. Plaintiffs' Fraud and Misrepresentation Claims Fails As a Matter of Law.

Plaintiffs' claims for fraud, fraudulent concealment, constructive fraud and negligent misrepresentation collectively fail because Plaintiffs cannot establish an element common to all of these causes of action: justifiable reliance. *See* Defs.' Mot. at 26-28, *and see* Pls.' Resp. at 59-60 (discussing elements of claims).

As a threshold matter, Plaintiffs agree the only communication about the product at issue was between Ms. Blockus and Dr. Plucknett, not between Ms. Blockus and Ethicon. *See* Pls.' Resp. at 60. Accordingly, there are no representations made by Ethicon to Plaintiffs which could putatively form the basis of any reliance. Rather, Ms. Blockus concedes that she relied solely upon the representations and medical advice of Dr. Plucknett. *Id.* ("She got information about these products from Dr. Plucknett . . . when deciding on which surgery to undergo ")

Under Pennsylvania law, a plaintiff cannot assert reliance on the manufacturer when all of the representations originate from the physician. *See Kee v. Zimmer, Inc.*, 871 F. Supp. 2d. 405, 411-412 (E.D. Pa. 2012) ("the 'learned intermediary doctrine breaks the chain in terms of reliance, [because] the patient cannot obtain prescription drugs without the physician no matter what [the patient] believe[s] about them'") (citing two Philadelphia Court of Common Pleas opinions) (citations omitted); *and see Albertson v. Wyeth Inc.*, 63 Pa. D. & C. 4th 514, 540 (Pa.

> required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be "all but meaningless."

Id. at 2478.

Ct. Com. Pl., Phila. Cty. 2003) ("plaintiffs have no cause of action for . . . fraud in light of the learned intermediary doctrine").

While acknowledging the authority of *Kee*, Plaintiffs ask this Court to establish new Pennsylvania medical device law, finding that 1) Dr. Plucknett was the legal agent of Ethicon, and 2) to construe the physician's words to be those of Ethicon, upon which Ms. Blockus stakes her alleged reliance. *See* Pls.' Resp. at 60. Plaintiffs do not, and cannot, establish that Ms. Blockus's physician was Ethicon's legal agent under Pennsylvania law. Pennsylvania law recognizes an "agent" as someone who has agreed to act in the capacity of a fiduciary on behalf of, and under the control of, a principal. *See Basile v. H & R Block, Inc.*, 761 A.2d 1115, 1120 (Pa. 2000) (collecting Pennsylvania agency case law) (citations omitted). The full extent of this illogical premise is illustrated on page 61 of Plaintiffs' Response, where Plaintiffs asks the Court to find that Ethicon made material representations to Dr. Plucknett (*i.e.*, that Ethicon made material representations to themselves). Of course, this undercuts Plaintiffs' fraud claim, which requires the person making the alleged misrepresentation to have knowledge of its falsity.

Nor can Plaintiffs prove causation. Doctors are not mouthpieces for drug or device manufacturers, but rather make prescribing decisions based on their experience, information gathered from conversations with colleagues, and information gleaned from the medical literature—Dr. Plucknett was no different. Ex. T, Plucknett Dep. At 191:7-21. Dr. Plucknett's choice to prescribe Prolift was based on her own independent medical judgment, as it was required to be by law, not simply Ethicon's warnings, which breaks the chain of causation. *See Liebowitz v. Ortho Pharma. Corp.*, 307 A.2d 449, 458 n.3 (Pa. Super. 1973) ("Even if Ortho had

failed to adequately warn of dangers, said reason is not actionable" because doctor "testified that he was aware of other data and did not rely solely on the package insert in prescribing drug").

Separately, Plaintiffs' fraud-based claims fail outright because, under long-settled Pennsylvania law, a plaintiff is required to put forward evidence of economic loss—and Plaintiffs have not. Economic loss is the only damages theory recognized for a fraud or misrepresentation claim. *See, e.g., Restituto & Carmen Estacio h/w v. Trauma Serv. Grp.*, 1995 WL 1315961 (Pa. Com. Pl. Apr. 24, 1995) ("It is well-settled that '[d]amages for fraud are limited to what losses were immediately and proximately caused by the fraud'" (quoting *Lokay v. Lehigh Vall. Cooperative Farmers, Inc.*, 492 A.2d 405, 410 (1985)); *Delahanty v. First Pa. Bank, N.A.*, 464 A.2d 1242, 1257 (1983) ("Under Pennsylvania law, in an action based on fraud, the measure of damages is 'actual loss,' and not the benefit, or value, of that bargain. The victim is entitled to all *pecuniary losses* which result as a consequence of his reliance on the truth of the representations." (emphasis added; citations omitted)). Plaintiffs, however, have adduced *no proof* of pecuniary loss, such as medical bills, insurance co-payments, etc. *See* Ex. A, Blockus Dep. 169:3-5. The failure to adduce any evidence of this element of their claims is fatal.

G. Plaintiffs' UTPCPL Claim Fails As a Matter of Law.

Plaintiffs' UTPCPL claims also fail for lack of justifiable reliance. Because medical devices are only available by prescription, Pennsylvania courts recognize that the patient's relevant relationship is with the doctor, not the defendant manufacturer. *See Creazzo*, 903 A.2d at 24 (the physician has a duty to communicate risks and other information to the patient, not the device manufacturer). Again, the learned intermediary doctrine breaks the chain of causation and abrogates the essential element of reliance. *See Heindel v. Pfizer, Inc.*, 381 F. Supp. 2d 364,

384 (D.N.J. 2004) (granting summary judgment in defendants' favor on UTPCPL claim); *Yocca v. Pittsburgh Steelers Sports, Inc.*, 854 A. 2d 425, 438 (Pa. 2004); *and see Zafarna v. Pfizer, Inc.*, 724 F. Supp. 2d 545, 558 (E.D. Pa. 2010) ("Plaintiffs' claims depend on a chain of reliance from Defendants to the prescribing physicians and the prescribing physicians to patients. This, however, cannot be used to allow Plaintiffs to claim that they justifiably relied on any representation made by Defendants.") The strength of this relationship and the learned intermediary doctrine "makes it difficult, if not impossible, for plaintiffs to successfully bring a UTPCPL claim based on a prescription drug" in Pennsylvania. *Zafarana*, 724 F. Supp. 2d at 557 (commenting on two Philadelphia Court of Common Pleas opinions) (citations omitted).

Here, Plaintiffs raise the same challenge to the learned intermediary bar that was unsuccessful in *Avandia* and *McLaughlin*. *See In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, No. 07-MD-01871, 2013 WL 3486907 (E.D. Pa. July 20, 2013); *McLaughlin v. Bayer Corp.*, No. 15-384, 2016 WL 1161578,(E.D. Pa. Mar. 22, 2016). In both of those cases, plaintiff argued the learned intermediary doctrine was inapplicable because defendant allegedly withheld information about the product from the physician, and thus the physician was not "learned" on the critical issue. *Compare Avandia*, 2013 WL 3486907 at *2, *and McLaughlin*, 2016 WL 1161578, at *19, *with* Pls.' Resp. at 63. As the *McLaughlin* court articulated, "whether or not the physicians were appropriately 'learned' does not affect our conclusion that Plaintiffs cannot prevail on their UTPCPL claim against Bayer because, as patients, they were required to rely on the advice and counsel of their doctors." (citations omitted).

Plaintiff further challenges the application of the learned intermediary doctrine on the basis of *Lance v. Wyeth*. *See* Pls.' Resp. at 63. Pennsylvania federal courts, however, have

repeatedly held that *Lance* did not overrule the longstanding learned intermediary bar to UTPCPL claims against a medical device manufacturer, and this court need not take that step here. *See McLaughlin*, 2016 WL 1161578, *19 ("[W]e conclude that *Lance* in no way altered existing Pennsylvania law as to the application of the learned intermediary doctrine in UTPCPL cases."); *White v. Medtronic, Inc.*, No. CV 16-2638, 2016 WL 4539494, at *3 (E.D. Pa. Aug. 31, 2016) ("Since a manufacturer of a medical device has no duty to disclose information to a consumer such as plaintiff, such a consumer has no cause of action under the statute.") (citations omitted).

In dismissing the plaintiff's UTPCPL claim as a matter of law, the *Avandia* court echoed the words of the Philadelphia Court of Common Pleas, recognizing that the "dissemination of information concerning the existing of these drugs does not enhance the public's ability to acquire them, as the skill and knowledge of the physician still must be brought to bear in a determination of whether the pharmaceutical is appropriate for the patient." *Avandia*, 2013 WL 3486907 at *2 (citing *Albertson*, *supra*). Here, Plaintiff could not have obtained the Prolift device without Dr. Plucknett (or another physician), and thus there is no justifiable reliance or causation recognized by Pennsylvania law with respect to the defendant manufacturers. Ethicon respectfully submits that Plaintiffs' UTPCPL allegations must be dismissed as a matter of law.

H. Ethicon Is Entitled to Summary Judgment on Mr. Blockus's Derivative Loss of Consortium Claim.

Nothing in Plaintiffs' Response alters the conclusion that because Ms. Blockus's substantive claims fail as a matter of law, Mr. Blockus's derivative claim for loss of consortium also fails.

I. Ethicon Is Entitled to Summary Judgment on Plaintiffs' Claim for Punitive Damages (Count XVII).

The facts of this case do not support a finding of "actual malice" or "wanton and willful disregard" as required by New Jersey law for the imposition of punitive damages. *See* N.J.S.A. §2A:15-5.10. At the outset, it bears observing that Plaintiffs grossly mischaracterize the history of the pelvic-mesh litigation. Plaintiffs brashly claim that "[n]o Court applying New Jersey law has ever precluded punitive damages in a transvaginal mesh trial." Pls.' Resp. at 65. False. The courts in *Edwards v. Ethicon, Inc.*, 30 F. Supp.3d 554, 564 (S.D.W. Va. 2014); *Lewis*, *Huskey*, and *Budke*, all ruled as a matter of law that punitive damages were unavailable. *Edwards v. Ethicon, Inc.*, *Lewis v. Johnson & Johnson*, 2014 WL 186869, at *10 (S.D.W. Va. Jan. 15, 2014); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 736, 746 (S.D. W. Va. 2014); *Budke v. Lake Area Womens Ctr*, No. 10CM-CC00085 (Mo. Cir. Ct. 2014).[8] Indeed, the MDL court has *never*—not once—sustained an award of punitive damages against Ethicon. For good reason: As detailed in Defendants' opening brief, New Jersey law is designed to be *more stringent and restrictive* than in most states. And the facts relating to Ethicon's conduct are not malicious under any state's standard, for the reasons that follow.

1. Ethicon warned of the very risk that befell Plaintiff.

Ethicon warned about a risk of mesh erosion, as well as a host of other potential adverse events, even though physicians familiar with the device would understand the risk of these and other events that Ms. Blockus experienced. Ethicon had no duty to warn of risks commonly

[8] Plaintiffs cite both *Lewis* and *Huskey* for the proposition that punitive damages are available, but in both cases Judge Goodwin granted Ethicon judgment as a matter of law on plaintiffs' punitive damages claims.

known to the surgeons who implanted the device. And, in addition, Dr. Plucknett, Ms. Blockus's implanting surgeon, knew about those potential risks. *See* Defs.' Mot. SOF ¶4. Plaintiffs do not dispute that fact in their response brief. Rather, their argument is that Ethicon breached a duty to warn of risk frequency, severity, or permanency which, if it exists at all, certainly was not well-established so as to subject Ethicon to punitive damages for breaching it. *Villa Enters. Mgmt. Ltd. V. Fed. Ins. Co.*, 360 N.J. Super. 166, 188-89 (Law Div. 200) (holding that insurer did not act with willful or wanton disregard of its insured's legal rights where no reported decisions defined the scope of advertising injury coverage). And even if Ethicon's warnings were inadequate for those reasons , the fact that Ethicon gave warnings —it simply did not make them forcefully enough, according to Plaintiffs—contradicts a finding of wanton and willful disregard. *See Toole v. McClintock*, 999 F.2d 1430, 1436 (11th Cir. 1993) (under Alabama's similar punitive damages standard, "the issue of punitive damages should not go to the jury when a manufacturer took steps to warn plaintiff of the potential danger that injured [her]; those facts bar a finding that defendant was 'consciously indifferent'." The warning "describes the main harms that [plaintiff] has actually suffered" even though "[m]ore could have been said or done.") (internal citation omitted); *Schedin v. Ortho-McNeil-Janssen Pharms, Inc. (In re Levaquin Prods. Liab. Litig.)*, 700 F.3d 1161, 1169 (8th Cir. 2012) (reversing punitive damages award, noting that "[b]y warning of that risk in its package insert, OMJP 'actively sought ways to prevent the dangers associated with its product.'").

2. Plaintiffs are not entitled to punitive damages for their design defect claim.

Plaintiffs fundamentally misstate Ethicon's argument as to why punitive damages are unavailable for any design defect claim, as they conflate the FDA's Class II designation of Prolift

with the FDA's 510(k) clearance of the device. Indeed, Plaintiffs imply that Ethicon's argument is based solely upon the fact that Prolift was cleared through the 510(k) process.[9] It is not, and as the following section shows Plaintiffs' evidence—and Plaintiffs bear the burden of proving through clear and convincing evidence their entitlement to punitive damages—falls well short.

To place Prolift in Class II, the FDA necessarily determined that Prolift did not present a potential unreasonable risk of illness or injury. That is because devices that present such a risk have to be placed in Class III. This follows from the plain statutory language of 21 U.S.C. § 360c, which provides that a device should be designated Class II if special controls provide "reasonable assurance of safety and effectiveness," and that, if there is no such assurance, the device must be placed in Class III if it "*presents a potential unreasonable risk of illness or injury*. . . . ." 21 U.S.C. § 360c(C) (emphasis added). In other words, the placement of the device in Class II, and not Class III, necessarily means the FDA believed there was no such risk. *See* 21 U.S.C. §§ 360c(B)-(C).

The history of the classification of the device in issue here begins with the fact that the surgical mesh at issue here is PROLENE* mesh, a "polymeric mesh" knitted from filaments of the same PROLENE* polypropylene material approved by the FDA for use as PROLENE* suture.[10] Three different FDA medical panels—plastic surgery, orthopedics, and gastroenterology/urology—evaluated the safety and effectiveness of all "polymeric mesh" for MDA classification in 1982—including PROLENE* mesh.[11] These panels recommended that all

[9] Neither the *Carlino* court nor the Fourth Circuit in the *Huskey* appeal addressed the importance of the FDA's classification of Class II devices, perhaps because the case authorities on which they exclusively relied dealt with Class III devices, not Class II devices.

[10] *See* Ex. U, Declaration of Reynaldo Librojo, ¶ 22.

[11] *Id.* ¶ 23.

polymeric mesh be placed in Class II because it "has an established history of safe and effective use" and meets "a generally accepted satisfactory level of tissue compatibility." 47 Fed. Reg. 2810, § 878.3300, surgical mesh (Jan. 19, 1982) (emphasis added).[12]

The FDA subsequently agreed, finding that "the biocompatibility of the materials now being used in these devices has been established through their successful use for a number of years" and "performance standards will provide reasonable assurance of *the safety and effectiveness of these devices*." 53 Fed. Reg. 23856 at J(11)-J(12) (June 24, 1988) (emphasis added).

The FDA's classification of Prolift as Class II devices rested on this previous medical panel and FDA determination of the safety and effectiveness of all pelvic mesh. There was nothing like this in the cases on which *Carlino* and *Huskey* relied, all of which involved clearance of a risky Class III device based on equivalence to a pre-1976 device without any formal medical panel review.

The FDA's determination that Prolift belonged in Class II—i.e., was a device that did not present an unreasonable risk of illness or injury—renders punitive damages on Plaintiffs' design defect claim inappropriate.

3. The list of alleged "bad acts" enumerated by Plaintiffs does not show "wanton and willful disregard" in view of the evidence supporting Prolift's safety at the time of implantation.

Charged by Congress with providing "reasonable assurance of the safety and effectiveness of the device," 21 U.S.C. §360c (a)(1)(B), the FDA convened medical panels that

[12] The Court must take judicial notice of the Federal Register. *See* 44 U.S.C. § 1507 ("The contents of the Federal Register shall be judicially noticed . . . .").

placed surgical mesh in Class II because "the biocompatibility of the materials now being used in these devices has been established through their successful use for a number of years." 53 Fed. Reg. 23856 (June 24. 1988). That classification was based on a determination that it did not present a "potential unreasonable risk of illness or injury." *See* 21 U.S.C. §360c(a)(1)(C)).

The FDA later adopted as a special control a guidance document to be followed when establishing the safety and effectiveness of surgical mesh – a guidance which was in effect at the time of Prolift's clearance. *See* Ex. V, Guidance for the Preparation of a Premarket Notification Application for a Surgical Mesh (March 2, 1999). When the FDA ultimately cleared Prolift for sale, it did so following a determination based on medical evidence that the device's safety and effectiveness was equivalent to that of the surgical mesh of which it is made and that the device did not present a "potential unreasonable risk of illness or injury." *See* 21 U.S.C. §360c(a)(1)(C)). The device it cleared was the same as the device implanted in Ms. Blockus in 2007.

Allegations that the Prolift inventors were dissatisfied with the product. In their Response, Plaintiffs imply that Prolift's inventors were dissatisfied with the Prolift mesh. That is not true. The French surgeons who invented Prolift were very pleased with the Prolift mesh and the results achieved. *See* Ex. W, Email dated July 16, 2004 from L. Angelini. Plaintiffs overlook that it was the inventors who, after analyzing a variety of meshes chose to use PROLENE* Soft mesh in the Prolift device. Likewise, Plaintiffs mischaracterize various statements by the inventors who debated how the product might be made better. Striving to make a better product does not constitute wanton disregard for safety.

Nor did Ethicon show any disregard for safety by choosing to use mesh with a long history of safety, which was casually referred to in an email as relying on an "existing bag of tricks." That phrase, which is highly inflammatory, has no relevance here. It did not in any way cause Mrs. Blockus's injury—in fact, the whole discussion *postdated* her surgery. And in any case, it provides no basis for an award of punitive damages because it was used when its author was advocating more modest and more accurate language in a patient brochure—Mrs. Blockus, though, admitted she never saw an Ethicon patient brochure. In response to a suggestion that the brochure include a statement that Prolift mesh was a "specifically designed synthetic mesh," the author stated:

> This mesh was not "specifically designed" for Prolift application, we pulled a mesh out of our existing bag of tricks.

Pls.' Resp. Ex. 50. But the mesh as it appeared in the Prolift kit was "specifically designed" because of the *shape* of the mesh. It was specially cut for use with the Prolift trocars. The author failed to consider that, because of the special shape, the "specifically designed" statement was true, even though the mesh itself had previously been used for other purposes.

Claims of improved sexual health. Plaintiff claims that Ethicon falsely marketed Prolift as "curing" women's sexual health problems and capable of achieving "restoration" of sexual function. There is, however, nothing false in the patient brochure—which Mrs. Blockus did not see, and therefore could not in any event have caused her injuries and therefore cannot give rise to punitive damages. Studies have found improved quality of life one year after vaginal mesh

implantation.[13] Moreover, the Lowman study found that, although Prolift is associated with a 17% de novo dyspareunia rate, 83% of those patients would have the procedure done again, indicating they did believe that the device helped them. Again, the bottom line is that punitive damages cannot be awarded based on anything in the patient brochure because it is not causally related to Mrs. Blockus's injuries.

Delay in the IFU revisions. The FDA did not require Ethicon to send out a "Dear Doctor" letter related to the changes being made to the Prolift IFU. In any event, Dr. Plucknett explicitly warned Plaintiff of the potential risks and complications associated with implantation of the Prolift device – including bleeding, infection, injury to the bladder, rectum, bowel, and blood vessels, mesh exposure, which may require further surgery, and scar tissue formation. Ex. D, Plucknett Dep. 50:13-52:21, 180:9-181:4. She also discussed symptoms associated with an erosion including spotting, discharge, drainage, and painful intercourse.

Ex. T, Pluncknett Dep. at 194:8-20.

Allegations that Prolift should never have been brought to market. Plaintiffs' citation to Jim Hart's testimony does not provide his full testimony on the topic:

> Q. Based on everything you've seen in all the risk assessments, would you think it would be a reasonable opinion that Prolift should not have been brought to the market, based on its safety profile?
>
> ***
>
> THE WITNESS: No.

[13] *See* Yesil, A., *Mesh implantation for pelvic organ prolapse improves quality of life*, Arch Gynecol Obstet (2014) 289:817-821; Lowman, JK, *et al. Does the Prolift System cause dyspareunia?*, Am J. Obstet Gynecol (2008) 199:707.e1-707.e6.

Ex. X, Deposition of Jim Hart ("Hart Dep.") at 866:22 – 867:2.

Allegedly "experimental" kit and/or surgery. Plaintiffs' allegations that "Ethicon worked behind the scenes, through its paid consultants such as Vincent Lucente and Barbara Levy, to coerce ACOG to delete the description of surgery with pelvic floor repair kits such as the Prolift as 'experimental'" is irrelevant to this case and fails to support a punitive damages claim. *See* Pls.' Resp. at 10. For that reason, Ethicon has moved to exclude this evidence in a contemporaneously-filed motion in limine. Indeed, in the federal MDL, Judge Eifert ruled that such evidence was inadmissible. In doing so, she noted that the ACOG evidence was not relevant to punitive damages and that she did not see anything improper in Ethicon's actions. Ex. Y, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, Hearing Transcript (Feb. 25, 2015) at 26, 33.

Physical characteristics of Prolift mesh: bi-directional elasticity and "softness." The statement included in the IFU that Prolift's "bidirectional elastic property allows adaptation to various stresses encountered in the body"[14] was based upon mechanical data/benchtop testing data submitted to the FDA. Ex. Z, Deposition of Brian Lisa (12-19-11) ("Lisa Dep.") at 210:8 – 211:23. The FDA cleared Prolift based in part on that data. Later, the FDA requested an *in vivo* model to support the statement about bi-directional elasticity. *See generally*, Ex. AA, Deposition of Jennifer Paine ("Paine Dep.") at 667:10-17. Plaintiffs never explain, moreover, how alleged misrepresentations relating to elasticity or subjective "softness" in any way contributed to Mrs. Blockus's injury.

[14] *See* Ex. O, Prolift IFU.

The fact that the FDA and Ethicon had differing views post-clearance about the data needed to support this statement does not equate to willful or wanton behavior on the part of Ethicon. And it is simply true that mesh can stretch more than one way, and the degree to which it stretches is a matter of opinion.

Further, Axel Arnaud's testimony concerning the "softness" of mesh being an "illusion" is taken out of context. To begin with, Mr. Arnaud – a non-native English speaker – is clear that he does not "know if that is the correct word in English." Ex. BB, Deposition of Axel Arnaud (11-15-12) at 68:22-69:1. It is clear from his testimony as a whole that it is in the patient's best interest to use a "softer" or less "stiff" mesh when performing vaginal repairs. *See id.* at 68:10-69:13. This is precisely why PROLENE* Soft Mesh – the mesh in Prolift – was "knitted into a unique design that results in a mesh that is approximately 50 percent more flexible than standard PROLENE mesh." *See* Ex. W, Librojo Decl. at ¶30, Ex. 17 (ETH-01655); *id.* at ¶¶32, 33, 35.

Risk of exposure into the vaginal canal. The patient brochure at issue warned about a risk of exposure. *See* Pls.' Resp., Ex. 31. This statement was supported by TVM studies at the time showing a 10-14% exposure rate. In other words, the studies showed that 86-90% of patients do ***not*** experience exposure. Thus, on a patient-by-patient basis, there is a "risk" of this event. And in any case, it bears repeating that Mrs. Blockus *did not see* the patient brochure, so any evidence concerning it cannot be the basis for punitive damages because it did not cause her injuries.

Patients for which Prolift was appropriate. Plaintiff suggests that Ethicon did not adequately warn regarding risks for sexually active women. Ethicon had no duty to warn of a

risk that is obvious to any surgeon who implants polypropylene mesh around a patient's vagina. In any event, the Prolift Surgeon's Resource Monograph clearly states:

> ***Patient Selection***
>
> GYNECARE PROLIFT SYSTEM is ***useful in any patient that a surgeon feels would require synthetic graft augmentation. Only the treating surgeon can determine where it is best used,*** although in patients with previous failure, patients with risk factors for failure and/or the most severe degree of prolapse it has been very successfully employed and has the clearest indications.

See Ex. CC, Prolift Surgeon's Resource Monograph at 3 (emphasis added).

Irrelevant Regulatory Action. Neither the FDA's issuance of a 522 Order in 2012 to manufacturers of pelvic organ repair meshes nor the FDA's recent order to reclassifying pelvic organ repair meshes as Class III devices is relevant here. For that reason, Ethicon has moved *in limine* to exclude evidence and argument concerning the orders. Both events occurred long after Ms. Blockus's 2007 Prolift surgery, and neither has any causal connection to her alleged injury. Ethicon fully complied with the regulatory requirements in place at the time of implantation. For the same reason, it is irrelevant that Ethicon ultimately withdrew Prolift from the market for business reasons. The mesh used in Prolift continues to be used safely for both pelvic organ prolapse repairs and other indications in several different products that are on the market today.

4. The cases cited by Plaintiffs do not support an award of punitive damages.

None of the cases cited by Plaintiffs holds that punitive damages are appropriate under circumstances similar to those here. The court in *Ripa v. Owens-Corning Fiberglass*, 282 N.J. Super. 373 (App. Div. 1995), reached no holding on sufficiency of the evidence as to wanton and willful disregard. Instead, the court ordered a new trial on punitive damages in light of evidentiary and instructional errors.

The remaining cases cited by Plaintiffs are equally without force. *Zakrocki* is an unpublished decision with no precedential value. *See Zakrocki v. Ford Motor Co.*, No. A-75769-06T3, 2009 WL 2243986 (App. Div. July 29, 2009). Moreover, *Wolf v. Procter & Gamble Co.*, 555 F. Supp. 613, 618 (D.N.J. 1982), was decided under the common law, which has since been displaced by the Punitive Damages Act. *See id.* at 618.

Viviano v. CBS, 251 N.J. Super. 113 (App. Div. 1991) is not a product liability case. It has nothing to do with women's health. Instead, it involved a tort suit about discovery responses.

Likewise, *Smith v. Whitaker*, 160 N.J. 221 (1999) is not a product liability case. Rather, it involved a claim against a car owner who failed to maintain his car.[15] *See id.* at 229-230.

The cases cited by Plaintiffs actually help *Defendants*. The standard to cross the threshold to a punitive phase is a high one. Under New Jersey law, "'[t]here must be circumstances of aggravation or outrage, which may consist of such a conscious and deliberate disregard of the interests of others that the [defendant's] conduct may be called wanton and willful.'" *Plasencia v. Orgill, Inc.*, Civil No. 09-5727, 2012 WL 819063, *4 (D.N.J. Mar. 9, 2012) (quoting *Dong v. Alape*, 361 N.J. Super. 106, 116 (App. Div. 2003)). Juries may consider an award of punitive damages in only "exceptional cases." *Id.* at *12. This is not such a case.

[15] Ultimately, the court did find a punitive damages claim supported by a far greater quantum of evidence than presented by Plaintiff here: the company had been cited with numerous safety violations concerning the vehicle, including two "out-of-service" conditions indicating that the vehicle would not be considered safe until corrected; the company knew the vehicle's brakes were not working properly but made no repairs; the brakes were "so far out of adjustment as to render the vehicle unsafe;" the company provided no instruction or training regarding brake safety or maintenance; and the company ignored record-keeping requirements regarding its vehicle maintenance. *Smith*, 160 N.J. at 229-30.

5. Punitive Damages Cannot Constitutionally Be Imposed Because Ethicon's Conduct Has Already Been Punished And Deterred—Repeatedly.

Plaintiffs' brief only underscores the constitutional problem if punitive damages are permitted in this case. *See* Defs. Mot. at 26-27. The Supreme Court has made abundantly clear that a punitive damages award can be justified on two—and only two—bases: punishment and deterrence. *See BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 568 (1996). Where those goals are not served by a punitive damages award, it is necessarily arbitrary and thus violative of due process. *Id.* Here, those goals have already been fulfilled by prior punitive damages awards against Ethicon for the manufacture of Prolift in particular and other pelvic-mesh devices in general.

Indeed, Plaintiffs tout the fact that Ethicon has already been punished for the very same conduct that will form the basis for any punitive damages award here. As Plaintiffs observe, a Pennsylvania jury already awarded $7,000,000 in punitive damages in a case involving "the exact same pelvic organ prolapse device at issue in this case," Pls.' Resp. at 65, and a New Jersey jury awarded $7,760,000 in punitive damages in the *Gross* case, which also involved the Prolift. Ethicon has thus already been punished to the tune of about $15,000,000 for the same conduct at issue here. And that is just the beginning. In *Carlino* and *Ebaugh*, Philadelphia juries awarded a combined $60,000,000 in punitive damages "based on Ethicon's conduct" concerning pelvic mesh devices, Pls.' Resp. at 65, and in *Engleman*, a Pennsylvania jury awarded another $17,5000,000, *see* Ex. DD, Jury Verdict Sheet. In total, juries have imposed under New Jersey's punitive damages statute more than $90,000,000 in punitive damages. Yet Plaintiffs seek to support punitive damages award in this case with "nearly identical evidence." Pls.' Resp. at 35.

The Due Process Clause does not permit Ethicon to be punished over and over and over again for the same conduct—which is, admittedly, what Plaintiffs seek to do.

Nor can punitive damages here be based on the need for deterrence. Prolift (and the later-developed Prolift +M) are no longer on the market, so Ethicon's specific conduct here at issue cannot, by definition, be deterred. To the extent Plaintiffs believe an award can be sustained based on deterrence of *similar* conduct, that purpose has *already* been fulfilled based on multiple punitive damages awards, totaling almost $100,000,000 million, based on fundamentally similar conduct.

Under these circumstances, there is no constitutional purpose to be served by an award of punitive damages, and so the question should never be submitted to the jury.

CONCLUSION

For the reasons stated, Defendants respectfully request that the Court grant their motion and grant any such additional relief to which Defendants may be entitled.

Respectfully submitted,

/s/ Melissa A. Merk
Kenneth A. Murphy
Melissa A. Merk
DRINKER BIDDLE & REATH LLP
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996

Julie A. Callsen
TUCKER ELLIS LLP
950 Main Avenue, Suite 1100
Cleveland, Ohio 44113-7213

Nils Burton Snell

BUTLER SNOW LLP
500 Office Center Drive, Suite 400
Fort Washington, PA 19034

Kimberly Gustafson Bueno (admitted *pro hac vice*)
SCOTTDOUGLAS & MCCONNICO LLP
303 Colorado Street, Suite 2400
Austin, TX 78701

James M. Campbell (admitted *pro hac vice*)
Campbell, Campbell, Edwards & Conroy
Constitution Center, 3rd Floor
Boston, MA 02129

Attorneys for Defendants
Ethicon, Inc., and Johnson & Johnson

CERTIFICATE OF SERVICE

I hereby certify that, on October 6, 2017, I caused a true and correct copy of Defendants Ethicon, Inc. and Johnson & Johnson's Reply Brief in Support of Motion for Summary Judgment to be served via electronic mail on counsel of record, as follows:

Lee Balefsky
Christopher Gomez
Christine Clark
Kline & Specter, P.C.
1525 Locust St., 19th Floor
Philadelphia, PA 19102

Attorneys for Plaintiffs

/s/ Melissa A. Merk
Melissa A. Merk