UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

BOBBY DON BOWERSOCK, and CHARLOTTE ROBINSON as Co-Personal Representatives of the Estate of Georgia J. Bowersock, deceased, and MARK BOWERSOCK Individually,	)	No. 1:08-cv-01313-LJM-TAB
Plaintiffs,	)	
vs.	)	
DAVOL, INC., C.R. BARD, INC.,	)	
Defendants.	)	

ORDER ON DEFENDANTS' MOTION FOR SUMMARY JUDGMENT

This case is before the Court on Defendants', Davol, Inc. and C.R. Bard, Inc. (collectively, "Bard"), Motion for Summary Judgment (Dkt.30) on Plaintiffs', Bobby Don Bowersock, Charlotte Robinson, and Mark Bowersock (collectively "Plaintiffs'"), Complaint. Dkt. 1. Plaintiffs allege that a hernia patch manufactured by Bard and implanted in Georgia Bowersock was defective and ultimately led to her death, in violation of the Indiana Products Liability Act. Ind. Code § 20-1-1. Mark Bowersock has also asserted an individual claim under the Indiana Wrongful Death Act. Ind. Code § 34-23-1-1.

In addition to its Motion for Summary Judgment, Bard has filed motions to exclude the testimony of Plaintiffs' experts Dr. Stephen Ferzoco (Dkt. 33) and Dr. William A. Hyman (Dkt. 39), as well as a motion to limit the testimony of Dr. Roland Kohr (Dkt. 37).

For the reasons set forth below, the Court **GRANTS** Bard's motions.

I. BACKGROUND

A. COMPOSIX KUGEL PATCH AND INSTRUCTIONS FOR USE

The Composix Kugle Patch ("CK Patch") is a prescription medical device created by Bard for use in hernia repair. Dkt. 43 at 2.[1] The CK Patch was declared by the Food and Drug Administration ("FDA") to be "substantially equivalent" to a device that had already been declared by the FDA to be safe and effective. *Id*. at 3. The CK Patch consists of a dual layer of polypropylene mesh on one side, and an expanded polytetrafluoroethylene layer ("ePTFE") on the other side. Hyman Report at 2. The ePTFE is intended to prevent damage to internal organs. *Id*. The CK Patch design also contains a polyethylene terephthalate ("PET") overlap-welded "memory ring." *Id*. The purpose of the ring is to facilitate initial placement of the mesh by the surgeon as a result of the ring's tendency to cause the mesh to lay flat. *Id*. at 5. The ring, however, remains implanted for the life of the patient along with the mesh components following insertion of the patch. *Id*. at 2, 9.

The CK Patch came with Instructions for Use ("IFU"), which detailed indications, contraindications, warnings, and precautions associated with the patch. Dkt. 43 at 5. The IFU did not, however, warn against potential dangers associated with the ring. *Id*.; Lynch Dep. 148:7-149:6. The IFU states that "there is a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera." Dkt. 43 at 6. The

[1] The Court has attempted to set out the facts that are either undisputed or, if disputed, in the light most favorable to the Plaintiffs as the non-moving parties. In order to streamline this Order, unless otherwise noted the Court will cite to the ECF page number or numbers where the relevant facts are set forth in a party's brief and such citation should be presumed to include the exhibits cited therein. It should also be presumed that when using the Plaintiffs' Statement of Disputed Facts (Dkt. 43), the Court incorporates the citations utilized by Bard in its Statement of Undisputed Facts as well (Dkt. 32).

Warnings section of the IFU provides that "[i]f an infection develops, treat the infection aggressively. The prosthesis may not have to be removed. An unresolved infection, however, may require removal of the prosthesis." *Id*. The IFU also warns against "plac[ing] the mesh surface against the bowel" because "[t]here may be a possibility for adhesion formation." *Id*. at 7.

B. CK PATCH RECALL

In December 2005, Bard initiated a recall of extra-large models of the CK Patch following reports that memory recoil rings were breaking. Dkt. 31, Ex. 7. In March 2006, Bard expanded the recall to other models, specifically the 202 and 204 CK Patches manufactured before January 2004, as well as model 209 CK Patches manufactured before March 2006. *Id*., Ex. 8.

C. IMPLANTATION OF CK PATCH INTO GEORGIA BOWERSOCK

Georgia Bowersock presented to Dr. Mark Lynch in May 2005 with an abdominal wall hernia. Lynch Dep. 86:9-19. Dr. Lynch indicated that Georgia was at a high risk of infection and recurrence, and that she exhibited severe chronic obstructive pulmonary disease ("COPD"), cardiac issues, obstructive sleep apnea, morbid obesity, and was a long-term smoker. *Id*. at 79:12-22; 80:14-82:5. Dr. Lynch went over the risks and benefits of hernia repair surgery with Georgia, to which she consented. *Id*. at 86:1-87:2; 91:16-92:7. Dr. Lynch implanted the CK Patch into Georgia in July 2005. *Id*. at 89:21-90:8.

Following the implantation of the CK Patch and several follow up appointments for discharge and wound healing issues, on September 19, 2005, Dr. Lynch instructed Georgia to return if she had any problems with her incision, signs of infection, or any

issues in her abdominal area. *Id*. at 111:8-113:18; 115:7-16. Georgia did not call Dr. Lynch's office or return for treatment. *Id*. at 115:15-116:4.

D. GEORGIA BOWERSOCK'S OCTOBER 2006 HOSPITAL VISITS

Over a year later, on October 4, 2006, Georgia presented to the emergency room at Terre Haute Regional Hospital, with an abdominal wall abscess that was draining pus and blood. Dkt. 31, Ex. 13 at 7. A culture of the abscess revealed the presence of staphylococcus aureus, a common skin bacteria. Kumar Dep. 47:9-48:3. Georgia was prescribed antibiotics and sent home. *Id*. at 48:4-10. She returned to the hospital on October 13, 2006. Dkt. 31, Ex. 13 at 10. By October 17, 2006, she was on a ventilator and immobile; Georgia had an abscess in the anterior abdominal wall, which her primary care physician and attending physician at the hospital, Dr. Pardeep Kumar, believed to be the source of the infection. Kumar Dep. 14:4-12; 41:17-21. On October 17, 2006, a second culture of the abdominal wall abscess revealed the presence of enterococcus faecalis – a bacteria that often inhabits the gastrointestinal tract – as well as staphylococcus epidermidis, a skin bacteria. *Id*. 48:21-49:5. *See also*, Dkt. 31, Ex. 13 at 8.

Georgia passed away on October 31, 2006. Dkt. 31, Ex. 14. Dr. Kumar signed her death certificate, listing the cause of death as pneumonia and renal failure. *Id*.

E. GEORGIA BOWERSOCK'S AUTOPSY

Dr. Roland Kohr performed an autopsy on Georgia on October 31, 2006. *See* Dkt. 31, Ex. 15. Dr. Kohr listed the cause of death as "[p]neumonia and diffuse alveolar damage." *Id*. at 2. The Autopsy Report further indicated that the "small bowel and colon are intact without perforation, diverticula or palpable tumors." *Id*. at 5. The Autopsy Report also mentioned anatomic findings of dense abdominal adhesions and abdominal wall fistula. *Id*. at 2.

In his summary, Dr. Kohr stated, "Georgia Bowersock was a 59 year old white female who presented to Regional Hospital on October 13 complaining of an abdominal wall draining wound. She had undergone a herniorrhaphy many months earlier, and had developed questionable complications." *Id*. at 3. It further stated that "[d]uring her admission she developed sepsis, and then progressed eventually to respiratory failure." *Id*.

F. EXHUMATION OF GEORGIA BOWERSOCK

On September 19, 2013, Dr. Kohr exhumed Georgia's body at Plaintiffs' request. *See* Dkt. 38, Ex. 6. The exhumation was conducted to retrieve the CK Patch for further study. *Id*. at 3.

G. DR. STEPHEN FERZOCO

Dr. Stephen Ferzoco is the former director of Brigham and Women's Hernia Center at Faulkner Hospital. Dkt. 31, Ex. 27 at 2. He is a board certified general surgeon that specializes in gastrointestinal and general surgery with a particular interest in complex abdominal hernias and he has used the CK Patch in his practice. *Id*. Following the CK

Patch recall, Dr. Ferzoco developed and ran a medical monitoring program to follow and evaluate patients that had received CK Patch implants. *Id*.

Dr. Ferzoco was hired as the Plaintiffs' expert to opine about Georgia's case. *Id*. Dr. Ferzoco reviewed the explanted mesh taken from Georgia post-exhumation, as well as her medical records and autopsy reports. *Id*. at 3. In his expert report, Dr. Ferzoco states that his "opinions are based on my review of the above referenced materials, my education, my medical training, and my practice as a general surgeon with a specialty in gastrointestinal surgery, including surgeries involving the Composix Kugel Mesh patches." *Id*. In his report, Dr. Ferzoco opined that Georgia's death was a result of sepsis caused by a defective CK Patch. He states:

> It is my opinion that the abscess and sepsis were caused by a defective mesh product leading to warping of the mesh and dense adhesions to the intestines. This insult of the warped or buckled patch led to the infection and need for hospitalization. Upon my inspection of the mesh, it is apparent that the mesh is buckled. On further examination, I do not identify any ring break.

Id. at 4.

Dr. Ferzoco then speaks in general with respect to the cause of defects in the CK Patch indicating that the fixed ring allows the material to buck and warp into dangerous conditions. *Id*. He further states, "It is my opinion that forces acting on the ring caused the mesh to buckle and fold in an abnormal configuration. These forces include required forces [sic] used to implant the device, body forces and contracture forces." *Id*. Dr. Ferzoco also mentions that Bard's own medical literature review on contracture forces identifies dozens of articles that pre-date the commercialization of the CK Patch implanted in Georgia. *Id*. He states that the buckling that results from these forces "can cause a multitude of injuries including, but not limited to perforation and fistula as a result of ring

break or puncture caused by a sharp, buckled patch edge." *Id*. Dr. Ferzoco concludes, to a reasonable degree of medical certainty, "that Ms. Bowersock's defective Composix Kugel Mesh patch placed in 2005 buckled, causing adhesions leading to an abcess formation and sepsis ultimately leading to her death." *Id*. at 5.

At his deposition, Dr. Ferzoco opined that the ring buckled, creating a sharp edge, which could breach the bowel. Ferzoco Dep. 22:18-23:4. He reviewed the CK Patch and stated that it was "contorted, buckled, [and] certainly could have led to exposure of the underlying bowel, a nidus for possible adhesions, erosions, and infection." *Id*. at 25:20-26:3. He admitted that he did not see any direct evidence of eroded bowel. *Id*. at 26:4-6. Nonetheless, Dr. Ferzoco believed that there was communication between the bowel and the wound based on the presence of fecal bacteria, which was found during the second culture on the microbiology report. *Id*. at 27:20-28:10. He believed that the communication occurred "with the mesh rubbing up against the bowel causing a fistula or break and then sealing up prior to explanation or discovery of the mesh in the bowel." *Id*. at 109:6-15. Dr. Ferzoco admitted that, other than the second culture, he saw no evidence of bowel involvement. *Id*. at 28:22-3; 46:3-9; 72:12-24. He stated, however, that he believed that enterococcus (fecal) bacteria was present on the first culture from October 4, 2006, but that it was not properly cultured. *Id*. at 100:12-20. Dr. Ferzoco based this latter opinion on his education, training, and experience with similar patients. *Id*. at 100:21-24.

Dr. Ferzoco conceded that the autopsy did not demonstrate any visual perforations of the bowel. *Id*. at 46:10-47:6. When questioned further about the lack of perforations found during the autopsy, Dr. Ferzoco stated, "Well, there had to be some perforation for

her to get her bacteria. Again, my opinion is there had to be some perforation, whether or not it had sealed at the time by the autopsy … [and] [t]hat they were unable to visualize a perforation." *Id*. at 58:17-4. He also stated that it could have been a "microperforation that was unable to be well-visualized at the time of the autopsy." *Id*. at 58:4-6. Dr. Ferzoco believed that the bacteria from the bowel would travel through the edge of the CK Patch's material "because of the buckling, [forming] a channel that allows it to egress through the midline of the wound." *Id*. at 68:18-69:6. He believed that the physicians who treated her, as well as Dr. Kohr, simply missed the bowel perforation. *Id*. at 179:7-11.

Dr. Ferzoco ruled out cross-contamination due to the location of the wound. *Id*. at 88:24-89:16. He found that it was "highly unlikely" that the enterococcus came in through the skin. *Id*. at 112:20-22. He stated that his review of the medical literature, the records in Georgia's case and the patch itself "demonstrates to me that it is a very strong possibility, more likely than not, that she had a violation of her GI tract that caused the development of an abscess, which subsequently grew out a bowel species of bacteria that led to her death." *Id*. at 112:23-113:10.

Dr. Ferzoco admitted that he had not seen any published medical literature that describes a theory such as the one he was offering, i.e. where there was not a ring break or mesh erosion, but where "the ring rubbed against the bowel and the bowel opened up, allowed infection to develop, and then closed before anybody could discover the source of the infection." *Id*. at 108:10-23. He stated, however, "Based on my education, training, and experience my discussions with other surgeons, it is not a unique possibility." *Id*. at 108:24-109:5. Dr. Ferzoco indicated that there was medical literature that discussed

microperforations in patients that suffered from diverticulitis. *Id*. at 174:14-175:13. He admitted, that his "nidus" theory was not described in the medical literature, but stated that he had seen it occur in other patients. *Id*. at 124:2-125:1; 1515:14-18. Dr. Ferzoco could not identify in which patients he had seen the nidus effect take place, nor could he produce those records to defense counsel. *Id*. at 149:13-150:1. *See also id.* at 193:1-9 ("Q: Are you relying on your specific patient experience of these nidus and infection cases with ringed products for your opinions about Ms. Bowersock having, in your mind, a nidus causing an infection in ring product? A: Yes. Q: Are you going to produce those records? A: I don't know if I will be able to have access to those records."). Dr. Ferzoco also stated that he had never presented his nidus theory in a formal or professional setting. *Id*. at 153:4-10.

H. DR. ROLAND KOHR

As previously stated, Dr. Kohr performed an autopsy on Georgia in October 2006 at the request of her family. Kohr Dep. at 5:13-15; 13:2-11. He listed pneumonia and diffuse alveolar damage as the cause of death following the autopsy, both of which are issues with the lungs. *Id*. at 17:12-17. Dr. Kohr stated that he did not find that any internal organs were breached, but stated that "there could have been superficial breaches scarred over with additional inflammation and as much inflammation as scarring without adhesions, what could have happened earlier is not necessarily going to show up at this time." *Id*. at 44:3-14. He admitted that he could not see any breach of Georgia's intestines, colon, bowel or any other internal organs "with the naked eye." *Id*. at 44:15-21. Dr. Kohr was aware of the CK Patch implant, but did not smell or see any pus or abnormalities where it was placed. *Id*. at 48:8-51:5. Nonetheless, he indicated that the

"presence of the extensive adhesions in the suprapubic area, lower abdomen, suggest that there is a possibility that there had been a breach." *Id*. at 59:17-19. When questioned about this latter statement, Dr. Kohr stated, "I'm very suspicious that some of that did happen, yes." *Id*. at 60:9-13. Dr. Kohr acknowledged that enterococcus faecalis, the bacteria found in Georgia's second culture, could enter through an open wound or incision and that he has seen this occur in other patients. *Id*. at 101:10-103:16. He also indicated that the course of her cultures does not necessarily indicate that there was a breach of Georgia's bowel. *Id*. at 104:18-105:8. In fact, Dr. Kohr looked for communication from the bowels to the abdominal wall during Georgia's autopsy but did not see any. *Id*. at 108:17-109:14. He stated that he did not notice any bowel adhered to the CK Patch when he performed the autopsy and that it would be obvious if that had been the case. *Id*. at 119:11-21. Nonetheless, Dr. Kohr concluded that the breach of the bowel, in the "absence of having documented any major problems at the time of surgery a year earlier, it's got to be related at some point to inflammation." *Id*. at 138:21-139:9.

Dr. Kohr stated that he considered himself a retained expert of the Plaintiffs when he drafted an affidavit at their request. *Id*. at 69:13-70:8; 73:22-74:8. In preparation of his affidavit, Dr. Kohr reviewed medical literature, as well as information relating to the CK Patch sent to him by Plaintiffs' counsel. *Id*. at 70:9-18; 78:12-79:8; Kohr Aff., ¶¶ 5, 6. He stated in his affidavit, "[I]t is my opinion based on reasonable medical probability that complications with the Kugel mesh caused the abscess and infection in the anterior abdominal wall leading to Ms. Bowersock's severe sepsis, multi-organ failure, pneumonia and diffuse alveolar damage, and was therefore the proximate cause of her death." Kohr Aff., ¶ 7.

I. DR. WILLIAM HYMAN

Dr. William Hyman, an expert retained by the Plaintiffs, has been a professor of biomedical engineering at Texas A&M University since 1972 and has previously served as chair of the biomedical engineering program. Dr. Hyman Curriculum Vitae at 1. Dr. Hyman has written extensively on medical device safety and taught classes on that subject as well as medical device design, implant materials, and FDA regulations. *Id*. at 2-16.

Dr. Hyman stated in his expert report, "[i]n summary, my opinion is that the design of the Composix Kugel Hernia Patch is defective, and that its defects were a direct cause of Ms. Bowersock's injuries and death." Hyman Report at 3. He further noted that "alternative economically feasible and fundamentally safer designs were available and, in fact, known to and considered by Davol/Bard, who nonetheless chose to pursue and maintain the patch's defective design." *Id*.

Dr. Hyman testified that he had never examined Georgia's exhumed CK Patch nor viewed any pictures of it, but that he had seen the patch in Dr. Ferzoco's video. Hyman Dep. 34:25-35:16. Dr. Hyman stated that based on the inference of a bowel injury, the CK Patch more likely than not curved towards the bowel. *Id*. at 46:4-19. He concluded that a bowel injury occurred in Georgia on the basis of the second bacterial culture as well as the medical testimony of Dr. Ferzoco, whose deposition he read prior to his own deposition. *Id*. at 46:20-47:3. Dr. Hyman conceded, however, that he was not an expert on bacteria extracted from cultures and that he only has "some knowledge about it." *Id*. at 47:4-11. He also admitted, "I'm not a microbiologist and I'm not offering an independent opinion on the microbiology of her infection." *Id*. at 59:5-20.

Dr. Hyman stated that he was not aware of any medical literature that describes an intact ring CK Patch issue where the patch rubs against the bowel causing damage, but stated that the case reports he has worked on are consistent with that damage mechanism. *Id*. at 60:18-61:17. When questioned further, Dr. Hyman conceded that he could not remember any case similar to the injury he believes Georgia suffered. *Id*. at 63:18-64:18; *see also id*. at 66:3-11 ("Q: … is there some other case that you can point to of another patient from any source, published, unpublished, just that you saw in litigation, whatever, that describes the same mechanism of injury to what you're talking about here? [Objection]. A: Not that I recall at this time.").

Dr. Hyman admitted that he did not know the source of Georgia's bacteria when she first presented in October 2006. *Id*. at 49:4-8.

II. PROCEDURAL HISTORY

Plaintiffs filed suit in this Court on September 20, 2008. Dkt. 1. It was subsequently transferred to the United States District Court for the District of Rhode Island by the Judicial Panel on Multidistrict Litigation to the *In Re: Kugel Mesh Hernia Patch Products Liability Litigation*, 1:07-md-01842-ML-LDA (D.R.I.) ("MDL"). The case was remanded back to this Court on November 29, 2016. All pretrial filings have been completed, including this motion for summary judgment filed by Bard. Bard has contemporaneously filed motions to exclude or limit Plaintiffs' experts in support of its motion for summary judgment.

III. SUMMARY JUDGMENT STANDARD

As stated by the Supreme Court, summary judgment is not a disfavored procedural shortcut, but rather is an integral part of the federal rules as a whole, which are designed

to secure the just, speedy, and inexpensive determination of every action. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 327 (1986); *see also United Ass'n of Black Landscapers v. City of Milwaukee*, 916 F.2d 1261, 1267-68 (7th Cir. 1990). Motions for summary judgment are governed by Federal Rule of Civil Procedure 56, which provides in relevant part: "The Court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a).

Once a party has made a properly-supported motion for summary judgment, the opposing party may not simply rest upon the pleadings but must instead submit evidentiary materials showing that a fact either is or cannot be genuinely disputed. Fed. R. Civ. P. 56(c)(1). A genuine issue of material fact exists whenever "there is sufficient evidence favoring the nonmoving party for a jury to return a verdict for that party." *Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 249, (1986). The nonmoving party bears the burden of demonstrating that such a genuine issue of material fact exists. *See Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586–87 (1986); *Oliver v. Oshkosh Truck Corp.,* 96 F.3d 992, 997 (7th Cir. 1996). It is not the duty of the Court to scour the record in search of evidence to defeat a motion for summary judgment; rather, the nonmoving party bears the responsibility of identifying applicable evidence. *See Bombard v. Ft. Wayne Newspapers, Inc.,* 92 F.3d 560, 562 (7th Cir. 1996).

In evaluating a motion for summary judgment, the Court should draw all reasonable inferences from undisputed facts in favor of the nonmoving party and should view the disputed evidence in the light most favorable to the nonmoving party. *See Estate*

of Cole v. Fromm, 94 F.3d 254, 257 (7th Cir. 1996). The mere existence of a factual dispute, by itself, is not sufficient to bar summary judgment. Only factual disputes that might affect the outcome of the suit in light of the substantive law will preclude summary judgment. *See Anderson,* 477 U.S. at 248; *JPM Inc. v. John Deere Indus. Equip. Co.,* 94 F.3d 270, 273 (7th Cir. 1996). Irrelevant or unnecessary facts do not deter summary judgment, even when in dispute. *See Clifton v. Schafer,* 969 F.2d 278, 281 (7th Cir. 1992). If the moving party does not have the ultimate burden of proof on a claim, it is sufficient for the moving party to direct the Court to the lack of evidence as to an element of that claim. *See Green v. Whiteco Indus., Inc.,* 17 F.3d 199, 201 & n. 3 (7th Cir. 1994). "If the nonmoving party fails to establish the existence of an element essential to his case, one on which he would bear the burden of proof at trial, summary judgment must be granted to the moving party." *Ortiz v. John O. Butler Co.,* 94 F.3d 1121, 1124 (7th Cir. 1996).

IV. ANALYSIS

A. APPLICABLE INDIANA LAW

Plaintiffs allege claims for negligence, violation of the "Indiana Deceptive Trade Practices Act,"[2] strict product liability, intentional infliction of emotional distress, failure to warn, breach of implied warranty, and fraud.[3] Dkt. 1. The parties agree that Plaintiffs' claims should be consolidated under the Indiana Products Liability Act ("IPLA"), which the

[2] There is no such claim in Indiana, but Plaintiffs cite to the Indiana Deceptive Consumer Sales Act ("IDCSA"), Ind. Code § 24-5-.5. *et seq*. Accordingly, the Court construes this count as a claim under the IDCSA.

[3] Plaintiffs concede that they are not pursuing claims for a manufacturing defect, implied warranty of merchantability, or negligent infliction of emotional distress. Dkt. 41, pp. 27-28.

Indiana legislature intended "to govern all product liability actions, whether the theory of liability is negligence or strict liability in tort." *Dague v. Piper Aircraft Corp*., 418 N.E.2d 207, 212 (Ind. 1981). *See also*, dkt. 41, p. 27. Indeed, the IPLA governs all actions "(1) brought by a user or consumer; (2) against a manufacturer or seller; [] (3) for physical harm caused by a product; regardless of the substantive legal theory or theories upon which the action is brought." Ind. Code § 34-20-1-1. Importantly, both negligence and strict products liability claims under the IPLA require Plaintiffs to demonstrate that the alleged defect in the CK Patch was a proximate cause of Georgia's injury. *See Ford Motor Co. v. Rushford*, 868 N.E.2d 806, 810 (Ind. 2007); *see also Kovach v. Caligor Midwest*, 913 N.E.2d 193, 197 (Ind. 2009).

Plaintiff Mark Bowersock has also brought a claim under the Indiana Wrongful Death Act ("IWDA"). The elements for a claim under IWDA are "a duty owed by the defendant to the decedent, breach of that duty, and an injury proximately caused by the breach." *Tom v. Voida*, 654 N.E.2d 776, 787 (Ind. Ct. App. 1995).

Bard alleges that the Plaintiffs' experts are not qualified to testify under Federal Rule of Evidence 702 ("Rule 702") and *Daubert*. Thus, Bard argues that Plaintiffs are unable to establish causation and therefore their claims must fail.[4] For the following reasons, the Court agrees.

[4] Bard does not seek summary judgment for lack of causation on Mark Bowersock's IWDA claim, but rather argues that Mark Bowersock cannot bring this claim as an incapacitated adult, which is a prerequisite to bringing a claim. As the element of causation is not met, the IWDA claim must fail. Accordingly, the Court need not address any alleged defects of the Complaint.

B. EXPERT TESTIMONY ON CAUSATION

1. Dr. Ferzoco Testimony

Bard asserts that Dr. Ferzoco's opinions are not based on any scientific support and must be excluded under Rule 702. Bard also seeks exclusion of Dr. Ferzoco's theory because it is based solely on his own patient experience, but he has failed to produce any patient records, rendering such an opinion unreliable and therefore inadmissible.

Under Rule 702 and *Daubert*, the Court follows a two-prong framework: the Court must determine whether "(1) the proposed witness would testify to valid scientific, technical, or other specialized knowledge[,] and (2) [the Court must determine whether] his testimony will assist the trier of fact." *Ammons v. Aramark Unif. Servs., Inc.*, 368 F.3d 809, 816 (7th Cir. 2004) (quotations and citations omitted). The first prong "of this framework evaluates the reliability of the testimony." *Id.* To determine whether an expert's opinions are reliable, the Court "'must determine whether the expert is qualified in the relevant field and whether the methodology underlying the expert's conclusions is reliable.'" *Id.* (quoting *Zelinski v. Columbia 300, Inc.*, 335 F.3d 633, 640 (7th Cir. 2003)). This requires the Court to consider whether the testimony has been subjected to the scientific method, ruling out any subjective belief or unsupported speculation. *See Porter v. Whitehall Labs. Inc.,* 9 F.3d 607, 614 (7th Cir.1993).

Under the second prong, the Court "evaluates the testimony's relevance." *Id.* The opinion may assist the trier of fact with any issue involved in the case; the expert need not opine about the ultimate issue. *See Smith v. Ford Motor Co.*, 215 F.3d 713, 718 (7th Cir. 2000). An expert may opine as to the hypothetical or probable causes of an event if such testimony would aid the jury. *Id.* at 718-19. However, the hypothetical alternative must itself have an analytically sound basis such that it is more than mere speculation.

Id. at 719 (citing *DePaepe v. Gen. Motors Corp.*, 141 F.3d 715, 720 (7th Cir. 1998)). The Court may not decide if the expert's opinion is correct; rather, it must only determine whether the expert's testimony is pertinent to an issue in the case. *Id*.

Dr. Ferzoco essentially puts forth two interrelated opinions: (1) the presence of fecal bacteria in Georgia's second of three cultures indicates bowel involvement; and (2) the CK Patch, whose ring did not break, buckled and rubbed against Georgia's colon causing bowel contents to be released through an opening that either closed back up prior to being discovered or was not visible, either of which led to the infection (the nidus theory). Ferzoco Dep. 28:22-3; 46:3-9; 72:12-24; 108:10-23. While it might be said that Dr. Ferzoco utilized the scientific method in determining bowel involvement based on this second culture, Dr. Ferzoco is unable to set forth a reliable, scientific opinion as to how the CK Patch's alleged buckling caused Georgia's injury. Dr. Ferzoco admits that the type of "buckling" he describes in Georgia's case is markedly different than that found in other cases in the MDL of which this case was a part, which involve the polypropylene side of the patch being exposed to the bowel. *Id*. at 24:16-19; 29:15-20; 63:3-22; 64:15-65:5; *see also*, Ferzoco Report at 4 ("The buckling and warping allows the polypropylene side of the mesh to come into contact with bowel and intra-abdominal organs, leading to a wide range of complications including adhesions, fistula formation and abscess formation."). Consequently, Dr. Ferzoco proposes his new opinion, the nidus theory, which he asserts is the result of the CK Patch rubbing against the bowel to create a perforation that allows bowel contents to spill over.[5] The rubbing against the colon

[5] Plaintiffs argue that the "nidus" theory is simply Dr. Ferzoco's word to describe the point of infection. Dkt. 45 at 8. In other words, the nidus is the location that the CK Patch rubbed against the bowel creating an opening that allowed for bowel contents to spill over.

creates either microperforations too small to be seen with the naked eye or perforations that closed up prior to performance of the autopsy, but Dr. Ferzoco could not say definitively which occurred in the instant case. *Id*. at 58:17-59:11.

Dr. Ferzoco readily admits that his nidus theory has not been described in the medical literature or peer review. *Id*. at 108:10-23; 124:2-12; 126:9-13; 152:8-18. Moreover, none of the symptoms he describes are found in Georgia's medical records or the autopsy report. *Id*. at 28:22-29:3; 31:6-11; 46:3-9; 47:13-48:14; 59:22-60:10. Furthermore, his theory is not based on any of the materials provided in connection with other CK Patch cases. *Id*. at 183:22-184:6. Finally, Dr. Ferzoco admits that his nidus theory has never been presented in a formal or professional setting. *Id*. at 153:4-10.

Dr. Ferzoco's sole support for his nidus theory is his previous patient experience. *Id*. at 124:2-125:1; 193:1-6. However, Dr. Ferzoco stated that he could not identify any patients by name or produce medical records to substantiate his theory. *Id*. at 149:13-150:1; 193:1-9. Moreover, his expert report is devoid of any information relating to the treatment of patients that received a similar diagnosis to Georgia Bowersock. *See* Ferzoco Report. Accordingly, his testimony does not withstand the reliability strictures set forth in *Daubert* and Rule 702.

It is the Court's duty to ensure that "any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589. In doing so, the Court must "determine whether the evidence is genuinely scientific, as distinct from being unscientific speculation offered by a genuine scientist." *Rosen v. Ciba-Geigy Corp.*, 78

For purposes of clarity, however, the Court will refer to this type of alleged bucking as the nidus theory.

F.3d 316, 318 (7th Cir. 1996). "Either 'hands-on testing' or 'review of experimental statistical, or other scientific data generated by others in the field' may suffice as a reasonable methodology upon which to base an opinion." *Clark v. Takata Corp*., 192 F.3d 750, 759 (7th Cir. 1999) (citing *Cummins v. Lyle Indus.*, 93 F.3d 362. 369 (7th Cir. 1996)).

While it appears from his curriculum vitae that Dr. Ferzoco certainly has the requisite knowledge, skill, experience, education, and training to provide an expert opinion in this matter, the underlying reasoning for his conclusions is insufficient to deem his testimony reliable. Plaintiffs claim that his opinions and knowledge of the human body, his experience in hernia repair surgery, his training and experience in implanting hernia mesh prosthetics, and the well-documented problems found with the CK Patch should be sufficient to qualify Dr. Ferzoco to testify as an expert on causation in this case. But Plaintiffs fail to connect any of these qualifications with Dr. Ferzoco's specific opinion here. In fact, Dr. Ferzoco is only able to base his nidus causation theory, which has not been tested or subjected to peer review, on his prior experience with other patients. Setting aside the fact that Dr. Ferzoco is unable to produce any documentation or recollection relating to his previous patients exhibiting the nidus theory, it is clear that his methodology cannot be based on any of the factors set forth in *Daubert*. *See Takata Corp.*, 192 F.3d at 758 ("In determining whether an expert's testimony is reliable, the *Daubert* factors are applicable in cases where an expert eschews reliance on any rigorous methodology and instead purports to base his opinion merely on 'experience' or 'training.'").

As has been stated more fully above, Dr. Ferzoco's theory has not been "(1) tested, (2) subjected to peer review and publication, (3) analyzed for known or potential error rate, and/or is (4) generally accepted within the specific scientific field." *Lapsley v. Xtek, Inc.*, 689 F.3d 802, 810 (7th Cir. 2012). Plaintiffs provide no other medical doctor or literature that has reviewed, tested, or described similar diagnoses to that advocated by Dr. Ferzoco. The fact that Dr. Ferzoco has allegedly seen his nidus theory occur in unnamed patients is simply not enough; for while experts "commonly extrapolate from existing data[,] … nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the expert." *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). *See also, Zenith Elec. Corp. v. WH-TV Broad. Corp.*, 395 F.3d 416, 419 (7th Cir. 2005) ("A witness who invokes 'my expertise' rather than analytic strategies widely used by specialists is not an expert as Rule 702 defines that term.").

Plaintiffs respond that an expert's experience alone may provide sufficient foundation for expert testimony. They cite to Dr. Ferzoco's extensive experience with hernia repair and his post-recall CK Patch monitoring program to establish his credentials as an expert in this field. Although it is true that experience alone may provide a sufficient foundation for expert testimony, Dr. Ferzoco is unable to point to any specific experience that would provide that necessary foundation. By simply alluding to prior patient experience to support his causation theory without providing any explicit details that could be explored by Bard's counsel, Dr. Ferzoco's opinions cannot be deemed sufficiently reliable under Rule 702. *See Olinger v. U.S. Golf Ass'n*, 52 F. Supp. 2d 947, 950 (N.D. Ind. 1999) ("This record discloses a well-credentialed expert who employs an undisclosed

methodology to arrive at disclosed opinions. The court cannot evaluate the reliability of the undisclosed methodology or [] the principles that support the methodology.").

Accordingly, the Court finds that Dr. Ferzoco's testimony as to the causation of Georgia's injuries must be excluded and Bard's Motion *in Limine* must be GRANTED.

2. Dr. Hyman Testimony

Bard also seeks the exclusion of Dr. Hyman's testimony on the basis of reliability. Bard points to the fact that Dr. Hyman never performed any testing on his causation theory, nor could he estimate or quantify the amount of deformation required to cause an injury to occur. Hyman Dep. 76:4-23; 78:23-79:5. Moreover, Dr. Hyman never performed any testing on a CK Patch or any other hernia mesh products with a composite ring. *Id*. at 92:19-93:24. Furthermore, Dr. Hyman was unaware of any test or study demonstrating his proposed failure mechanism or any test that resulted in a bowel injury due to the deformation of the CK Patch as he described it. *Id*. at 113:9-114:20; 119:3-121:17; 122:5-125:6. Dr. Hyman never examined Georgia's CK Patch nor viewed images of the CK Patch after removal of the tissue. *Id*. at 34:25-35:6; 36:7-37:5. He could not state where Georgia's CK Patch ring distorted. *Id*. at 46:3-11. Dr. Hyman was only able to cite to a bowel injury on the basis of the medical culture and the opinion of Dr. Ferzoco, despite admitting that he is not an expert on cultures and only had "some knowledge about [them]." *Id*. at 46:16-47:11.

Plaintiffs do little to establish the reliability of Dr. Hyman's causation opinion. Plaintiffs concede that Dr. Hyman is not a medical doctor and cannot offer medical opinions, but believe that he should be able to testify as to: "1) why the patch buckled, and 2) why the well-known phenomenon could cause the injuries suffered by Ms. Bowersock and opined to by Dr. Ferzoco." Dkt. 48 at 24.

With respect to the instant motions, the latter opinion is of most concern. Plaintiffs do not cite to any of the *Daubert* factors or any specific qualifications or expertise that would allow Dr. Hyman to testify as to how the CK Patch buckled and caused Georgia's injury. Plaintiffs focus on Dr. Hyman's ability to talk about buckling and contracture forces, but fail to set forth any evidence to establish the reliability of his opinion as to medical causation. "The proponent of the expert bears the burden of demonstrating that the expert's testimony would satisfy the *Daubert* standard." *Lewis v. CITGO Petroleum Corp.*, 561 F.3d 698, 704 (7th Cir. 2009) Accordingly, Plaintiffs have failed to meet their burden to establish that Dr. Hyman is qualified to testify as to the cause of Georgia's death and any such evidence to be proffered by Dr. Hyman is hereby excluded; Bard's Motion *in Limine* is GRANTED.

3. Dr. Kohr Testimony

Bard also seeks to exclude Dr. Kohr as an expert in this case. Bard argues that Plaintiffs' failure to disclose Dr. Kohr as an expert under Rule 26 of the Federal Rules of Civil Procedure ("Rule 26) requires exclusion of any expert testimony that he may offer. Bard also contends that Dr. Kohr did not submit an expert report and therefore cannot offer expert testimony

Rule 26 requires plaintiffs to disclose any person that it intends to use as an expert. Rule 26(a)(2)(A). Such witnesses must provide a written report that sets forth the facts and bases for their opinions. Rule 26(a)(2)(B). "The sanction for failure to comply with this rule is the 'automatic and mandatory' exclusion of the omitted evidence, 'unless non-disclosure was justified or harmless.'" *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 824 (7th Cir. 2010) (citing *Hammel v. Eau Galle Cheese Factory*, 407 F.3d 852, 869 (7th Cir. 2005)).

Plaintiffs concede that Dr. Kohr is not an expert in this case, and argue that he is only testifying as a fact witness with respect to his treatment of Georgia, i.e. the autopsy and exhumation of her body. Plaintiffs do not even attempt to argue that the non-disclosure was justified or harmless. Plaintiffs state that Dr. Kohr will testify that he possessed a lack of information relating to safety issues in the CK Patch and that, had he been provided such information prior to the autopsy, he would have rendered a different cause of death. But this fact alone – that Dr. Kohr will testify as to facts outside his treatment of Georgia – renders his testimony expert in nature. Plaintiffs' counsel paid Dr. Kohr a $4,000.00 retainer and provided him with records to review prior to his deposition testimony. Kohr Dep. at 73:22-79:8. Moreover, Plaintiffs' counsel sent Dr. Kohr medical records and literature about the CK Patch, met with him, and paid him to draft an affidavit approximately seven years after the initial autopsy. *Id*. at 67:13-69:1. Thus, it is clear that Plaintiffs seek to have Dr. Kohr testify outside of his actual treatment of Georgia; therefore, it would be deemed expert testimony and subject to the disclosure requirements of Rule 26. *See Meyers v. Nat'l R.R. Passenger Corp. (Amtrak)*, 619 F.3d 729, 734-35 (7th Cir. 2010) ("a treating physician who is offered to provide expert testimony as to the cause of the plaintiff's injury, but who did not make that determination in the course of providing treatment, should be deemed to be one 'retained or specially employed to provide expert testimony in the case,' and thus required to submit an expert report in accordance with Rule 26(a)(2)" (citing Rule 26(a)(2)(B)). Although Dr. Kohr may present treatment evidence concerning the autopsy and exhumation of Georgia's body, he may not testify as to any newly formed opinions that exceed that role, which includes evidence of causation not included in his Autopsy Report.

C. CAUSATION

Both the IPLA and IWDA require that a plaintiff prove causation to establish a claim.[6] *See infra*, pt. IV, A. In support of their claims, Plaintiffs have proffered the testimony of Drs. Ferzoco and Hyman, but, as stated more fully above, these experts do not withstand the standards set forth in *Daubert* and Rule 702.[7] Further, Dr. Kohr's proffered opinions on causation failed to satisfy the disclosure requirements of Rule 26. Because Plaintiff is unable to submit any admissible evidence with respect to causation, Bard's Motion for Summary Judgment is hereby **GRANTED**.

V. CONCLUSION

For the reasons stated herein, the Defendants', Davol, Inc. and C.R. Bard, Inc., Motions *in Limine* to exclude the testimony of Dr. Stephen Ferzoco (Dkt. 33) and Dr. William A. Hyman (Dkt. 39), as well as the Motion *in Limine* to limit the testimony of Dr. Roland Kohr (Dkt. 37), are **GRANTED**; in addition, Defendants', Davl, Inc. and C.R. Bard, Inc., Motion for Summary Judgment (Dkt. 30), is **GRANTED**. The Court will enter judgment accordingly.

IT IS SO ORDERED this 23d day of February, 2017.

LARRY J. McKINNEY, JUDGE
United States District Court
Southern District of Indiana

Distribution attached.

[6] Bard also seeks summary judgment on various other grounds, but, because the causation analysis is dispositive as to all claims, the Court declines to address the remaining arguments.

[7] Plaintiffs have also proffered the expert testimony of Suzanne Parisian, M.D., but admit that she offers no case-specific testimony with respect to Georgia's cause of death. *See* Dkt. 46 at 5.

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