LINDA GROSS and JEFFREY GROSS, Plaintiffs-Respondents, vs. GYNECARE; ETHICON, INC.; and JOHNSON & JOHNSON, Defendants-Appellants.	:	SUPERIOR COURT OF NEW JERSEY, APPELLATE DIVISION DOCKET NO. A-11-14T2 CIVIL ACTION ON APPEAL FROM SUPERIOR COURT OF NEW JERSEY, LAW DIVISION ATLANTIC COUNTY DOCKET NO. ATL-L-6966-10 MASTER CASE NO. ATL-L-6341-10 CASE NO. CT 291 Sat Below: Hon. Carol E. Higbee, P.J.Cv.

PLAINTIFFS' BRIEF

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PRELIMINARY STATEMENT

This was the first case to go to trial of the thousands of Ethicon pelvic mesh cases across the nation. This bellwether trial, decided under South Dakota law by stipulation of the parties, resulted in a verdict for plaintiffs on common law failure to warn and the South Dakota statutory cause of action of deceit, S.D.C.L. § 20-10-1. The jury awarded Linda and Jeffrey Gross compensatory damages of $3.35 million and punitive damages of $7.76 million. **Defendants have not appealed the jury's findings that their warnings were inadequate and their statements deceitful, or the amount of damages awarded.**

Defendants' appeal is premised on a draconian application of the learned intermediary doctrine. However, the doctrine does not apply where, as here, the manufacturers' warnings are inadequate. Perez v. Wyeth Labs. Inc., 161 N.J. 1, 19, 32 (1999). More fundamentally, no South Dakota court has ever accepted the learned intermediary doctrine, and its Legislature has never adopted it. Defendants' singular support for application of the doctrine is an "Erie prediction" by the Eighth Circuit in Schilf v. Eli Lilly Co., 687 F.3d 947 (8th Cir. 2012). However, such "predictions" of how South Dakota's common law may evolve must be consistent with the established legal rights and policies of South Dakotans. Fantis Foods, Inc. v. N. River Ins. Co., 332 N.J. Super. 250, 260-65 (App. Div. 2000). Thus, if this Court predicts that South

Dakota would accept the learned intermediary doctrine, it should apply a form of the doctrine that does not interfere with South Dakota's clear law and policy safeguarding patients' rights. Wheeldon v. Madison, 374 N.W.2d 367, 372, 374 (S.D. 1985). Consistent with this, the Schilf decision, which defendants heavily rely on, found it was error to apply a proximate cause standard that fails to factor in the patient's decision and autonomy. 687 F.3d at 957. This is consistent with the modern trend to severely restrict, or altogether reject, the learned intermediary doctrine, in part due to how pharmaceutical manufacturers now market their products directly to consumers on television, over radio, in magazines and on the internet. Perez, supra, 161 N.J. at 19. Linda Gross was persuaded to undergo the Prolift procedure only after reviewing misrepresentations on Ethicon's consumer internet website. Thus, under the modern version of the doctrine, Mrs. Gross has a viable, in fact overwhelming, claim for failure to warn.

Defendants then argue that there was insufficient evidence of proximate cause for failure to warn. Again, the defendants are off-base. Dr. Benson, the implanting surgeon, testified that if he had been fully apprised of the true risks, he would have included many more warnings in his informed consent discussion with Linda, and that he would not have recommended implantation of the Prolift. He also testified he no longer even uses mesh to

treat the health condition Linda had. Further, he testified unequivocally that he would defer to Linda's personal decision as to whether or not to proceed with the Prolift. This is significant as Linda testified emphatically that if adequately warned she would not have undergone the procedure. The jury's proximate cause verdict is well-supported and unassailable.

Defendants also argue that the jury's deceit verdict is extinguished by the learned intermediary doctrine. This simply is not so. A statutory right created by South Dakota's Legislature cannot be extinguished by a common law defense no South Dakota court has ever recognized. Hohm v. City of Rapid City, 753 N.W.2d 895, 903 (S.D. 2008). More significantly, the Supreme Court of South Dakota has already held that a manufacturer can be held liable for both failure to warn and deceit claims. Holmes v. Wegman Oil Co., 492 N.W.2d 107, 110, 114 (S.D. 1992).

After an 8-week trial involving voluminous, complex medical and regulatory issues, defendants nitpick at three isolated evidentiary rulings. Suffice it to say, Judge Higbee did not abuse her discretion and there was no prejudice to defendants.

Finally, defendants argue that there was insufficient evidence to support the jury's punitive verdict. The evidence of defendants' wanton and willful behavior was overwhelming and is more than sufficient to meet the standard. In sum, defendants received a fair trial, and the jury's verdict should be affirmed.

COUNTER STATEMENT OF FACTS[1]

On July 13, 2006, plaintiff Linda Gross, a 41-year old hospice nurse from Watertown, South Dakota, had the Prolift Total Pelvic Floor Repair System ("Prolift") surgically inserted to treat a rectocele,[2] which is a type of pelvic organ prolapse suffered by women. (Pa2). The rectocele was an "inconvenience," as she had no pain, no difficulty sitting, no urinary issues, no difficulty performing her job, no pain with sexual relations, and her intimate life with her husband Jeff was fully satisfying. (33T38:13-15, 44:17-46:1, 49:4-49:21, 50:4-51:3).[3]

A. The Prolift

The Prolift, sold by Johnson & Johnson subsidiary, Ethicon, was a surgical procedure which implanted polypropylene mesh through the vagina; it was comprised of a large central implant that stretched from Linda's rectum to her bladder, with six mesh "arms" that were pulled out through six separate incisions in the buttocks and groin. (Pa42-59). Although not disclosed to the jury, the Prolift was withdrawn from the market as of September 2012.

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1 Plaintiffs adopt defendants' procedural history (Db3-4).

2 This condition occurs when the pelvic floor weakens, and the rectum bulges down onto the vagina.

3 In 2001, Linda had stress incontinence that caused leaking of urine with activity, but that was successfully treated with a suture repair and caused no further problems. (33T49:22-25).

B. Linda's Catastrophic Injuries

Linda suffered catastrophic injuries due to implantation of the Prolift. The polypropylene mesh caused an intense inflammatory reaction, and became hardened due to scar tissue which formed across its face. (19T109:17-112:6, 166:10-167:18, 22T34:2-35:18, 45:18-47:16). This caused contraction/shrinkage of the mesh, erosion of the mesh through the wall of the vagina, anatomic distortion of the vagina, severe pelvic and vaginal pain, and dyspareunia (painful sexual intercourse). Id. The Prolift also caused permanent damage to nerves innervating Linda's bladder which has resulted in constant urinary retention (she cannot fully empty her bladder), and the need to self-catheterize herself four times per day. Id. The mesh has also caused Linda to suffer pelvic floor myalgia (extremely painful spasms) and pudendal nerve damage. She also had a spinal stimulator implanted to try to help with the chronic severe pain, a pain pump, injections for pain management, painful manual physical therapy of her pelvic floor through her vagina, and Botox injections into her pelvic floor at the Mayo Clinic in Minnesota. (33T87:7-91:15; 33T73:7-87:4; Pa64). Linda has undergone **22 separate surgeries** in an attempt to reverse the damage caused by the Prolift. (14T206:22-207:4; 21T28:15-24, 32:8-33:15; 33T75:16-77:5, 80:9-82:1; 21T34:2-5, 35:24-36:23, 38:12-48:2; 38T101:2-119:4, 21T48:22-49:17; Pa65). The surgeons

have repeatedly attempted to remove all of the mesh from her body, but they are unable to do so. According to Dr. Weber, **"[t]here's mesh that can't be removed. And she's going to have to live with that."** (22T46:18-23, see 39:23-40:14). Due to her severe injuries, Linda could not function in her job and was ultimately fired. (33T92:1-93:5). Every aspect of her life has been damaged due to the Prolift complications: she spends a great deal of time in bed due to pain, she self-catheterizes herself throughout the day, and due to the dyspareunia, she has not had sexual intercourse with her husband since 2009. (33T93:6-98:20).

C. Ethicon Knew of All Potential Complications

Ethicon's worldwide medical director, Piet Hinoul, M.D. was the designated corporate representative for Ethicon. (17T7:20-22, 17:9-12). Dr. Hinoul admitted that all of the risks of the Prolift were known "from Day One" when the Prolift was first marketed, and that none of the adverse events reported to the company were a surprise as they already knew they could occur:

> Q. **So, any adverse reaction, adverse event that's documented right up till the present, medical affairs knew it the day the Prolift was put on the market, right?**
>
> A. **Yes. So the adverse event profile hasn't changed over the period that we've put it on the market.**

(17T96:23-97:1). Defendants knew up front all of "the complications that have been reported with respect to Prolift."

(43T182:9-13). This includes the complications discussed in a February 19, 2009 email exchange initiated by Ethicon marketing product director Scott Jones with urogynecologist Fah Che Leong, M.D., who advised Ethicon that the mesh could retract, erode, and cause the loss of coital function, and cause "mutilated or destroyed vaginas due to the Prolift." (17T127:16-131:3; Da492). Plaintiffs' urogynecologic expert, Anne Weber, M.D., explained why Linda suffered similar complications. (19T6:13-34:1; 20T236:8-238:2; 22T44:15-45:17).

Ethicon admitted to a litany of severe Prolift complications that it knew would happen on "the day the Prolift went on the market," including: complex mesh erosions in multiple sites, mesh exposure that is difficult to treat and requires multiple operations, significant mesh contraction that causes pain and pain syndromes, incapacitating pelvic pain, dyspareunia, nerve damage due to direct irritation of nerves by the mesh or due to inflammation and scar tissue from nearby mesh, recurrence of prolapse due to failure of the mesh, the need for subsequent invasive operations to remove or revise contracted mesh, prolonged or permanent inability to void the bladder, and life changing complications. (17T46:11-22; 22T45:18-46:11; 17T132:16-23, 151:5-152:6; 152:25-153:13; 163:13-164:2; 164:18-165:3).

D. Ethicon Failed to Warn of the Complications it Knew

Perhaps most important, Ethicon knew that for some women the complications would "be complex and exceedingly difficult or impossible to treat." (17T155:14-156:7). Dr. Hinoul admitted that Ethicon should have warned that surgery would be necessary to remove the mesh, that the surgery would cause even more damage, and despite "repeat interventions" these mesh related complications could be permanent. (17T161:8-12, 163:3-12). Though Ethicon knew women would want -- and should have -- this information, it **was not warned** of by Ethicon in the package insert, known as the "Instructions For Use" ("IFU"), nor in the patient brochure. This is significant as all of the complications Hinoul discussed were suffered by Linda Gross. (38T95:25-97:15; 22T46:18-23, 47:17-24; Pa72-73).

Ethicon withheld other negative information such as the fact that **the mesh material was referred to internally as "the best of a bad lot."** (Pa75). Additionally, prior to Linda's Prolift surgery in July 2006, Ethicon was very concerned about the devastating complications from Prolift, and acknowledged the need to "reduce vaginal stiffness, mesh exposure and pain ... [and] the rate of tissue contraction and folding," yet at the same time Ethicon misleadingly marketed the Prolift as "a revolutionary new procedure" in the patient brochure. (17T88:19-89:21; Pa75; Da300).

Ethicon was aware from the beginning that due to the serious problems with the mesh young, sexually-active women like Linda were suffering severe complications, and doctors were reporting "doubts" about whether the Prolift should be used with these women. (17T112:14-116:15). Ethicon believed internally, but did not inform doctors, that the "procedure must be used cautiously in sexually active women," and "we cannot recommend this as the best procedure for a young woman." (35T9:4-15, 108:3-10, 117:7-11). **Significantly, two months before starting to sell the Prolift, Axel Arnaud of Ethicon Medical Affairs requested the addition of an explicit warning in the IFU that contraction of the mesh could lead to serious problems for sexually active women -- but this warning was not included because the Ethicon project leader did not want to reprint the IFU's.** (35T38:23-39:22; 29T21:18-23; Pa81-82).[4] In May 2006, just two months prior to the plaintiff's surgery, Ethicon was trying to develop "a short term way to reduce the sexual function issues" with the Prolift mesh. (Pa92, 124). It never did, and it still sold the Prolift "as is" for implantation in Linda Gross. (17T30:23-31:4).

[4] As early as 2003 the French doctors who developed the Prolift with Ethicon were "pressing repeatedly for changes to the mesh in the Prolift," and scientists at Ethicon were already trying to develop a new mesh that would not cause erosion and contraction, and would minimize scar formation on the mesh. (35T29:10-30:9; 17T200:6-24; 22T50:19-51:20). They wanted to reduce the stiffness and the shrinking effect "to ensure good sexual activity post-surgery." (18T205:7-23).

Despite the alarming risk profile for the Prolift, Ethicon only disclosed a limited set of generically stated potential risks, with no disclosure of the known catastrophic complications. (27T44:2-19; 29T42:11-43:3; Pa83). In fact, the IFU in use in July 2006 falsely claimed an attribute that "would be of great importance to surgeons": that the mesh had a unique "elasticity" that allowed "adaptation to various stresses encountered in the body" (Pa84), but Ethicon admitted it did not have a basis to make this statement (19T162:6-163:25). The IFU also falsely claimed that the mesh only caused "a minimum to slight inflammatory reaction, which is transient," when in fact the mesh caused a chronic inflammatory reaction that was severe and intense in some women. (19T164:1-165:13; 29T45:6-17). Ethicon also failed to warn of the heightened risk of Prolift-caused chronic pain to patients with a prior history of chronic pain, such as Linda; this was known to Ethicon from the outset. (19T168:19-171:15).

Other untrue or inadequate statements in the IFU included the representation that the mesh remains "soft and pliable." (19T166:8-167:18). Ethicon admitted that softness of the mesh was an "illusion," and it would not be elastic in the body over time. (35T17:12-18:4). Sean O'Bryan, the regulatory affairs project manager for the Prolift IFU, admitted the IFU failed to disclose "that a patient could potentially suffer serious complications with a significant effect on quality of life for the patient."

(29T50:5-8). In addition, Mr. O'Bryan testified that the IFU should have disclosed the consequences of scarring that results in mesh contraction "so surgeons would understand the consequences ... the severity and nature of what would follow from that," including pain, dyspareunia, and rectocele recurrence. (29T53:1-20). **Dr. Weber presented a long list of warnings that should have been given in the IFU, but were never provided by Ethicon.** (19T169:11-171:15, 174:2-178:21, 182:12-189:4, 190:14-196:19; 19T-20T197:5-209:19).

The purpose of the Prolift patient brochure is "to inform the patient about the Prolift product and procedure." (7T1398:14-18; 29T58:23-59:5). Ethicon used the patient brochure to market the Prolift on the Ethicon website, where a patient like Linda Gross "could read it on their own." Ethicon knew a "patient could read this after meeting with their doctor, be very, very impressed by it and make the decision and have that finalize her decision to have a Prolift." (44T227:24-228:10, 230:5-10). Ethicon expected patients to believe what they read in the brochure, and to rely on the brochure, at least in part, in deciding, "whether or not to let a surgeon put a Prolift in their body." (38T63:8-21).

However, the FDA found the brochure, which was relied on by Linda, to be "promotional, biased, and can be perceived as coercive to the patient." (Da449-50). The brochure misrepresented that the Prolift procedure was "minimally

invasive," there were "long-term study results," and the mesh was "soft" in actual use. (Da300). These statements were entirely untrue. The brochure also misrepresented that the mesh was "specially designed," even though, in the words of Mark Yale (Ethicon director of worldwide risk management), the mesh was actually a hernia mesh pulled from Ethicon's "existing bag of tricks." (19T128:15-131:23; Pa89). The brochure falsely guarantees the Prolift will work, as it "will correct these defects and restore normal support" (Da300), when Ethicon knew that retraction of the mesh could cause prolapse recurrence, thus not providing that support (19T165:8-166:7). The patient marketing brochure also misrepresented that the Prolift complications were "rare," and that there was a "small risk" that the mesh could be exposed into the vagina, despite internal knowledge that these claims were false and in fact mesh exposure through the vaginal wall was "common" and "not rare," occurring at a 20.7% rate. (35T28:12-24, 37:25-38:4). In addition, contrary to the representation in the IFU and brochure that the Prolift was appropriate for almost all patients, Dr. Weber opined that the warnings should have limited use to "a very restricted patient population," and a warning should have been included" to "[u]se caution before considering use in young or sexually active patients." (19T131:24-143:17).

E. Dr. Benson was Kept in the Dark by Ethicon

Though implanting surgeon Dr. Kevin Benson taught the Prolift procedure to other surgeons on behalf of Ethicon, "even he didn't have all of the information that Ethicon had as to the full range of risks and complications and important aspects of the surgical technique," including the inability to successfully treat mesh erosion into the vagina. (20T212:3-213:19; 22T22:22-23:8). Dr. Benson "read and relied on the IFU" as part of his training about the procedure, and assumed that the IFU provided "a complete statement of whatever risks and complications...existed with the Prolift." (26T26:13-27:10). He relied on the IFU regarding, "who are the right patients for this and what are the risks." (26T28:1-28:6). His personal practice was to take the disclosed risks into account in deciding what to recommend to a patient, and he would "provide risks to the patient that [he] had been made aware of." (26T28:22-29:6).

Dr. Benson was also influenced by Ethicon's misrepresentations about the Prolift and repeated that information to plaintiff. (26T17:17-131:25). For example, he described the Prolift to Linda, a nurse, as "a new revolutionary piece of mesh here that we've been using and it's having excellent results...it's nice and soft..." (33T51:10-52:16). **Linda specifically asked about removal of the mesh: "And I had asked him if a person reacts or has a rejection of that mesh,**

what do you do? And he said point blank, remove it." Dr. Benson did not indicate there could be difficulty removing the mesh. (33T53:2-53:11).

F. Linda Visits and Relies on Ethicon's Website

Linda had several options to address her condition aside from the Prolift, including observation (doing nothing), and low-risk, traditional repair with suture. (26T24:19-24). After meeting with Dr. Benson, Linda was still undecided about whether to proceed with the Prolift procedure. (33T129:5-7). Linda went home and read on the Ethicon website that the Prolift was "a revolutionary new procedure" with "long-term results," and that the mesh was "soft" and "specially designed." (Pa142). She relied on the information she read on the website. (33T53:15-56:5, 129:13-20). Linda also read and printed out the patient brochure from the website, and testified in detail regarding the representations in the brochure that induced her to agree to the Prolift. (33T56:6-63:19). **The Ethicon website sealed the decision: "It sold me on it.... It just – it was so positive, I just didn't have any worries. You know, I trusted Dr. Benson and I trusted what I was reading. I didn't continue to research."** (33T58:18-59:8).

G. If Dr. Benson was Adequately Warned, He Would Not Have Recommended the Prolift for Linda

Dr. Benson did not learn "a great deal more about the risks of the Prolift" until after he operated on Linda Gross in July

2006. (26T28:7-15). For example, in 2006 Dr. Benson "still felt the numbers were low" with regard to erosion of the mesh, and he testified **"I don't think we really had a good handle on how frequent or how significant it may be."** (26T35:14-36:5). Another important area he learned about later was the extent and consequences of Prolift mesh contraction. (26T122:3-9). Of critical importance, he believed in July 2006 that "removal of the mesh would improve the circumstances," and only learned thereafter that removing mesh when necessary would not always resolve the complications. (26T42:16-43:2). **As a result, after Linda's surgery he changed the information he provided and began to tell patients that despite "multiple surgeries to try to treat their complications ... it may not help them and they could end up left with permanent pain."** (16T45:22-46:9). **This is significant since Linda inquired of Dr. Benson what would happen if there was a need to remove the mesh, and he explained it could be easily removed.** (33T52:25-53:11, 62:12-15).

Based on what he learned about the risks of the Prolift after 2006, Dr. Benson's informed consent discussion with later patients became "much more robust," going from a "15-20 minute discussion" to "a 45-minute to an hour discussion that might take place twice before they had surgery." (26T44:17-45:17). The consent discussion evolved to address a more in-depth description of risks, "including dyspareunia, pelvic pain, vaginal

foreshortening, constricture, [and] impaired recovery," all of which the plaintiff suffered. (26T45:8-19).

Most important, as he learned information Ethicon had failed to disclose, Dr. Benson's "decision-making with regard to the Prolift changed a great deal following July 2006." (26T119:11-14). Dr. Benson testified that he learned of the "high risk" to patients with a history of chronic pain after July 2006, and that he is less likely to offer the Prolift to patients with such a history, like Linda. (26T30:4-31:08).

Dr. Benson agreed that Linda "had a catastrophic outcome," which Ethicon never warned him could happen: "**that what happened to Linda was something that could happen to women with the Prolift, they certainly didn't warn about it.**" (26T131:18-25). If he had been warned, his discussion with Linda would have been very different, including "a much more extensive explanation of the risks of using the Prolift," and if he had known, he would have warned about what ultimately happened to the plaintiff herself. (26T128:2-15).

Dr. Benson also testified that had he known in 2006 what he later learned about the risks of the Prolift, **his behavior would have (and did) change**: he would have had "a much more robust discussion about everything that can go on," and **he would have told Linda that "based on her risk profile ... [his] recommendation would have been a suture repair as opposed to the**

Prolift." (26T130:3-14). Moreover, as a result of what he later learned with regard to the risks for a woman like Linda: a young, sexually active woman, who was having her first prolapse repair, he was "not choosing mesh for primary repair of posterior prolapse," and this would have applied to Linda. (26T46:11-47:6). **In other words, if adequate warnings had been given, he would not have recommended the Prolift to Linda.**

Finally, Dr. Benson made it perfectly clear that ultimately the decision of whether to undergo the Prolift implantation was solely Linda's. (26T129:18-22). Linda testified that if she had been warned of the risks, she would not have consented to undergoing the Prolift procedure. (33T63:20-74:3).

LEGAL ARGUMENT

POINT I

THE LEARNED INTERMEDIARY DOCTRINE DOES NOT APPLY

Defendants predicate their arguments challenging liability on a draconian application of the learned intermediary doctrine, even though no South Dakota court has ever accepted it.[5] Even if *arguendo* South Dakota would adopt the doctrine, it would be a version that does not conflict with that state's existing law and policies, as was applied by Judge Higbee below.

[5] The parties stipulated that South Dakota law governs substantive issues and New Jersey law governs punitive damages. (Da218-19; accord Db3).

A. The Learned Intermediary Doctrine Does Not Apply When There Are Inadequate Warnings

The learned intermediary doctrine is an affirmative defense based on the roles of patients, doctors, and manufacturers in the 1960s. The learned intermediary doctrine "generally relieves a pharmaceutical manufacturer of an independent duty to warn the ultimate user ... **as long as it has supplied the physician with information**" of its product's risks. Perez v. Wyeth Labs. Inc., 161 N.J. 1, 32 (1999) (emphasis added). But the doctrine does not apply where, as here, the warnings are found to be defective.

"The learned-intermediary doctrine is a *defensive* doctrine, not an *offensive* one." Kapps v. Biosense Webster, Inc., 813 F. Supp. 2d 1128, 1152 (D. Minn. 2011). The doctrine is "an exception to the manufacturer's traditional duty to warn consumers directly," so when "its premises are absent," the defense "simply drops out of the calculus, leaving the duty of the manufacturer to be determined in accordance with general principles of tort law." Perez, supra, 161 N.J. at 19. Because defendants have not appealed or contested the jury's determination that their warnings were inadequate,[6] the defense must "drop out" and general principles of tort law govern:

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[6] Defendants have waived any challenge to the jury's findings of an inadequate warning by not appealing the issue, nor arguing it in their opening brief. Liebling v. Garden State Indem., 337 N.J. Super. 447, 465-66 (App. Div.), certif. denied, 169 N.J. 606 (2001).

> In the absence of a finding that the warning provided by [the manufacturer] about [its product's] risks was adequate, no state's tort law insulates [defendant] from liability under the learned intermediary doctrine.

In re Zyprexa Prods. Liab. Litig., 489 F. Supp. 2d 230, 280-81 (E.D.N.Y. 2007); Hill v. Novartis Pharms. Corp., 944 F. Supp. 2d 943, 954 (E.D. Cal. 2013) (if "warnings to the prescribing physicians were inadequate, [plaintiff] would not be precluded under the [doctrine] from introducing such evidence and from arguing that [the manufacturer's] duty to warn ran to individual[]" patient); Giles v. Wyeth, 500 F. Supp. 2d 1063, 1066-67 (S.D. Ill. 2007) (if "company fails to warn doctors sufficiently, doctors cannot be considered learned intermediaries"; "Because [the manufacturer] did not warn of the risk, the [defense] never applied"); Stanger v. Smith & Nephew, 401 F. Supp. 2d 974, 984 (E.D. Mo. 2005) (because doctor "had no knowledge of the dangers involved .... he was not a 'learned intermediary' and therefore [the manufacturer] may not rely on this defense"); accord In re Avandia Prods. Liab. Litig., 624 F. Supp. 2d 396, 419-20 (E.D. Pa. 2009); Hyman & Armstrong v. Gunderson, 279 S.W.3d 93, 112 (Ky. 2008); Pittman v. Upjohn Co., 890 S.W.2d 425, 429 (Tenn. 1994).

Consequently, because the jury's determination that defendants' warnings are inadequate is undisputed, the learned intermediary doctrine does not apply as a matter of law.

B. The Trial Court Applied the Doctrine Consistent with *Schilf*

Judge Higbee applied the learned intermediary doctrine based on the case presented by defendants as governing the law of South Dakota: Schilf v. Eli Lilly & Co., 687 F.3d 947 (8th Cir. 2012), (Pa170; 13T5:18-19), which is the same case they rely on to assert the defense on appeal, (Db15-16). The trial court applied the doctrine consistent with Schilf, and the Eighth Circuit's modern understanding of the defense disposes of defendants' appeal.

Contrary to defendants' claim that almost every state has adopted the learned intermediary doctrine, the Supreme Court of West Virginia recently did a survey and found that only 22 state supreme courts/legislatures have accepted it. State v. Karl, 647 S.E.2d 899, 904 (W. Va. 2007). And over the past two decades courts have modernized the doctrine -- rejecting or severely limiting it -- because the relationship between patients, doctors, and the pharmaceutical industry has completely transformed: managed healthcare has undermined the traditional doctor-patient relationship, and the tide of aggressive marketing by the pharmaceutical industry has infringed upon this relationship. Perez, supra, 161 N.J. 1 (rejecting the doctrine as an absolute defense); Karl, supra, 647 S.E.2d 899 (same); Watts v. Medicis Pharm. Corp., ___ P.3d ____, 2015 WL 375985, at *8 (Az. App. Ct. 2015) (rejecting doctrine due to "modern-day

pharmaceutical marketing") (Pa171); Rimbert v. Eli Lilly & Co., 577 F. Supp. 2d 1174, 1215-19 (D.N.M. 2008) (rejecting doctrine as "largely outdated and unpersuasive").

South Dakota's jurisprudence dictates that it would not apply the doctrine, as its Legislature has modified and limited what it accepts from § 402A of Restatement (Second) of Torts. Wangsness v. Bldrs. Cashway, Inc., 779 N.W.2d 136, 144 n.3 (S.D. 2010). The genesis of the learned intermediary doctrine is traced to comment k of Restatement (Second). Whether a state adopts one of the defenses in comment k is a matter of state policy, Collins v. Eli Lilly Co., 342 N.W.2d 37, 52 (Wis. 1984); and the South Dakota Supreme Court has never endorsed comment k. In 1995, South Dakota's Legislature formally adopted the state-of-the-art defense, which is related to the comment k defenses. S.D.C.L. § 20-9-10.11; Robinson v. Brandtjen & Kluge, 500 F.3d 691, 694-95 (8th Cir. 2007); Murray, The State of the Art Defense in Strict Prod. Liab., Marq. L. Rev., 657 (1974) (Pa185). **But the Legislature did not adopt the learned intermediary doctrine, another comment k defense.** South Dakota's "pattern jury instructions have been carefully drafted to reflect the law." State v. Eagle Star, 558 N.W.2d 70, 73 n.2 (S.D. 1996). The jury instructions list South Dakota's "defenses to strict liability," including misuse of product, which is another Restatement (Second) defense, but there is no mention of the learned

intermediary defense. S.D. Pattern Jury Instr. § 20-120 (Pa188-93). It is therefore clear that South Dakota has selected only portions of Restatement (Second) that are consistent with its policies, and the learned intermediary doctrine is not a portion of the Restatement it adopted or consistent with its policies.[7]

Even if this Court were inclined to agree that South Dakota would adopt the defense, it certainly would not adopt an archaic interpretation of the doctrine that provides absolute immunity even when a manufacturer targets, communicates directly with and defrauds consumers in South Dakota, especially when the contemporary trend is to reject -- or extremely restrict -- the availability of the defense. This Court's Erie prediction must be conservative and cannot interfere with South Dakota's policies and the established rights of its citizens, like Linda Gross. Fantis Foods, supra, 332 N.J. Super. at 260-65, certif. denied, 165 N.J. 677 (2000); Lexington Ins. Co. v. Rugg & Knopp, Inc., 165 F.3d 1087, 1092-93 (7th Cir. 1999) (Erie predictions are "difficult" and require "caution" to avoid "skewing" the state's law); Labiche v. Legal Sec. Life Ins. Co., 31 F.3d 350, 354 (5th Cir. 1994) ("Erie guesses ... are many times wrong").

[7] Cf. Chimes v. Oritani Motor Hotel, Inc., 195 N.J. Super. 435, 443 (App. Div. 1984) (holding cross-appeals not required; "a respondent can argue **any point** on the appeal to sustain the trial court's judgment") (emphasis added).

South Dakota has adopted a progressive approach to patient rights, holding that informed consent is a "**fundamental right**" of South Dakotans. Savold v. Johnson, 443 N.W.2d 656, 659 (S.D. 1989); Wheeldon v. Madison, 374 N.W.2d 367, 372, 374 (S.D. 1985). Therefore, any prediction by this Court must account for and include the fundamental right of South Dakotans to have "autonomy" over their bodies. Because New Jersey champions these same rights, and has adopted the learned intermediary defense, our law is instructive on this issue:

> When a patient is the target of direct marketing, one would think, at a minimum, that the law would require that the patient not be misinformed about the product. It is one thing not to inform a patient about the potential side effects of a product; **it is another thing to misinform the patient by deliberately withholding potential side effects while marketing the product as an efficacious solution to a serious health problem....**
>
> [W]e must decide if a pharmaceutical manufacturer is free to engage in deceptive advertising to consumers. We believe that the answer in such a case should be no.

Perez, supra, 161 N.J. at 20-21, 32 (emphasis added).

Given South Dakota's strong interest in patient rights -- and its clear history of rejecting defenses that would shift responsibility from national manufacturers onto local intermediaries[8] -- if South Dakota adopted the doctrine at all, it

[8] Another clear trend in South Dakota product liability law is rejection of attempts by national manufacturers to shift responsibility for defective products onto local intermediaries. Wangsness, supra, 779 N.W.2d at 144 (unwilling to hold local

certainly would be a narrow version consistent with the modern trend. Perez, supra, 161 N.J. 1; Karl, supra, 647 S.E.2d 899; Watts, supra, slip op. at *8; Rimbert, supra, 577 F. Supp. 2d at 1218-19. The recent restrictions and rejections of the doctrine are due in significant part to the ever-present marketing by "Big Pharma" -- one cannot read a magazine, surf the web, or watch a television program without being bombarded with pharmaceutical advertisements. This new, direct relationship between the pharmaceutical manufacturer and the patient, without the physician, is one of the driving forces behind the modern movement to restrict or eliminate the defense as an anachronism.

Indeed, the Eighth Circuit in Schilf implicitly recognizes that South Dakota would not adopt the outdated defense that defendants seek on appeal, because the Court of Appeals predicted South Dakota would **also adopt the heeding presumption** to ameliorate the harshness of the learned intermediary doctrine. 687 F.3d at 949. Thus, the case defendants rely on to claim the defense, also demonstrates South Dakota would adopt a version that incorporates patient decision-making and patient rights.

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retailers strictly liable for defective products); Burley v. Kytec Innov. Sports Equip., Inc., 737 N.W.2d 397, 400-01, 410-11 (S.D. 2007) (rejecting defense that local intermediary, like physicians who read warning, was experienced with product and modified it was the proper plaintiff); Holmes, supra, 492 N.W.2d at 110, 114 (S.D. 1992) (rejecting defense that local intermediary with expertise was intervening/superseding cause).

In sum, defendants' challenge to liability should be rejected in its entirety because they rely on a defense that does not exist in South Dakota; even if the defense applied in South Dakota, it could not be invoked by defendants because the Prolift's warnings were found to be inadequate; and in any event the defense would be restricted and would not apply under these facts -- where the manufacturer directly communicated with and deceived the plaintiff.

POINT II

EVEN IF THE LEARNED INTERMEDIARY DOCTRINE APPLIED, THE JURY INSTRUCTION ON PROXIMATE CAUSE WAS ACCURATE AND DID NOT PREJUDICE DEFENDANTS

The jury was correctly permitted to consider whether the plaintiff would have consented to the Prolift if Dr. Benson had warned her of its actual risks. South Dakota law is "patient-oriented," Savold, supra, 443 N.W.2d at 659, and its Supreme Court has established Linda's "fundamental right" to receive all material information before consenting to the Prolift procedure:

> [T]he patient has the **right** to elect not to undergo a recommended treatment or procedure....
>
> We agree that **the right to know -- to be informed -- is a fundamental right personal to the patient and should *not* be subject to restriction by medical practices that may be at odds with the patient's informational needs.**

Wheeldon, supra, 374 N.W.2d at 372, 374 (emphasis added).

Therefore, Linda's right to choose her own medical care in South Dakota must be factored into any proximate cause charge

based on the learned intermediary doctrine, just as Judge Higbee did. Significantly, Schilf, the Eighth Circuit decision relied on by defendants, applies a proximate causation standard that factors in the patient's decision. In that case, the Court of Appeals reversed the district court, finding that a jury question on causation was presented as to how the young patient's father would have evaluated adequate warnings. 687 F.3d at 957. Schilf cites Prempro, id. at 957, where the court recognized that a physician's decision is based, in part, on the patient's decision after being warned, In re Prempro Prods. Liab. Litig., 586 F.3d 547 (8th Cir. 2009). In Prempro, the physician (like Dr. Benson) changed his prescription practices, and most significantly,

> also testified that he would respect a patient's wishes and not prescribe [the product] if she was concerned about the risk.... Thus, the jury could have concluded that [the plaintiff] would have chosen not to [use the product] if the warnings had been adequate.... [as plaintiff] testified that she would not have [used the product] if she had known of the risk as it was currently understood.

(Id. at 570). Therefore, the case relied on by defendants to assert the learned intermediary doctrine in South Dakota holds that the patient's decision is directly relevant on causation. This is of course consistent with the fact that once the warnings are found to be inadequate, the defense does not apply and the failure to warn the patient is actionable.

New Jersey law is also instructive on this issue. Our Supreme Court has held that a plaintiff's right to informed consent **requires** that proximate cause under the learned intermediary doctrine accommodate the patient's ultimate right to refuse to consent:

> The concept of proper warning by the learned intermediary will blend in this context with the concept of informed consent. Both are aspects of the patient autonomy that underlies our law of medical care....
>
> A patient warned of the drug's potential consequences and the increased susceptibility of patients in certain contraindicated circumstances might have delayed the [treatment] or responded to the [complications] more aggressively....
>
> **Plaintiff need generally show only** that the warning was inadequate and **that "an adequate warning or instruction would have prevented the harm.**"

Niemiera v. Schneider, 114 N.J. 550, 562, 565-67 (1989) (emphasis added) (footnote and citations omitted). Ethicon's "desire to leave the prescribing decision solely in the hands of the learned intermediary runs afoul of New Jersey's public policy," which is identical to South Dakota, because "the doctrine of informed consent requires the patient to determine ... in the first place" whether to use the product. In re Diet Drug Litig., 384 N.J. Super. 525, 541 (Law Div. 2005).

Consistent with these principles, Dr. Benson testified that the choice to implant the Prolift was Linda's, not his, and that he would have deferred to her decision whether to undergo the

procedure. (26T31:09-32:05). Accordingly, Judge Higbee correctly "tailor[ed] [the] instruction to the theories and facts presented." Reynolds v. Gonzalez, 172 N.J. 266, 288-89 (2002).

The proximate cause standard that Judge Higbee charged to the jury is also consistent with the modern trend across the nation: "Causation in both types of cases -- informed consent and failure to warn -- **ultimately rests with the patient's decision** to take or reject the medication." Payne v. Novartis Pharms. Corp., 767 F.3d 526, 532 (6th Cir. 2014) (emphasis added) (citation omitted).

> **The [learned intermediary doctrine] certainly does not allow health care professionals to substitute their judgment for that of their patients. Nor does it obviate the need to consider whether the plaintiff patient's decision concerning her recommended course of treatment would have been different**, assuming that the warning at issue had been more adequate.

Gilliland v. Novartis Pharm. Corp., 34 F. Supp. 3d 960, 972 (S.D. Iowa 2014) (emphasis added). Accord Fussman v. Novartis Pharms. Corp., 509 Fed. App'x 215, 224 (4th Cir. 2013); Gove v. Eli Lilly & Co., 394 Fed. App'x 817, 818 (2d Cir. 2010); McNeil v. Wyeth, 462 F.3d 364, 372-73 (5th Cir. 2006); Sanchez v. Boston Sci. Corp., ___ F. Supp. 2d ___, 2014 WL 4059214, at *2, 6 (S.D.W. Va. Aug. 18, 2014) (in pelvic mesh bellwether) (Pa194); Rowland v. Novartis Pharms. Corp., 34 F. Supp. 3d 556, 577-78 (W.D. Pa. 2014); Georges v. Novartis Pharms. Corp., 988 F. Supp. 2d 1152,

1157-58 (C.D. Cal. 2013); Fraser v. Wyeth, Inc., 857 F. Supp. 2d 244, 255 (D. Conn. 2012).

Defendants also misrepresent the jury instructions by claiming that Judge Higbee "specifically instructed the jury that it could consider the patient brochure viewed by Mrs. Gross in determining causation." (Db23). This is simply untrue. **The brochure is never referenced during the instruction on proximate cause**. (Da267-68). Instead, it was only mentioned during the instruction on failure to warn, during which the Judge emphasized to the jury **five separate times** that defendants' duty to warn only ran to the implanting surgeon (Da264-66), instructing that:

> **In the case of a medical device, an adequate warning must be given to the surgeons who will implant the device. This is true because it's the implanting surgeon who has to decide whether to prescribe the device.**

(Da265). The brochure was only referenced once in the jury instruction on the adequacy of the warnings, and then only as an example in a list of documents the jury "may consider." (Da266). Defendants do not claim its inclusion in that instruction is error, nor can they because they accepted it without objection. (49T109:10-21). In short, the brochure was not a factor at all in the proximate cause jury instruction.

Nor is defendants' restrictive interpretation of causation supported by the non-South Dakota cases they cite. (Db24-25). First, defendants overlook that the outcomes in Ackermann, Wheat,

Odom and Gaghan all turn on the lack of a heeding presumption in those states. By contrast, the Eighth Circuit in Schilf held that the South Dakota Supreme Court would adopt the heeding presumption, like New Jersey. 687 F.3d at 949.[9] Under the heeding presumption, once plaintiffs established that the Prolift's warnings were inadequate, the law presumes causation and shifts the burden to Ethicon to rebut the presumption by showing a different warning would not have made a difference in Dr. Benson's actions. Prempro, supra, 586 F.3d at 569.

Further, **every case** that defendants rely on is distinguishable because none involves testimony from the doctor that he completely overhauled his risk/benefit analysis, and the patient that she would not have consented if accurately warned. See Point III, infra. Indeed, even the cases defendants rely on acknowledge this important distinction. See Ackermann v. Wyeth Pharms., 526 F.3d 203, 210 (5th Cir. 2008) (recognizing that proximate cause remains jury question when testimony regarding whether doctor would have "alerted the patient" to the risk).

[9] Shortly after Strumph, New Jersey adopted the heeding presumption, Coffman v. Keene Corp., 133 N.J. 581 (1993), so "Strumph is not controlling precedent concerning the proper allocation of the burdens of proof respecting proximate cause in pharmaceutical product liability cases," In re Diet, supra, 384 N.J. Super. at 534, 542 (applying the heeding presumption); see McDarby v. Merck & Co., Inc., 401 N.J. Super. 10, 80-81 (App. Div. 2008).

More fundamentally, defendants' position -- based on South Carolina, Louisiana, Texas and Florida law -- is out-of-step with the progressive law and policies of South Dakota (and New Jersey) because it myopically focuses on the doctor's medical knowledge and judgment without balancing the patient's rights and autonomy. E.g., Odom v. G.D. Searle & Co., 979 F.2d 1001 (4th Cir. 1992) (focusing paternally on the doctor's expertise and ignoring the plaintiff's right to informed consent where product made her **sterile**); Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806 (5th Cir. 1992) (conceding issue of fact on "warning causation issue," then usurping jury's role of deciding proximate cause).

"Informed consent requires a patient-based decision rather than the paternalistic approach of the 1970s." Perez, supra, 161 N.J. at 18. The cases defendants stand by cannot be squared with South Dakota's "patient-oriented" law: **the "purpose of the learned intermediary rule ... is to enable patients to make informed and intelligent decisions** whether to undergo a recommended therapy by balancing the probable risks against the probable benefits of the course of treatment proposed by their physicians." Gilliland, supra, 34 F. Supp. 3d at 972 (emphasis added); accord Niemiera, supra, 114 N.J. at 562, 565-67; Payne, supra, 767 F.3d at 531-32. Nor can those cases be reconciled with South Dakota policy that "[q]uestions of proximate cause are for the jury in 'all but the rarest of cases.'" Fritz v. Howard

Twp., 570 N.W.2d 240, 244 (S.D. 1997); accord Schilf, supra, 687 F.3d at 951.

It was Linda's decision, and she unequivocally testified that she would not have consented if she had been told the truth. And Dr. Benson testified he would have changed his discussion -- and recommendation -- if he had been warned of the true risks and their consequences by defendants, and they have not appealed or disputed the jury's determination that their warnings were inadequate. The proximate causation charge was correct, and the verdict is just. It should be affirmed.

POINT III

THERE WAS MORE THAN SUFFICIENT EVIDENCE OF PROXIMATE CAUSATION ON FAILURE TO WARN

Defendants claim that there was insufficient evidence for the jury to find proximate causation. However, the evidence was overwhelming. Indeed, defendants **admit** that Dr. Benson "would have ultimately recommended suture repair, rather than Prolift surgery" if he had known the true risks and "his discussions with Mrs. Gross would have been 'much more robust.'" (Db30). Defendants also do not contest the jury's determination that their warnings were inadequate. This Court should affirm Judge Higbee's categorical rejection of defendants' argument:

> In this particular case, the evidence not only was sufficient, but **it was extremely strong in support of the plaintiffs' position.** There was a lot of evidence presented .... which showed that in fact the product

> could cause very severe injuries, that there was a risk of catastrophic injury....
>
> ... [I]t was obvious from [Dr. Benson's] testimony ... that the risks with this product ... were not known to the doctor, were not conveyed to the doctor and that in fact if it had been conveyed, the doctor would have made a different decision....
>
> And so the failure to warn claim has plenty of evidence to support it, both on the proximate cause issue and on the fact that there was in fact information that the company knew that they should have provided to the doctor but chose not to provide to the doctor. So, again, **I think that the evidence on that was fairly overwhelming**.

(Da220-26) (emphasis added). Judge Higbee's firsthand assessment of the evidence "shall not be reversed unless it clearly appears that there was a miscarriage of justice." R. 2:10-1. In order to overturn such a finding, the Supreme Court requires defendants to demonstrate clearly and convincingly "a pervading sense of 'wrongness'" that justifies "undoing of a jury verdict." Risko v. Thompson Muller Auto. Gp., Inc., 206 N.J. 506, 521 (2011); R. 4:49-1(a). This they have not done.

A. South Dakota Causation Law

Defendants begin by representing that "South Dakota employs a 'but for' test for legal causation." (Db28). However, in South Dakota a plaintiff need only prove that an inadequate warning was a "legal cause" of the injuries. Burley v. Kytec Innov. Sports Equip., Inc., 737 N.W.2d 397, 409-10 (S.D. 2007). "Such cause need not be the only cause of a result." First

Premier Bank v. Kolcraft Enters., Inc., 686 N.W.2d 430, 454 (S.D. 2004) (citations omitted). "[C]ausation is almost always a fact question" in South Dakota. Id.[10]

Defendants also omit Schilf's liberal causation standard, where the Eighth Circuit held that under South Dakota law proximate cause remains a jury question when **the prescribing doctor's "testimony and behavior indicate that knowledge of the [unwarned risks] ... may have changed his prescribing behavior,"** 687 F.3d at 951 (emphasis added) (citing Prempro, supra, 586 F.3d at 569-70) (holding sufficient evidence of proximate cause if doctor testifies "he would respect a patient's wishes" and had changed prescription practice).

Significantly, the Eighth Circuit in Schilf, and in Prempro, rejected as error Ethicon's rigid emphasis on a doctor's testimony "that he still believed his prescription decision was appropriate," because it is for the jury to determine whether the changes in the doctor's "prescribing behavior" established causation. 687 F.3d at 951. Equally significant, the Schilf court held that South Dakota would adopt the heeding presumption alongside the learned intermediary doctrine. Id. at 949. So,

[10] There is no dispute that the evidence is sufficient to establish proximate cause if this Court determines that (1) the learned intermediary doctrine did not apply because the Prolift's warnings were inadequate and the defense "dropped out," (2) it predicts that South Dakota would not adopt the defense, or (3) if it applies a narrow version of the doctrine to include patient decision-making. See Point I, supra.

because the jury determined that Prolift's warnings were inadequate, **in this case the burden shifted to defendants** to prove that Dr. Benson would still have used the Prolift with Linda or causation is presumed, which they failed to do. (13T8:1-16:14) (the heeding presumption was raised by plaintiffs, but the court declined to instruct the jury on it).

B. There is Overwhelming Evidence that Defendants' Inadequate Warnings were the Legal Cause of Mrs. Gross's Injuries

Both Dr. Benson and Linda Gross provided ample testimony supporting the jury's determination on proximate causation.

1. Dr. Benson Testified that If Properly Warned, He Would Not Have Prescribed the Prolift

Dr. Benson testified that he "read and relied" on Ethicon's warnings (26T26:11-25), and that he "trusted" defendants to provide a "truthful and complete" statement of the Prolift's risks. (26T120:20-121:8).[11] After Linda's surgery in reliance on defendants' warnings, Dr. Benson discovered that he did not have a full understanding of Prolift's actual risks and complications.

> Q. And after July of 2006 [Linda's surgery], did you learn a great deal more about the risks of the Prolift that you didn't know at that time?
>
> A. Yes.

[11] Defendants mistakenly rely on Rodriguez v. Stryker Corp., 680 F.3d 568, 570, 575 (6th Cir. 2012), and Motus v. Pfizer Inc., 196 F. Supp. 2d 984 (C.D. Cal. 2001), aff'd as mod., 358 F.3d 659, 661 (9th Cir. 2004) where courts held causation could not be proven when the doctor never read the manufacturer's warnings. Unlike Rodriguez and Motus, Dr. Benson read and relied on defendants' warnings.

(26T28:12-15). Dr. Benson explained to the jury he was not aware of the existence or gravity of numerous risks prior to Linda's procedure, including that if there were complications he might not be able to remove the mesh; the severity and prevalence of erosion and contraction; and the severity and prevalence of chronic pain and inflammation. (26T42:16-43:2, 37:6-10, 122:1-9; 126:10-14). Significantly, Dr. Benson testified that if he had known the true risks of the Prolift in July 2006, he would not have prescribed it to Mrs. Gross, and he no longer uses it at all for posterior prolapse repair/to treatment rectocele (Linda's condition):

> Q. If Ethicon knew on the day the Prolift was launched that what happened to Linda was something that could happen to women with the Prolift, they certainly didn't warn about it. Right? As far as you know?
>
> A. Correct.
>
> * * *
>
> Q. In terms of patient selection, with somebody like Linda Gross who at the time was 41, she was young and sexually active, had an active lifestyle, had not had surgery to repair a prolapse in the past, this was her first actual prolapse surgery, how would that have impacted on your decision in July of '06 if you knew then the things that you learned after that?
>
> A. Well, I think that with the environment that we're in today, it would essentially allow for the option of observation, of pessary, or a traditional suture colporrhaphy.

Q. And when you say allow for, what do you mean by that?

A. Meaning that at this point in time, with what we know today, **I'm not choosing mesh for primary repair of posterior prolapse**.

* * *

Q. And that [the risk/benefit] discussion would have been -- you would have indicated to Linda that based on her risk profile, that your -- ultimately, it was her choice, but **your recommendation would have been a suture repair as opposed to the Prolift. Correct**?

A. **Correct**. In her particular circumstance, yes.

(26T126:10-14, 46:11-47:6, 130:8-131:25) (emphasis added).

Thus, the jury's verdict is well-supported by Dr. Benson's "testimony and behavior" that (1) once he was made aware of the actual risks and potential complications that plaintiff's liability expert testified should have been warned of, he stopped using the Prolift; (2) he no longer uses any mesh for repair of posterior prolapse, the condition Linda suffered from; and (3) he would not have recommended the Prolift to Linda. This was more than enough evidence to support the jury's verdict, and there is no basis to disturb it.

2. Linda Gross Would Not Have Consented to the Prolift

Plaintiffs also established causation alternatively through Dr. Benson's testimony that he completely changed his prescribing practices by tripling the duration of his informed consent discussion, discussing "every possible potential adverse outcome"

including the risk of dyspareunia and catastrophic outcomes, and provides two separate discussions before surgery (26T44:17-45:7):

> Q. Tell me if you could the types of risks that you added to your discussion over the years after July of '06 based on the risks that you learned as time went on?
>
> A. As I said earlier, it would define about everything that could be possibly thought of that could happen related to a surgery: Infection, bleeding, injuring the bladder, the bowel, the ureters, the urethra, dyspareunia, vaginal discharge, pelvic pain, centralized pain, vaginal foreshortening, constricture, impaired recovery. These are just some of the topics that we talk about.

(Id.) Dr. Benson confirmed that he would have provided Linda with this comprehensive risk/benefit discussion (26T31:9-32:5), and then deferred to his patient's decision:

> Q. Well, **ultimately, the decision would have been Linda's**, with the more robust and the great deal more of information that you would have given her, she would have had to make that decision. Right?
>
> A. That's **correct**.

(26T31:9-32:5, 129:8-12) (emphasis added). And there is no dispute that Linda testified unequivocally that she "absolutely" never would have agreed to the Prolift if correctly advised of the risks. (33T68:7-11, 73:9-14, 74:1-3). In sum, the jury's verdict on proximate cause is supported by "overwhelming"

evidence, as Judge Higbee correctly held, and defendants have not overcome the "miscarriage of justice" standard.[12]

POINT IV

THE LEARNED INTERMEDIARY DEFENSE CANNOT DISPLACE PLAINTIFFS' STATUTORY DECEIT CLAIM

The jury found that defendants committed deceit, that is, they intentionally deceived Linda Gross by making untrue misrepresentations on their website and in their patient brochure to induce her to undergo the Prolift surgery in violation of S.D.C.L. § 20-10-1. (Da206). Defendants have **not** challenged or appealed the jury's finding of deceit, or the sufficiency of the evidence proving deceit. **Instead, they seek to evade responsibility for their deceit by claiming that Linda's statutory right as a South Dakotan to bring a deceit claim is negated by a common law defense that has never been recognized by South Dakota.** And even if South Dakota applied the doctrine, it

[12] Defendants rely on an unpublished trial decision where the heeding presumption did not apply and there was no causation because plaintiffs were never asked whether they would have consented if given a different risk/benefit discussion, and the physicians were never asked whether knowledge of the specific risks at issue would have altered their decisions. In re Nuvaring Litig., 2013 WL 1874321, at *3, 15 (Law Div. 2013) (Da879). Here, by contrast, South Dakota law governs, the heeding presumption applies, Linda testified she would not have consented, and Dr. Benson testified he would not have recommended the Prolift based on the specific risks in dispute, including erosion, contraction, pain, difficulty removing the mesh, dyspareunia, etc.

would not negate plaintiff's right to maintain a statutory claim for deceit under the facts of this case.

A. A Statutory Claim Created by the South Dakota Legislature Cannot be Supplanted by an Out-of-State Common Law Defense

Without citing any South Dakota law, defendants argue that the statutory claim of deceit should be subsumed within failure to warn because the two causes of actions are identical. This argument is not supported by South Dakota law, as Judge Higbee explained in denying their motion for a new trial. (Da230-31).

Strict liability failure to warn in South Dakota is different than deceit as it does not require any proof of a manufacturer's motive, intent or state of mind, nor does it require proof that a warning "induced" reliance. Burley, supra, 737 N.W.2d at 409-10. It only requires a plaintiff to prove: (1) a danger associated with a foreseeable use of the product, (2) an inadequate warning regarding that danger, and (3) that the inadequate warning rendered the product defective and unreasonably dangerous. Id.

In contrast, South Dakota's deceit statute requires an additional quantum of wrongful conduct: that the defendant "**willfully** deceive[d] ... with **intent** to **induce** [plaintiff] to alter [her] position to [her] injury or risk." S.D.C.L. § 20-10-1 (emphasis added); see Delka v. Cont'l Cas. Co., 748 N.W.2d 140, 151 n.16 (S.D. 2008) (Deceit generally requires an "affirmative

misrepresentation or intentional suppression"); see also Alberts v. Giebink, 299 N.W.2d 454, 456 n.4 (S.D. 1980) ("Failure to disclose certain medical information" is sufficient).

Moreover, deceit and failure to warn further different South Dakota policies. **Compare** Peterson v. Safway Steel Scaffolds Co., 400 N.W.2d 909, 912 (S.D. 1987) (adopting Restatement (Second) of Torts § 402A, comment c of which states that the policy underlying strict liability is the public's right to expect safe products and that the seller is best positioned to bear the cost of injuries caused by accidents), **with** Grynberg v. Citation Oil & Gas Corp., 573 N.W.2d 493, 501 (S.D. 1997) (analyzing deceit, finding it is **independent of economic and market considerations**, and holding that it **falls within the "wider range of legal duty which is due from every man** to his fellow, to respect his rights of property and person, and refrain from invading them by force or fraud"). Clearly, failure to warn and deceit are two distinct causes of action, with differing proofs, and carrying out distinct South Dakota social policies.

The Supreme Court of South Dakota has made clear that the two causes of action exist independently of each other when it affirmed a verdict against a manufacturer under both theories. Holmes v. Wegman Oil Co., 492 N.W.2d 107 (S.D. 1992) (affirming verdict and punitive award in product liability case based on strict liability and deceit claims). Ignoring Holmes and failing

to analyze any South Dakota law, defendants erroneously assert that non-South Dakota "courts have consistently applied" the learned intermediary doctrine to preclude fraud-based claims. (Db18).[13] But even if this Court predicts South Dakota would adopt the learned intermediary doctrine, there would be no legal basis for a judge-made common law defense (never applied in a reported South Dakota decision) to eliminate a statutory cause of action enacted by South Dakota's Legislature.

Whether a particular state allows both fraud-based and failure to warn claims depends on the policies and precedents of the particular jurisdiction, as illustrated by defendants' primary case, In re Norplant Contr. Prods. Liab. Litig., 955 F. Supp. 700 (E.D. Tex. 1997). In Norplant -- a trial-level, Texas-law decision -- a consumer fraud statute was subsumed by a

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[13] Defendants rely on sundry cases, none involving a patient who was induced by a deliberate misrepresentation directly from the manufacturer. Compare Conte v. Wyeth, 168 Cal. App. 4th 89, 95, 101-02, 111 (App. Ct. 2008) (rejecting argument that product liability bars fraud; facts involved only misrepresentation to doctor); Catlett v. Wyeth, 379 F. Supp. 2d 1374, 1381-82 (M.D. Ga. 2004) (rejecting fraud allegation against local pharmaceutical employees designed to defeat diversity jurisdiction); Miller v. Pfizer, 196 F. Supp. 2d 1095, 1119 (D. Kan. 2002) (facts insufficient to establish fraud; no misrepresentation directly to patient); Talley v. Danek Med., 179 F.3d 154, 162-63 (4th Cir. 1999) (same); Alexander v. Danek Med., 37 F. Supp. 2d 1346, 1350 (M.D. Fla. 1999) (same); Edgar v. Danek Med., 1999 WL 1054864, at *6 (M.D. Fla. 1999) (finding no fraud only because misrepresentations "were not communicated directly to" patient). In sum, the statement in Beale v. Biomet that "the learned intermediary doctrine encompasses all claims" is **an oversimplification that cannot withstand scrutiny**. 492 F. Supp. 2d 1360, 1372 (S.D. Fla. 2007).

failure to warn claim and the learned intermediary doctrine. On appeal, the Fifth Circuit acknowledged the general rule that the common law cannot supplant a statutory right, but nevertheless affirmed based on an idiosyncratic wrinkle in Texas law distinguishing between "common law defenses" and "common law doctrines." In re Norplant, 165 F.3d 374, 377-78 (5th Cir. 1999). The result in Norplant simply reflects a peculiar aspect of Texas law, has no applicability in South Dakota; Norplant has been explicitly rejected by other courts, including the New Jersey Supreme Court. Perez, supra, 161 N.J. at 19.[14]

South Dakota, unlike Texas, has not recognized any exception to the basic principle that a statutory cause of action cannot be defeated by a purely common law defense. See Hohm, supra, 753 N.W.2d at 903 (S.D. 2008) (statutes control and "override the common law"); accord Gustafson v. Alloyd Co., Inc., 513 U.S. 561, 589 (1995) (same). Nor does New Jersey law permit a common law rule to override a statutory right: "The common law must bow when in conflict with a legislative scheme. A statute does not stand in an inferior status to the common law." Farmers Mut. Fire Ins.

[14] Defendants' reliance on the unreported decision in Bellew v. Ethicon is equally misplaced because that court clarified its ruling at a pre-trial conference, stating the fraud claim is an open issue since "it is certainly foreseeable that there is fraud that goes outside the ... boundaries of what would be a failure-to-warn claim.... I'll rule on it when it comes up" during the trial. *Bellew v. Ethicon*, No. 13-cv-22473 (W.D. Va. Nov. 24, 2014), Hearing Tr. 11:14-20 (Pa213-14).

Co. v. N.J. Prop.-Liab. Ins. Guar. Assoc., 215 N.J. 522, 528 (2013).

There is no basis under South Dakota law to conclude that the legislatively-made cause of action of deceit should be displaced by the learned intermediary doctrine, an affirmative defense never enacted by the South Dakota Legislature nor accepted by any South Dakota court.

B. Defendants are Responsible for the Deceptive Statements They Made Directly to Consumers

Tacitly conceding that the warnings in their brochure (and website) were in fact deceptive, defendants argue that they are not responsible for their deceptive statements because "brochures are not full-fledged risk disclosures." (Db17). But this Court need not look past Eighth Circuit precedent which holds -- just like Perez -- that "[w]hile the Learned Intermediary Doctrine provides that adequate warning to a patient's physician can suffice to defeat a patient's failure to warn claim, **this doctrine does not preclude informing a patient directly**." In re Prempro Prods. Liab. Litig., 514 F.3d 825, 830 (8th Cir. 2008) (emphasis added).[15] In fact, South Dakota recognizes the universal principle that once a party voluntarily undertakes to

[15] To the extent this Court will rely on federal decisions to predict South Dakota law, the Eighth Circuit's decisions are entitled to deference. Casey v. Merck & Co., 653 F.3d 95, 101 (2d Cir. 2011); Dawn Equip. Co. v. Micro-Trak Sys., Inc., 186 F.3d 981, 989 n.3 (7th Cir. 1999).

act beyond the duties imposed by law, the party is liable for acting in a wrongful manner. Englund v. Vital, 838 N.W.2d 621, 634 (S.D. 2013) ("even though a duty may not exist in law, a duty can be voluntarily assumed, and once assumed, a person must exercise reasonable care in the performance of that duty"); Hoekman v. Nelson, 614 N.W.2d 821, 824 (S.D. 2000) ("one who assumes to act ... may thereby become subject to the duty of acting carefully, if he acts at all"). Thus, once defendants created their website to be accessed by consumers like Linda Gross, they became duty bound to make certain any information they communicated was truthful.

Ethicon admitted that its statements were targeted at consumers (38T63:8-21); to that end, it created a website to disseminate information to consumers directly over the internet to influence them outside the presence of a surgeon (Pa142). **The FDA found these statements to be "promotional," "biased," and "coercive."** (Da450). Linda did not make a decision when she spoke to Dr. Benson. Later she accessed, read and was swayed by Ethicon's website and brochure at her home, rather than in the presence of her surgeon, Dr. Benson. (33T53:15-54:8).[16]

[16] Nor do the non-South Dakota cases defendants cite disagree, as they recognize that when a manufacturer communicates directly to a patient, it can be held liable. See Seley v. G.D. Searle & Co., 423 N.E.2d 831, 840 (Ohio 1981) (holding manufacturer did not trigger "voluntary duty rule" only because plaintiff "did not receive the allegedly deficient informational material

In sum, the jury's deceit verdict should be affirmed. A non-existent common law defense cannot eliminate a South Dakotan's established statutory right. Nor can defendants hide behind the learned intermediary doctrine, when they voluntarily and intentionally disseminated deceptive marketing materials directly to consumers, expanding their duties and giving rise to liability for not doing so in a truthful manner.

POINT V

THE EVIDENCE RULINGS WERE CORRECT

After an 8-week trial involving an enormous volume of complex medical and regulatory evidence, and numerous evidentiary rulings by Judge Higbee, defendants nitpick at three discrete rulings: (A) the application of Rule 407 to FDA-mandated revisions to the Prolift's warnings, (B) the application of Rule 803(c)(6) to an email chain initiated by an Ethicon marketing executive with a physician who Ethicon was targeting for sales, and (C) the application of Rule 403 to the questioning of a defense expert related to her credibility. These discrete evidentiary rulings were all correct; and even if they were not, defendants cannot overcome the "manifest injustice" standard. Lancos v. Silverman, 400 N.J. Super. 258, 275 (App. Div.),

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directly from the manufacturer"); Polley v. Ciba-Geigy Corp., 658 F. Supp. 420, 421-22 (D. Alaska 1987) (recognizing that a manufacturer's duty to warn a doctor is a "distinct process[]" from communicating directly to patients).

certif. denied, 196 N.J. 466 (2008) ("relevance and admissibility determinations ... will not [be] disturb[ed] absent a manifest denial of justice"). Review is "limited to examining the decision for abuse of discretion." Hisenaj v. Kuehner, 194 N.J. 6, 12 (2008).

A. Involuntary Remedial Measures are Admissible

In 2007 and 2008 the FDA required defendants to make specific corrections to the IFU and patient brochure. Defendants claim that it was error to admit into evidence the FDA-mandated changes to the warnings because they were inadmissible subsequent remedial measures. However, **defendants have failed to advise this Court that plaintiffs never admitted into evidence** the 2008 corrected IFU and patient brochure, nor the documents detailing the FDA's disapproval of defendants' warnings. (51T91:24-92:4; see Da393-491). These items were only generically referred in passing during the two month trial. (10T85:22-86:2; 19T163:2-15, 188:24-189:24). These isolated references were properly allowed by Judge Higbee, and she correctly ruled that N.J.R.E. 407 did not apply "because [the change] was mandated and it's simply not remedial conduct." (8T27:24-28:1).

This Court has held that **Rule 407 only applies to a defendant's voluntary remedial measures**. Harris v. Peridot Chem. (N.J.), Inc., 313 N.J. Super. 257, 292 (App. Div. 1998). Accord Cepeda v. Cumberland Eng'g Co., 76 N.J. 152, 193 n.11 (1978);

Biunno, Weissbard & Zegas, N.J. Rules of Evid., Comment 1 to N.J.R.E. 407 (2013). The rationale for this limitation is to facilitate **voluntary** corrective action by private citizens to efficiently protect the public -- that does not exist where, as here, a government agency compels the changes. Id.

The "voluntary" requirement of Rule 407 has been applied in analogous cases to admit evidence of FDA-mandated changes to the warnings on regulated medical products. E.g., Schedin v. Ortho-McNeil-Janssen Pharms., Inc., 808 F. Supp. 2d 1125, 1137-37 (D. Minn. 2011), aff'd in part, 700 F.3d 1161 (8th Cir. 2012) (affirming verdict for plaintiff where trial court held FDA-mandated changes to warning were admissible); In re Yasmin & Yaz Prods. Liab. Litig., 2011 WL 6740391, at *8 (S.D. Ill. 2011) (an FDA letter "asking" for change in marketing is sufficient to demonstrate manufacturer's response was not voluntary) (Pa215).

Like the manufacturers in Schedin and Yasmin, Ethicon only changed the Prolift warnings in direct response to FDA directives which required corrections to the warnings. Indeed, even **defendants admit** that:

- the FDA "first" approached Ethicon, raising the problems with the Prolift's warnings (Db36);
- "Ethicon made numerous changes to the Prolift IFU, removing several statements from the prior version and adding a variety of warnings" (Db35);

- the "revised labels ... included changes requested by the FDA" (Id.); and,

- "in many cases, Ethicon did what the FDA requested" (Db37 n.10).

Defendants' attempt to whitewash the FDA's role as the driving force behind the new warnings is simply not supported by the trial record. The FDA found that Ethicon's labeling was "deficient," required it to "revise[the] labeling," and chided Ethicon for omitting the Prolift's "labeling and other essential items." (Da413 ¶12-13). In response, Ethicon finally submitted the labeling of the Prolift for FDA review. (Da426-27). After reviewing defendants' supplemental submission, the FDA found that defendants did "not completely respond to the deficiencies listed"; instructed defendants that the Prolift needed "revised" warnings -- including more "prominent text"; required a change in the order of the information; required a statement regarding the lack of clinical data; required additional adverse warnings regarding pain, infection, contracture, voiding dysfunction and procedure failure; and directed that Ethicon "not market this device" until the FDA was satisfied. (Da433-38).[17] At a 2008 meeting, the FDA reiterated the numerous flaws in Prolift's

[17] The FDA found that Ethicon needed to "develop a Patient Brochure" that disclosed the lack of clinical studies of the Prolift, described alternate procedures, and advised that it is a "permanent" implant, and it **found the existing brochure to be "promotional, biased, and can be perceived as coercive to the patient**." (Da436, 449-50) (emphasis added).

warnings and Ethicon finally relented and "agreed to readjust the information and submit the updated labeling." (Da440-41).

Ultimately, Ethicon followed the FDA directives and changed the Prolift IFU (compare Da308-13 with Da456-66) and patient brochure (compare Da300-07 with Da449-52, 479-91). These changes were not "voluntarily made." Judge Higbee's finding that the changes in the Prolift's warnings were FDA-mandated is supported by the record, and she did not abuse her discretion in allowing mention of these changes.[18] And even if the FDA-mandated changes were inadmissible, defendants cannot demonstrate any prejudice from the limited references to those changes during the trial. **Plaintiff never entered in evidence, and the jury never saw, the revised IFU and brochure.**

Moreover, it was defendants who "opened the door" to this evidence. The court decided pretrial motions and permitted defendants to bring before the jury that the Prolift was eventually "cleared" by the FDA in May 2008, but in fairness allowed plaintiffs to counter that the FDA only cleared it with the revised warnings. (8T28:14-29:5). Thus, this post-implant

[18] Nor do the non-New Jersey cases that defendants rely on have any bearing because they do not involve involuntary warning changes in response to an FDA halt of marketing, nor do they apply our Rules of Evidence, precedent or policy. Compare Salvio v. Amgen Inc., 2012 WL 517446, at *6 (W.D. Pa. Feb. 15, 2012) (Da925); Gerber v. Hoffmann-La Roche Inc., 392 F. Supp. 2d 907, 919, 926 (S.D. Tex. 2005); Werner v. Upjohn Co., 628 F.2d 848, 859 (4th Cir. 1980).

evidence was injected into the case by defendants, not plaintiffs. Defendants placed plaintiffs on notice that they were going to introduce evidence that the Prolift had obtained FDA clearance, and it was fully within plaintiffs' rights to bring to the jury's attention that the clearance came with the proviso that the Prolift's warnings be changed.

Consistent with their stated intention during pretrial proceedings, defense counsel's opening included repeated, lengthy argument regarding the Prolift obtaining regulatory clearance in 2008, after it was implanted in Mrs. Gross. (9T130:12-131:8, 136:1-10, 140:3-21, 142:25-144:21). The passing reference to the revised warnings in plaintiff's opening was not prejudicial, and merely rebutted defendants' stated intention that they were going to bring before the jury that Prolift had obtained FDA clearance. (Pa294).

Thereafter, defense counsel made a tactical decision mid-trial to not mention the FDA clearance, but by then it was too late because they had placed plaintiffs on notice that they were going to bring the clearance before the jury, and plaintiff had sought to rebut their defense during opening argument by bringing out the requirement of changing the warnings as part of the clearance. Judge Higbee made the following observations concerning the defendants' tactical decision:

> [**Defendants'] claim, which I think ... borders on the disingenuous or is disingenuous**, ... that the evidence that [Ethicon] later got 510(k) clearance wasn't presented to the jury.... [The] defense had the right to bring that evidence in, and I repeatedly told them, go ahead and ask the question....
>
> There was a string of ... interactions with the FDA. And basically what I said, plaintiffs want to cut it at one point and then the defendants wanted to cut it at another point.... And basically what I said was ... [l]et's let them know the whole truth up to a point, and certainly they could know that this 510(k) clearance was subsequently approved, but then they also could know about other things that had occurred....
>
> Defendants chose not to do that. **They chose not to put the evidence in because they didn't want some of the subsequent actions in. That was their choice. It was a strategy call that they made during the trial**....

(Da235-36) (emphasis added). Thus, when plaintiffs' counsel briefly mentioned the changes in the warnings during his opening, he was addressing an issue that the defense had injected into the case. Plaintiffs' counsel was entitled to raise the issue and this brief reference was not prejudicial.

For the same reason, Dr. Weber's isolated comments alluding to the revised warnings could not have altered the outcome of this eight-week trial. Defendants did not object to the first comment: that defendants conceded to the FDA that they had no evidence that their mesh had "special" elastic characteristics. (19T163:2-14). And Judge Higbee rejected defendants' objection to Dr. Weber's testimony regarding the dyspareunia warning as being "cumulative," finding it was not "nearly prejudicial enough

to even come close" to denying defendants a fair trial. (19T189:18-190:11). Neither comment was the "central issue" at trial, because plaintiff produced overwhelming evidence of numerous other deficiencies -- and falsities -- in the warnings. And the falsity of the "special properties" of the mesh and the deficient warning regarding dyspareunia came in through other testimony, which defendants have not challenged. Thus, there is no prejudice as the jury learned the same information from other sources as well.

In sum, Judge Higbee did not abuse her discretion because Rule 407 does not apply to involuntary remedial actions, and in any event defendants cannot establish a "manifest injustice."

B. The Ethicon Email Chain Was Properly Mentioned

Defendants claim Judge Higbee abused her discretion by finding that an Ethicon email chain, which was initiated by Ethicon and contained information on complications of a Prolift patient reported by Dr. Fah Che Leong, was admissible under Rule 803(c)(6). Judge Higbee ruled as follows:

> The issue before the Court is ... an email between the company ... and a doctor concerning complications he had with a patient, which postdates the date of the surgery in this case. I have reviewed the deposition testimony about the same topic.
>
> I had indicated early in the case that adverse event reports were business records, that they were part of what the company and part of what the FDA relies on .... and adverse event reports, both before events and

> after events, are in fact routinely admitted in pharmaceutical and medical device cases.[19]
>
> And in the deposition, when the witness who is the designated company rep on medical affairs was questioned about this email, ... he identified it, the witness, as an adverse event report. And he indicated that they have to report these to the FDA and ... that part of their plan for monitoring the product and part of the procedures they used in their business was to in fact reach out to customers, to open up wide dialogue between the company and the surgeons who were using the product, and that this was part of their practice, that they would get feedback, ... and it became part of their records, it would be circulated to everybody....
>
> Based on all that, I'm going to overrule the objection and allow it to be used.

(17T125:21-127:3).

The email is clearly relevant to establishing the catastrophic dangers of Prolift, dangers which Hinoul admitted Ethicon was aware of prior to the launch of the Prolift, and causation of Linda Gross's severe injuries, which was hotly disputed by defendants. According to Hinoul, Ethicon knew "the day the Prolift was put on the market" of every "adverse event that's documented right up till the present." (17T96:25-97:11). All dangers known, or which reasonably could have been known, by a product manufacturer prior to a plaintiff's injury constitute

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19 The court denied defendants' motion to exclude all adverse event reports, holding they were admissible to prove notice and reports that post-dated Linda's surgery would be ruled on a case-by-case basis. (Da494l; 3T26:14-27:13); Chism v. Ethicon Endo-Surgery, Inc., 2009 WL 3066679, at *2 (E.D. Ark. 2009) (holding adverse reports "are records of regularly conducted activity for which [Rule] 803(6) makes an exception") (Pa250).

relevant evidence which can be brought before a jury. Contrary to defendants' mistaken claim (Db42), South Dakota applies the so-called hindsight rule: its strict liability law imputes knowledge of all dangers to the manufacturer regardless of whether they knew of a danger at the time of sale. Burley, supra, 737 N.W.2d at 408 (a manufacturer "cannot avoid liability simply because at the time of production it did not know or could not have known of the product's dangerous proclivities"); accord Peterson, supra, 400 N.W.2d at 912 (S.D. 1987).

Since South Dakota imputes knowledge to the manufacturer, and Ethicon admitted that it was actually aware of all complications that could occur prior to sale, the complications discussed by Dr. Leong in the email chain constitute relevant evidence for the jury's consideration on the adequacy of the warnings and design defect claims. It was also highly relevant to the issue of whether Linda Gross's catastrophic injuries were "outlier" injuries (as Ethicon argued), or of the type that Ethicon knew or should have known could occur.

Defendants also callously claim that Dr. Leong's report was irrelevant because Linda "healed well from Prolift surgery" and "remained fairly healthy." This is a ridiculous statement considering the overwhelming evidence introduced at trial that Linda's vagina was destroyed by the Prolift; including a loss of

coital function, just like the patient that Dr. Leong was treating. The email chain was clearly relevant.

And because it constitutes proof of Ethicon's knowledge prior to launch of the product, and **notice** to it of the dangers, it does not constitute hearsay. Reports and correspondence of a business are not hearsay when entered in evidence to establish notice, motive, reasonableness, or good faith. Toto v. Princeton Twp., 404 N.J. Super. 604, 619 (App. Div. 2009) (correspondence to business not hearsay when purpose was to show notice); Spragg v. Shore Care, 293 N.J. Super. 33, 57 (App. Div. 1996) (record of clients not hearsay when purpose was to show reasonableness or good faith). Plaintiffs' limited use of the email to question Hinoul and defense expert Dr. Miles Murphy was appropriate as it related to notice to Ethicon of such dangers, the extent of the Prolift's dangers, and the reasonableness of Ethicon's failure to warn about those dangers.[20]

It was similarly appropriate to question Dr. Weber as to the email because it was relied on by her in arriving at her opinion that the warnings were inadequate. (19T35:13-19). Rule 703 makes clear that an expert may rely on inadmissible hearsay in

[20] Use of the email to cross-examine and impeach Dr. Murphy was appropriate as it brought out that he had changed his opinions from when he had testified at deposition, conceding at trial that Ethicon had not provided him with complete information when he offered his initial opinions. (41T212:14-214:11).

arriving at her opinion. Rubanick v. Witco Chem Corp., 125 N.J. 421 (1991). Dr. Weber also used the description in the email to illustrate how the mesh was inserted, and she pointed out that this is how it was performed with Mrs. Gross. (20T207:18-208:7). Thus, regardless of whether the email constituted hearsay, it was appropriately used with Hinoul, Dr. Murphy and Dr. Weber.

Finally, defendants cannot demonstrate any prejudice as the Prolift changes described in the email were known to Ethicon before the launch of the Prolift, and all came in through other evidence at trial.

C. The Questioning of Dr. Kavaler was Proper

Defendants claim that Judge Higbee abused her discretion by allowing plaintiff to ask questions relating to defense expert Dr. Elizabeth Kavaler's bias and credibility. However, there is no legal or factual support for defendants' convoluted argument.

First, the cross-examination of Dr. Kavaler is irrelevant to the issues on appeal as she only testified regarding plaintiff's case-specific injuries. (45T178:15-199:12). Thus, any attack as to her bias is of no consequence to the issues on appeal. Second, this Court permits "[e]xtensive cross-examination of experts" and it "will not interfere" with the trial court in this area "'unless clear error and prejudice are shown.'" Nowacki v. Cmty. Med. Ctr., 279 N.J. Super. 276, 290 (App. Div.), certif. denied, 141 N.J. 95 (1995). Further, "**any fact which bears**

against the credibility of a witness is relevant" and a party "has a **right** to have that fact laid before the jury." State v. Pontery, 19 N.J. 457, 472 (1955) (emphasis added). The evidence that Dr. Kavaler was an active promoter of the Prolift device, who was unwilling to respond to the attorney her Prolift patient selected, was clearly relevant to show bias, and Judge Higbee correctly concluded the probative value of this evidence was not substantially outweighed by any undue prejudice. N.J.R.E. 403.

Finally, defendants mistakenly rely on In re Pelvic Mesh/Gynecare Litigation, 426 N.J. Super. 167 (App. Div. 2012), which actually supports Judge Higbee's ruling. In Pelvic Mesh this Court clearly stated that a "physician's duties in litigation are to **cooperate procedurally when called upon** and to provide truthful information," and that **defendants' "expert's credibility may be addressed to the jury at trial**." Id. at 186, 190 n.6 (emphasis added). In short, the Pelvic Mesh decision did not in any way limit Judge Higbee's discretion to permit plaintiffs' counsel to cross-examine Dr. Kavaler regarding her bias in favor of defendants, whose product she actively promotes. There was no error and certainly no manifest injustice.

POINT VI

THE PUNITIVE VERDICT IS SUPPORTED BY SUFFICIENT EVIDENCE

Defendants' argument concerning the punitive damages verdict is flawed, predicated on the wrong standard and ignored a

majority of the evidence. "The New Jersey Supreme Court has been in the vanguard of the development of a responsive and progressive products liability law," Fischer v. Johns-Manville Corp., 193 N.J. Super. 113, 124 (App. Div. 1984), recognizing that punitive damages "serve as the **only deterrent** to manufacturers who would purposefully market dangerous products with insufficient warnings," Ripa v. Owens-Corning Fiberglas Corp., 282 N.J. Super. 373, 396 (App. Div.) (emphasis added), certif. denied, 142 N.J. 518 (1995). New Jersey's policy is well served by this verdict.

The Punitive Damages Act, N.J.S.A. 2A:15-5.9 to -5.17, provides that punitive damages are warranted when a defendant's acts or omissions are "accompanied by a wanton and willful disregard" of its foreseeable consequences. "Wanton and willful disregard" is "a deliberate act or omission with knowledge of a high degree of probability of harm to another and reckless indifference to the consequences of such act or omission." N.J.S.A. 2A:15-5.10. In determining whether to award punitive damages, the jury "shall consider all relevant evidence," including the following factors: the likelihood of serious harm, defendant's awareness of its harmful conduct, defendant's response upon learning of its recklessness, the duration of the recklessness, and any concealment of its conduct. N.J.S.A.

2A:15-5.12b. Although any one of these factors can support punitive damages, here the evidence satisfied all the factors.

Because defendants limit their objection to evidentiary sufficiency, this Court reviews only for an abuse of discretion. Saffos v. Avaya Inc., 419 N.J. Super. 244, 264 (App. Div. 2011); Maul v. Kirkman, 270 N.J. Super. 596, 620 (App. Div. 1994). In reviewing Judge Higbee's decision holding the evidence was sufficient (Da240-44), the appellate court accepts as true all evidence supporting punitive damages and must draw all inferences in plaintiffs' favor. Verdicchio v. Ricca, 179 N.J. 1, 30 (2004); R. 4:40-2. "Appellate courts are enjoined not to 'intrude upon the rightful province of the jury.' In terms of standards of review, a punitive damage verdict is no different from any other." Conte v. Mayor & Council of Garfield, 2003 WL 22019955, at *5 (App. Div. 2003) (citation omitted) (Pa258).

In their attack on the punitive damages verdict, defendants brazenly misrepresent the record and claim that they warned of all risks suffered by Linda; this completely ignores Dr. Weber's testimony as to 28 separate warnings that should have been communicated but were not. (19T169:12-20T208:7). The following list is **illustrative** of the eight weeks of evidence introduced at trial that permitted the jury to conclude that Ethicon acted with wanton and willful disregard in selling the Prolift:

- Defendants marketed Prolift as curing women's sexual health problems, but internal company documents revealed they knew that severe dyspareunia would occur and that their product should not be used in young, sexually-active women, like Linda Gross. (Pa81, 264).

- Ethicon executive, David Robinson, admitted that defendants knew in October 2005 that the Prolift was linked to severe, untreatable urinary complications, but chose to suppress and not warn of the problem because it would "scare the daylights out of doctors." (Pa266).

- To sell Prolift, defendants claimed it would provide "long term results" and "long lasting" relief to women (Da300); this was false and defendants had no data whatsoever about Prolift's long term function after implanted (19T98:22-101:3).

- Defendants knew that once implanted, removing a "bad Prolift" would be a "disaster"; but suppressed and did not warn that the Prolift cannot be fully removed. (Pa72).

- Defendants manipulated the two prototype studies so that it appeared that the Prolift had been tested and claimed it was "proven" to be safe and effective, while the actual data indicated it failed both studies and was unsafe. (27T115:11-28T230:25).

- Defendants marketed the Prolift as "revolutionary" and "safe and effective," but internal emails admit the material was simply pulled from Ethicon's "bag of tricks" and that management ignored repeated requests by Prolift's inventors for a safer mesh due to the excessive contraction and erosion risks. (Pa89; Pa267).

- Defendants' expert Dr. Murphy admitted that the professional education which Linda's doctor attended contained explicit misrepresentations as to the outcome of studies of the Prolift, for example omitting that the authors of a factual study concluded Prolift should only

be used on an experimental basis because of high erosion rates. (42T79:2-80:12).

- The IFU falsely reported that the Prolift had a "bi-directional elastic property" that allowed it to uniquely adjust to the pelvic region's stresses, however the company had absolutely no data or basis for this claim. (29T43:18-44:04; see Da426).

- The IFU misleadingly reported the Prolift elicits a transient, mild inflammatory reaction, but Ethicon knew that the reaction was chronic and severe. (29T46:6-17).

- The IFU falsely stated that the mesh was soft and pliable, but Ethicon's medical director Axel Arnaud, admitted this statement is false, and softness is an "illusion." (35T17:12-18:4).

- In the marketing brochure targeted at consumers and placed on Ethicon's website, defendants made numerous misrepresentations, including that: (1) complications were "rare" or "small" when Ethicon knew that the risks were common, (2) describing the mesh as soft, when they knew this was untrue, and (3) claiming the mesh was "specially designed," when they knew it was not. (Da300).

- Ethicon failed to disclose its internal knowledge of the benefits of lighter weight mesh that was available from the outset, and chose to sell the Prolift with the more dangerous mesh for financial gain, *i.e.*, its "high price strategy." (22T52:11-52:25; 18T229:10-22).

Ignoring the lion's share of evidence -- which overwhelmingly supports the jury's punitive judgment -- defendants claim that the deliberations were tainted by consideration of the brochure during the punitive phase. However, our Legislature has established that the jury "**shall**"

consider "**all**" evidence that tends to prove defendants acted with wanton disregard. N.J.S.A. 2A:15-5.12b (emphasis added); N.J.R.E. 401. This Court applies a "totality of the circumstances analysis, rather than analyzing each of the plaintiff's allegations in isolation." Mancini v. Twp. of Teaneck, 349 N.J. Super. 527, 568 (App. Div. 2002); accord Berg v. Reaction Motors Div., 37 N.J. 396, 414 (1962).[21]

Not only was the patient brochure relevant to punitive damages, but Ethicon took the position that it "was, in form and function, a part of the patient-physician relationship." (Pa257). Moreover, there is no dispute that defendants held out the brochure to the general public and expected individuals like Linda Gross to rely on it. Ethicon Director of Medical Affairs, David Robinson, admitted this:

> Q. Did you expect patients to think that what was written in the Prolift patient brochure was true?
>
> A. Yes.
>
> Q. Did you expect patients to rely on Ethicon to tell them the truth about the Prolift procedure in the patient brochure that was dedicated to the Prolift?
>
> A. As best we knew at the time it was created, yes.

[21] Defendants claim, in Point V, the general punitive verdict must be reversed if one of the underlying verdicts is reversed. However, evidence is reviewed under the "totality of the circumstances analysis" so Judge Higbee correctly used a general verdict sheet. See Model Civil Jury Charge § 8.60, 8.62 (2011).

Q. You know that there were patients who would read the patient brochure for the Prolift and rely on Ethicon's statements to them about the benefits and risks of the procedure as part of their decision about whether or not to let a surgeon put a Prolift in their body. Right?

A. As part of that, yes.

(38T63:8-63:21). Ethicon knew and expected that doctors and patients would read and rely on their promotional brochure in deciding whether to proceed with Prolift implantation, and the brochure's misrepresentations and omissions were clearly relevant to the jury's consideration of punitive damages.

The evidence presented at trial was more than sufficient to support a punitive damages award under New Jersey law. Indeed, the following cases demonstrate circumstances where far less evidence of a defendant's willful and wanton conduct has been found to adequately support an award of punitive damages:

- In a failure to warn case, evidence was sufficient where the manufacturer's documents revealed it "generally believed ... that [its product] might present a significant health risk but that the danger was not definitively known," the manufacturer ignored internal testing and external reports that revealed serious health risks, and it never conducted a follow-up test despite knowledge of potential serious risks. Ripa, supra, 282 N.J. Super. at 380-82, 394-95 (App. Div. 1995).

- In a product liability case, evidence was sufficient where defendants marketed and promoted a women's health product as safe and tested, but did not conduct the testing that would have revealed the inherent dangers in their product before marketing it, and they failed to notify the FDA about a change to the product to avoid FDA-mandated testing, which also would have revealed the defects. Wolf

v. Procter & Gamble Co., 555 F. Supp. 613, 619 (D.N.J. 1982) (applying New Jersey common law that was later codified in the Punitive Damages Act).

- In Zakrocki v. Ford Motor Co., Judge Sabatino held the evidence was sufficient where product users reported a defect to the manufacturer, a government report indicated risk of serious injury, and despite knowledge of the consumer reports and the government report, the manufacturer took no action. 2009 WL 2243986, at *23 (App. Div.) (Pa270), certif. denied, 200 N.J. 505 (2009).

- In fraud case relating to a product liability case, evidence was sufficient where defendant suppressed evidence plaintiff needed to prove defect in product. Viviano v. CBS, Inc., 251 N.J. Super. 113, 118-19, 129-30 (App. Div. 1991), certif. denied, 127 N.J. 565 (1992).

- In negligence case, evidence was sufficient where defendant knew its vehicle was defective and unsafe to operate, did not repair the defective brakes, did not have a policy or train employees to identify and eliminate defects, and continued to use vehicle. Smith v. Whitaker, 160 N.J. 221, 229-30, 246-47 (1999).

In sum, the evidence in this case is greater than that in other product liability precedents where punitive damages were affirmed, and the jury's punitive verdict should be affirmed.

CONCLUSION

For all the foregoing reasons, the judgment below should be affirmed.

Respectfully submitted,

ADAM M. SLATER

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