UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

In Re: COOK MEDICAL, INC., IVC FILTERS MARKETING, SALES PRACTICES AND PRODUCT LIABILITY LITIGATION	)	1:14-ml-02570-RLY-TAB MDL No. 2570
This Document Relates to:	)	
Tonya Brand, 1:14-cv-06018-RLY-TAB	)	

ENTRY ON THE COOK DEFENDANTS' MOTION FOR JUDGMENT AS A MATTER OF LAW and MOTION FOR NEW TRIAL

Cook Incorporated, Cook Medical LLC (f/k/a Cook Medical Incorporated), and William Cook Europe APS (collectively "the Cook Defendants" or "Cook") develop, manufacture, sell, and distribute medical devices for use in medical applications throughout the United States and the world. The medical device at issue in this case is the Cook Celect® Inferior Vena Cava Filter. This type of medical device is used for the prevention of pulmonary embolism by trapping blood clots as they travel through the inferior vena cava (or "IVC") toward the heart and lungs.

Plaintiff Tonya Brand was implanted with a Celect IVC filter prior to a complex spine surgery at Northside Hospital in Atlanta, Georgia. A little over two years later, she realized it had fractured when one of the filter struts (or legs) emerged through her thigh.

She brought this products liability action on November 13, 2014 in the Northern District of Georgia. Her case was transferred here by the Judicial Panel on Multidistrict Litigation soon thereafter.

Plaintiff's bellwether case went to trial on January 14, 2019 on her claims for strict-liability design defect and negligent design. On February 1, 2019, the jury returned a verdict[1] for Plaintiff in the amount of $3 million.

The Cook Defendants now move for judgment as a matter of law and for a new trial under Federal Rules of Civil Procedure 50 and 59. The court, having read and reviewed the parties' submissions, the trial record, the parties' oral argument, and the applicable law, now **DENIES** the Cook Defendants' Motion for Judgment as a Matter of Law but **GRANTS** the Cook Defendants' Motion for New Trial.

I. Background

A. Cook's IVC Filters

The IVC is a large vein located next to the spinal cord that carries deoxygenated blood from the legs and lower torso to the heart. It is pliable and expands and contracts as one breathes, coughs, sneezes, bends, and moves. IVC filters, therefore, have a challenging job; the filter must attach to the walls of the IVC, which are only 1 millimeter thick, and the filter itself must expand and contract in unison with the IVC.

The predecessor to the Cook Celect IVC filter is a filter called the "Tulip." It was cleared in 2000 for permanent placement and in 2003 for retrievable use. The Tulip

[1] Plaintiff's claim for punitive damages was tried on February 5, 2019, with the jury returning a verdict against Plaintiff.

acquired its name from its appearance. It has four primary struts and four "leaves" or "petals" that hook around each strut. The struts and leaves emanate from a "cap" on the top, much like an umbrella without the cloth cover.

The Celect was cleared in the United States in 2007 as a permanent filter and in 2008 as a retrievable filter. Like the Tulip, it employs a conical shape and has four primary struts with "feet" or "anchors" on the end. In designing the Celect, the "petals" were removed and replaced with eight shorter secondary curved wires (or "shoulders") which flank both sides of each primary strut. This design change was meant to make the filter easier to retrieve because the removal of the leaves meant there was less surface area against the IVC wall around which tissue could grow (also known as endothelialization).

The Tulip and Celect have "feet" or "anchors" which are meant to hold the filter in place while blood circulates through it. The anchors are important; without them, the filter would migrate to the heart and lungs resulting in catastrophic injury. The leaves of the Tulip and the secondary legs of the Celect are meant to center the filter and to guard against tilt.

IVC filters may be prescribed by a physician if a patient presents with a history of deep vein thrombosis ("DVT") and anticoagulant therapy is contraindicated.

IVC filters, like all medical devices, have risks associated with their use. IVC filters may tilt, perforate the IVC, and fracture. Tilt refers to when the filter is at an angle to the direction of the IVC; perforation refers to when a filter strut punctures through the

wall of the IVC; and fracture is when the filter breaks apart. Once a filter fractures, it may also migrate, or move, to another part of the body.

B. Plaintiff's Experience with the Celect

Dr. Mark Rheudasil, a vascular surgeon, prescribed an IVC filter for Plaintiff as a prophylactic measure because she was facing a complex spine surgery and had a history of DVT. He chose the Celect IVC filter.

On March 19, 2009, Dr. Rheudasil implanted the Celect into Plaintiff's IVC, with the tip of the filter in line with her renal veins. Immediately after the filter was inserted, Plaintiff underwent a six-hour, two-level anterior lumbar interbody fusion ("ALIF") surgery performed by Dr. Thomas Morrison. In this type of spinal fusion surgery, Dr. Morrison reached Plaintiff's lumbar spine (L4-5, L5-S1) from the anterior (or through the abdominal region) of the body, not the back. The surgery thus required retraction of Plaintiff's blood vessels (including the iliac blood vessels) and intestines to gain exposure to her spine. During the exposure, her left common iliac vein, which feeds into her IVC, was damaged, requiring repair with at least 20 surgical clips.

Imaging taken on April 10, 2009 showed that the filter was perforating Plaintiff's IVC in multiple places. One of the filter's struts rested on a large osteophyte (i.e., a bone spur) located at L2-L3 and became hooked on it. The filter subsequently fractured in three places. One of the fragments emerged from Plaintiff's right thigh on June 17, 2011. Dr. Rheudasil attempted to retrieve the filter percutaneously on July 14, 2011 but was unsuccessful. Dr. Rheudasil and Plaintiff elected to leave the filter in place until October 11, 2015, at which time Dr. Rheudasil removed it through open surgery.

Two fractured struts remain in Plaintiff's body; one near her spine and one in her psoas muscle.

All other facts material to the disposition of Cook's motion for judgment as a matter of law and for new trial will be addressed *infra.*

II. Motion for Judgement as a Matter of Law

A. Standard of Review

Under Seventh Circuit law, a district court may enter judgment against a party who has been fully heard on an issue during a jury trial if "'a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue.'" *Passananti v. Cook Cnty.*, 689 F.3d 655, 659 (7th Cir. 2012) (quoting Fed. R. Civ. P. 50(a) (motion for judgment as a matter of law), (b) renewed motion for judgment as a matter of law)). In resolving a Rule 50(b)[2] motion, the court construes the evidence strictly in favor of the party who prevailed before the jury and examines the evidence to determine whether the jury's verdict could reasonably be based on the evidence. *Id.* "'Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge.'" *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000) (quoting *Anderson v. Libery Lobby*, 477 U.S. 242, 255 (1986)). "Thus, although the court should review the record as a whole, it must disregard all evidence favorable to the moving party that the jury [was] not required to believe." *Id.* at 150-51.

[2] The parties cite to Rule 50(a). Because the jury returned a verdict in this case, the court will treat this motion as one made under Rule 50(b).

B. Discussion

The parties agree that Georgia law applies to Plaintiff's design defect claims. Under Georgia law, there is no significant difference between negligence and strict liability for purposes of design-defect analysis. *Ogletree v. Navistar Int'l Transp. Corp.*, 500 S.E.2d 570, 575 (Ga. 1998). Therefore, the court will address both Plaintiff's strict liability and negligent design defect claims together.

To recover on a design defect claim, a plaintiff must establish that: (1) the product was defectively designed, (2) the defect existed at the time the product was sold, and (3) the defective design caused plaintiff's injuries. *Bryant v. BGHA, Inc.*, 9 F.Supp.3d 1374, 1383 (N.D. Ga. 2014); *Carmical v. Bell Helicopter Textron, Inc.*, 117 F.3d 490, 494 (11th Cir. 1997) ("To prevail in a Georgia products liability action, whether based on negligence or strict liability, a plaintiff must show that the proximate cause of the injury was a defect which existed when the product was sold."). The Cook Defendants argue Plaintiff failed to offer sufficient evidence for a jury to find in her favor on all three elements.

1. Causation

To satisfy the causation requirement under Georgia law, a plaintiff must establish both general and specific causation. *In re Mentor ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F.Supp.2d 1348, 1365 (M.D. Ga. 2010) (citing *Guinn v. AstraZeneca Pharms. LP*, 602 F.3d 1245, 1249 n.1 (11th Cir. 2010) (per curiam)). In other words, a plaintiff "must prove that [the medical device] can cause the type of injury suffered by

[her] (general causation) and that [the medical device] did in fact cause [her] injuries (specific causation)." *Id.*

Specific causation is the "actual cause" or the "but-for" cause of the event. Another way of thinking about specific causation is this: "The defendant's conduct is not the cause of the event if the event would have occurred without it." *Cowart v. Widener*, 697 S.E.2d 779, 787 (Ga. 2010); *Mann v. Taser Int'l, Inc.*, 588 F.3d 1291, 1304 (11th Cir. 2009).

Plaintiff presented three experts on specific causation at trial: (1) Dr. Robert McMeeking, a mechanical engineer and materials scientist; (2) Dr. Harlan Krumholz, a cardiologist and epidemiologist; and (3) Dr. Gregory Gordon, an interventional and diagnostic radiologist.

The court now turns to Cook's first argument; namely, whether Plaintiff established that "but-for" the Celect's design defect, she would not have been injured.

a. Design defect—lack of perforation limiters

Cook characterizes Plaintiff's theory of design defect as the Celect's lack of "perforation limiters," defined by Dr. McMeeking as "something that stops perforation." (Filing No. 10295-1, Trial Transcript ("Tr.") at 2152:16-19). The Tulip's petals act as perforation limiters, he explained, by "reduc[ing] the pressure that the strut applies against the wall of the vena cava, . . . [making] it less likely for the strut to cut through the wall of the vena cava." (*Id.* at 2152:17-22, 2165:20-25). According to Cook, the "but-for" requirement therefore required Plaintiff to prove that if Dr. Rheudasil had placed a Tulip or any other filter with a "perforation limiter" in the same place as the

Celect, that the filter would not have perforated and fractured. Because none of Plaintiff's experts testified that the Tulip or any other filter with a "perforation limiter" would not have perforated and fractured under the same circumstances that existed in her body at the time, Plaintiff failed to prove this essential element of her case.

Dr. McMeeking's opinion on the Tulip filter was part of his opinion on safer alternative designs. (*Id.* at 2090:21-24) (stating his opinions are "that the Tulip filter, or the addition of a perforation limiter to the Celect filter, are safer alternative designs")). The existence of a safer alternative design is one the factors that a jury may consider in determining whether a product has a *defective design*. *See Banks v. ICI Americas, Inc.*, 450 S.E.2d 671, 675 & n.6 (Ga. 1994). Evidence that a safer alternative design would have produced a different result, however, is not necessary to establish "but-for" causation. *See, e.g., In re C.R. Bard, Inc. Pelvic Repair Sys. Prods. Liab. Litig.*, 810 F.3d 913, 930 (4th Cir. 2016) (upholding jury's finding of proximate causation based on expert testimony that design defects in pelvic mesh resulted in the plaintiff's injuries without any mention of whether an alternative design would have had a different result). Accordingly, the court agrees with Plaintiff; she was not required to prove that a safer alternative design would not have perforated and fractured in her body.

b. Dr. McMeeking

Next, Cook argues Dr. McMeeking's testimony established only general causation, not specific causation. Specifically, Cook contends Dr. McMeeking failed to show that the perforation and fracture of Plaintiff's filter was caused by the design of the Celect and was not caused by Plaintiff's osteophytes or by the manipulation of her IVC

during her spinal fusion surgery, both of which were identified by Dr. Krumholz and Dr. Gordon as possible causes of the filter failure. (*See* Filing No. 10295, Cook's Mem. at 13 ("Indeed, unlike Dr. Krumholz and Dr. Gordon, Dr. McMeeking did not even claim to have performed a differential diagnosis, nor did he claim to have eliminated other possible causes of the perforation and fracture.")). But Dr. McMeeking was not asked to give a medical causation opinion; he is a technical expert and offered testimony on the design components of the Celect to a reasonable degree of engineering certainty.

At trial, Dr. McMeeking explained the Celect is like a spring that exerts pressure against the walls of the vena cava, and because the legs are so narrow and end in sharp barbs, they apply a great amount of pressure on a small surface area of the vena cava. (Tr. at 2094:20-2095:25). Based on mathematical calculations he performed, Dr. McMeeking concluded that perforation of a strut and rotation (tilt) of the filter "is probably going to happen." (*Id.* at 2097:21-2098:25). Because the walls of the vena cava expand and contract as we breath and move, perforation of the strut through the walls of the vena cava "progressively gets bigger," leading to filter fatigue and fracture. (*Id.* at 2103:1-25; *id*. at 2110:24-2111:8). He called this progression of events "the cascade effect." (*Id.* at 2183:14-16).

As for specific causation, Dr. McMeeking opined that "[Plaintiff's filter] would not have fractured had it not perforated." (*Id.* at 2323:21-22). Dr. McMeeking's opinion is consistent with Cook's own assessment in its Single Complaint Report regarding Plaintiff, which was authored by Cook consultant and interventional radiologist, Dr. Dennis Griffin. He noted "there are no reported cases of fracture that have occurred

without first demonstrating perforation in patients not undergoing retrieval." (PX 1483 at 12; Tr. at 2324:16-2325:11). He also wrote, "To the best of Cook Medical's belief reported leg fracture is secondary to filter perforation of IVC." (PX 1483 at 13; Tr. at 2323:17-2325:11).

To reach his opinions, Dr. McMeeking reviewed: (1) Cook design and testing documents for the Celect; (2) internal reports by Cook-employed engineers Dr. Brian Choules and Dr. James Carlson, who analyzed Celect fracture cases; (3) the depositions of Dr. Choules and Dr. Carlson; (4) the peer-reviewed literature; (5) Plaintiff's medical records; and, as stated previously, (6) he performed mathematical calculations, including finite element analysis, on the performance of the Celect. (*See* Tr. at 2143:9-2148:7; 2205:19-25, 2207:18-2208:12). Based on this evidence, a reasonable jury could conclude that but-for the Celect's propensity to perforate progressively, Plaintiff's injury would not have occurred.

c. Plaintiff's medical experts

Dr. Krumholz and Dr. Gordon used a differential diagnosis or ("etiology")[3] to establish specific causation. "Differential diagnosis is an accepted and valid methodology for an expert to render an opinion about the identity of a specific ailment." *Myers v. Ill. Cent. R. R. Co.*, 629 F.3d 639, 644 (7th Cir. 2010); *see also Higgins v. Koch Dev. Corp.*, 794 F.3d 697, 705 (7th Cir. 2015) (excluding expert's causation opinion for

[3] Differential diagnosis "refers to a method of *diagnosing* an ailment, not determining its cause." *Higgins*, 794 F.3d at 705. On the other hand, differential etiology "is a causation-determining methodology." *Id.* Because the experts use the term "differential diagnosis," the court will as well.

his failure to employ a differential diagnosis). In a differential diagnosis, "the doctor rules in all the potential causes of a patient's ailment and then by systematically ruling out causes that would not apply to the patient, the physician arrives at what is the likely cause of the ailment.'" *Schultz v. Azko Novel Paints, LLC,* 721 F.3d 426, 433 (7th Cir. 2013) (quoting *Myers*, 629 F.3d at 641).

Cook argues Dr. Krumholz and Dr. Gordon failed to "rule out" two alleged possible causes of the perforation and subsequent fracture of Plaintiff's Celect filter: (1) osteophytes and (2) manipulation of the vena cava during her back surgery. Before reaching this issue, the court must address Plaintiff's argument that she was not required to "rule out" her osteophyte or spinal fusion surgery.

i. Requirement to "rule out" other causes

Under Georgia law, manufacturers have a duty to exercise reasonable care to make products that are reasonably safe for their intended or foreseeable uses. *Chrysler Corp. v. Batten*, 450 S.E.2d 208, 211 (Ga. 1994). Because back patients in need of surgery commonly present with osteophytes,[4] Plaintiff argues her osteophyte and spinal fusion surgery were "intended or foreseeable risks which [Cook] had to design the Celect to withstand, not alternative causes [her] experts had to 'rule out.'" (Filing No. 10850, Pl.'s Resp. at 15; *see also* Tr. at 2217:2-4 & 8-16 [McMeeking] (testifying that common conditions need to be taken into consideration in the design process and that it is his

[4] Dr. Gordon testified: "Pretty much everybody who has back surgery who's had any type of trauma or degenerative disease is going to have some form of osteophyte." (Tr. at 1722: 12-14).

understanding that osteophytes are common in spinal patients who are implanted with IVC filters)).

Plaintiff cites no legal authority for the proposition that Cook had a duty to design the Celect to withstand any type of bodily malformation or intended use without perforation or fracturing.[5] The only authority she cites is from her retained expert, Dr. McMeeking. (Pl.'s Resp. at 17 ("Dr. McMeeking . . . specifically testified that under design engineering principles, Defendants had the duty to take into consideration in designing the Celect filter common conditions like osteophytes and surgery.")). Experts do not define legal duties; whether a party has a legal duty is a question of law to be answered by the court. *See Jiminez v. City of Chicago*, 732 F.3d 710, 721 (7th Cir. 2013) ("It is the role of the judge, not an expert witness, to instruct the jury on the applicable principles of law, and it is the role of the jury to apply those principles of law to the fact in evidence . . . accordingly, an expert may not offer legal opinions."); *see also Pawlik v. Indus. Eng'g & Equip. Co.*, No. 2:07-cv-220, 2009 WL 857476, at *10 (N.D. Ind. Mar. 27, 2009) ("Whether a duty exists is a matter of law, not a matter for [an] expert.").

Moreover, the legal question of whether a manufacturer had a duty to prevent or protect against a particular complication from a medical device is separate from the factual question posed in a differential diagnosis of whether the complication was a possible or probable cause of the injury. Here, both Dr. Krumholz and Dr. Gordon "ruled

[5] IVC filters are used not just for patients like Plaintiff. They are also used in trauma patients (including soldiers) and patients who, for a variety of reasons, cannot take anticoagulants due to the risk of bleeding to death. (Tr. at 752:4-5, 1478:21-1479:2; 2965:18-21, 3235:13-3236:10).

in" Plaintiff's osteophytes and spinal surgery as possible causes of Plaintiff's injuries. They were therefore required to "rule them out."

Next, Plaintiff argues Cook "invited use of the Celect filter by doctors in connection with spinal surgeries performed on patients with osteophytes." (Pl.'s Resp. at 18). Therefore, Cook "cannot defend against [Plaintiff's] products liability claim on the basis that she did not exclude the possibilities that her osteophyte or her exposure surgery caused her Celect's perforation and cascade effect or fracture." (*Id.*). As support of her position, she cites an Illinois products liability case entitled *Welge v. Planters Lifesavers Co.*, 17 F.3d 209, 210 (7th Cir. 1994).

In *Welge*, plaintiff was injured when he snapped the lid of a Planter's jar of peanuts back in place. *Id.* at 210. The defendants (Planters, K-Mart, and Brockway) offered evidence that plaintiff's landlord, after buying the jar of peanuts from K-Mart, used an Exacto knife to remove the jar's bar code in order to participate in a rebate program. *Id.* The defendants argued that the use of the knife could have weakened the jar causing its later fracture and that the plaintiff had not offered evidence ruling out that possibility. *Id.* The Seventh Circuit reversed the district court's grant of summary judgment, holding that even if using the knife to remove the label could be considered product misuse, a partial defense, K-Mart invited the misuse by making the rebate promotion available. *Id.* at 211. "Invited misuse is no defense to a products liability case." *Id.* at 211.

Welge has no application to the present case. The *Welge* court based its decision on K-Mart's invitation to the plaintiff to misuse the jar of peanuts. Here, Plaintiff never claimed that her doctors misused the Celect or that Cook invited any such misuse.

With that preliminary argument aside, the court now turns to the sufficiency of Dr. Gordon's medical causation opinions.

ii. Dr. Gordon's Opinions

Dr. Gordon "ruled in" Plaintiff's osteophyte as a possible cause of the filter failure "because that was one of the theories posed." (Tr. at 1993:9-11, 1994:13-14). Cook argues Dr. Gordon failed to provide a scientifically reliable basis to "rule it out," because he admitted on cross examination that "[he] never really thought about [osteophytes]" in arriving at his differential diagnosis. (*Id.* at 1994:15-17 ("basically, all the OUS[6] patients had osteophytes . . . [s]o I never really thought about it")).

Read in context, Dr. Gordon's testimony is not so limited. Dr. Gordon testified that he reviewed Plaintiff's pre-surgery imaging (spot fluoroscopy) and post-surgery imaging (foreign body image) which established that the filter was "1 to 1.5 centimeters" (.4 to .6 inches) above the level of her osteophyte. (*Id.* at 1721:14, 1722:9). A CT scan taken twenty days post-surgery showed two filter struts had perforated her vena cava, one of which had migrated caudally (in a downward direction) toward the osteophyte and was "starting to sit on that osteophyte or at least on the tissue adjacent to it." (*Id.* at 1724:24-1725:2; 1726:24-1727:1). The filter strut in contact with the osteophyte, in turn, created

[6] "OUS" stands for the Cook-sponsored "Outside the United States" clinical study on the Celect which commenced in 2005.

a "fulcrum effect" which led to fracture. (*Id.* at 2016:25-2017:1). He explained: "[T]he theory behind this is that we had one leg that wasn't able to move, whereas everything else was moving, so it really changed all the force points on it." (*Id.* at 2017:4-6). Dr. Gordon concluded that "[the filter] would never touch the osteophyte if it didn't perforate." (*Id.* at 1729:4-5). Cook's defense expert engineer, Dr. Scott Robertson, agreed. (*Id.* at 4043:11-14 [Robertson] ("Q: You agree with me that primary leg, that first primary leg that – that perforated, it had to get outside the IVC wall in order to contact the osteophyte? A: Yes."); *id.* at 1729:6-9 [McMeeking] ("[Dr. Robertson] said there would never be touching of the osteophyte if it didn't perforate")).

Cook maintains Dr. Gordon's testimony "addresses only perforation; it does nothing to rule out the osteophyte as the cause of Plaintiff's fracture and the resulting injuries." (Filing No. 11281, Cook's Reply at 19). But Dr. Gordon's point is this: had the filter strut not perforated and migrated in a downward direction toward Plaintiff's osteophyte, it would never have become "stuck" on it. In other words, the filter failed (i.e., perforated) before coming into contact with the osteophyte. Dr. Gordon's reason for "ruling out" the osteophyte is consistent with Plaintiff's theory of design defect—that the Celect filter has a tendency to perforate and tilt, which over time leads to fatigue of the perforated strut(s), which eventually leads to fracture.

Dr. Gordon also "ruled in" Plaintiff's spine surgery as a possible cause of the filter failure. (Tr. at 1992:19-1993:1). In arguing Dr. Gordon failed to reliably "rule it out," Cook again focuses on an answer he gave during cross examination. There, Cook confronted Dr. Gordon with the opinion of Dr. Paul Timperman, a Cook-employed

interventional radiologist, who could *not* rule out the surgery as the cause of the perforation. Dr. Gordon responded:

> Right. So I guess we're reading it and – the way I read it and the way I at least interpreted [Dr. Timperman's opinion] combined with his report was that he did not think it happened, but he couldn't rule it out, as opposed to me, where I think, to a reasonable degree of medical certainty, I think that there's -- it's very, very unlikely, especially given the 80 to 90 percent perforation rates that we saw in the OUS studies in patients with a tremendous amount of osteophytes.

(*Id.* at 2011:11-18).

If this answer was the entire basis for Dr. Gordon's decision to rule out Plaintiff's spine surgery, the court would agree with Cook. Read in the context of his entire examination, however, Dr. Gordon "ruled out" Plaintiff's surgery for three primary reasons. First, based on his review of Plaintiff's medical records and the pre- and post-surgery imaging (spot fluoroscopy and foreign body images), the surgical bed was 6 to 8 centimeters (roughly 2.5 to 3 inches) below the filter. (*Id.* at 1709:15-18; 1978:24-1979:9). Second, the spot fluoroscopy taken immediately before Plaintiff's back surgery showed the filter to be in the correct position with the "legs expanding in a normal way." (*Id.* at 1719:13-20). The foreign body image taken right after her back surgery, while of poor quality, showed the "hook" in the same place as it was before the surgery. (*Id.* at 1720:1-1721:3). He opined the imaging when viewed side-by-side showed the filter "wasn't traumatized, that it wasn't manipulated." (*Id.* at 1718:8-9, 1721:4-5). Third, he considered the length of time to gain exposure to the spine, which "implie[d] that there's a lot of adhesions, meaning that there's not a lot of movement" of the filter. (*Id.* at 1987:21-1988:3).

The court finds the totality of Dr. Gordon's testimony establishes that he reliably ruled out Plaintiff's osteophytes and surgery as actual causes of Plaintiff's filter failure. As such, Dr. Gordon's differential diagnosis was a legally sufficient evidentiary basis for the jury to find the element of causation. Having so found, the court need not address the sufficiency of Dr. Krumholz's differential diagnosis.

2. The "same condition" requirement

Next, Cook argues Plaintiff failed to present sufficient evidence to support a reasonable jury finding that her Celect was in the same condition at the time Dr. Rheudasil placed the filter in her IVC as it was when it left Cook's manufacturing facility. For example, Plaintiff offered no testimony from Dr. Rheudasil concerning the condition of the Celect at the time he placed it in Plaintiff—whether the filter kit was sealed and undamaged and whether the filter appeared intact and undamaged prior to placement. In addition, she provided no evidence of how Northside Hospital obtained the Celect filters supplied to Dr. Rheudasil or what quality control measures the hospital had in place to ensure the integrity of medical devices like IVC filters. This failure of proof, Cook argues, requires judgment in its favor.

As an initial matter, Plaintiff disagrees with Cook's interpretation of Georgia law, arguing Georgia law only requires the plaintiff to show that the defect existed at the time the product was sold by the manufacturer. She even goes so far as to suggest that Cook should be sanctioned for raising a frivolous argument.

Georgia's Products Liability Statute provides, in relevant part:

> The manufacturer of any personal property sold as new property directly or through a dealer or any other person shall be liable in tort . . . to any natural person who may use, consume or reasonably be affected by the property and who suffers injury to his person or property because the property when sold by the manufacturer was not merchantable and reasonably suited to the use intended, and its condition when sold is the proximate cause of the injury sustained.

Ga. Code Ann. § 51-1-11(b)(1). The Georgia Supreme Court interpreted the "phrase 'not merchantable and reasonably suited to the use intended' . . . to mean the plaintiff must show that the manufacturer's product when sold by the manufacturer was defective." *Center Chemical Co. v. Parzini*, 218 S.E.2d 580, 582 (Ga. 1975); *Carmical v. Bell Helicopter Textron, Inc.*, 117 F.3d 490, 494 (11th Cir. 1997) (requiring plaintiff to show that proximate cause of injury was defect which existed when product was sold); *see also* Ga. Products Liability Law § 2.10 (4th ed.) (same)).

As the court interprets Cook's position, the same condition requirement means that the condition of the product when sold—i.e., with the defect—is the very "condition" that caused the plaintiff's injuries. The "same condition" requirement is meant to guard against manufacturers being held liable for design or manufacturing defect when the condition of the product has changed post-manufacture, and the changed condition—as opposed to the product defect—caused the plaintiff's injury. *See, e.g., Chaffin v. Atlanta Coca-Cola Bottling Co.*, 194 S.E.2d 513, 516 (Ga. Ct. App. 1972) (approving a "same condition" jury instruction where there was a showing that numerous other individuals had access to the Coca Cola in question from the time it left the bottling plant until it reached plaintiff's hands"). Thus, the court finds same condition requirement is just

another way of saying that the defect which caused the injury must be present in the product at the time the product is sold, as Georgia law requires.

Turning back to Cook's argument regarding Plaintiff's failure to provide affirmative proof that the Celect was in the "same condition" when it left Cook's manufacturing facility as when it was placed in her, the court finds such evidence was not required. Instead, the condition of the product may be inferred from circumstantial evidence. *See Skil Corp. v. Lugsdin*, 309 S.E.2d 921, 924 (Ga. Ct. App. 1983) ("Circumstantial evidence may be used to establish the existence of a manufacturing defect at the time the product left the manufacturer"); *McCullough v. Beech Aircraft Corp*., 587 F.2d 754, 759 (5th Cir. 1979) ("To establish a products liability case, a plaintiff must at least present evidence from which a jury can infer that when the defendant's product left its control it contained some sort of defect[.]").

Here, a jury could infer from the evidence presented that the Celect was in the same condition when it was placed in Plaintiff as when it left Cook's manufacturing facility for three reasons. First, there was never an allegation, nor any evidence, that the filter was damaged or altered prior to placement. Had there been a problem with the Celect, Dr. Rheudasil surely would not have used it. To do so would have placed Plaintiff's life (and Dr. Rheudasil's medical license) at risk. Second, according to Cook representative Mark Breedlove, the Celect only has a 3% return rate because of problems with packaging or an overstocked inventory. (Tr. at 2968:5-9). Finally, as a practical matter, "[a] design defect necessarily results in all products having the same defect," *Rose v. Figgie Int'l, Inc*., 495 S.E.2d 77, 83 (Ga. Ct. App. 1998), because a defect in a

product's design is *inherent* in the product itself. Based on this evidence, there was a sufficient evidentiary basis for a reasonable jury to find that the alleged defect in the Celect existed at the time it left Cook's control.

3. Design Defect

The last issue raised by Cook is whether the Celect was defective in its design. Under Georgia law, a product design is defective if "the risks inherent in the product's design outweigh the utility or benefit derived from the product." *Wheat v. Sofamor, S.N.C.*, 46 F.Supp.2d 1351, 1361 (N.D. Ga. 1999) (citation and internal quotation marks omitted). "When a jury decides that the risk of harm outweighs the utility of a particular design, it is saying that in choosing the particular design, the manufacturer exposed the consumer to greater risk of danger than it should have." *Dean v. Toyota Indus. Equip. Mfg., Inc.*, 540 S.E.2d 233, 237 (Ga. Ct. App. 2000). Factors relevant to the risk-utility analysis include, but are not limited to:

> the usefulness of the product; the gravity and severity of the danger posed by the design; the likelihood of that danger; the avoidability of the danger . . .; the user's ability to avoid danger; the state of the art at the time the product is manufactured; the ability to eliminate danger without impairing the usefulness of the product or making it too expensive[.]

Banks, 450 S.E.2d at 675 & n.6. Proof of compliance with industry-wide practices or federal regulations is also relevant. *Id.* The most important factor, however, "is whether the design chosen was a reasonable one from among the feasible choices of which the manufacturer was aware or should have been aware"; this factor is the "heart" of design defect cases. *Id.* at 674 (citation omitted).

In general, weighing the risk-utility factors is a matter for the jury. *Id.* at 674-75. Judgment as a matter of law "will rarely be granted in design defect cases when any of [the risk-utility] elements is disputed." *Ogletree v. Navistar Int'l Transp. Corp.*, 522 S.E.2d 467, 470 (Ga. 1999). To overturn a jury verdict, the defendant must "show plainly and indisputably an absence of any evidence that a product as designed is defective." *Id.*

Plaintiff offered evidence that the lack of a perforation limiter on the Celect made it more likely to perforate and tilt, leading to an increased incidence of fracture. (Tr. at 2106:24-2107:5). These adverse events can lead to serious health issues and in extreme cases, even death. Dr. Evan Fogel, a gastroenterologist, testified that "perforations can be potentially serious" and that "[a] patient can potentially die from a symptomatic perforation." (*Id.* at 3529:24-3530:3). Fracture of an IVC filter may pose serious risks, including embolization to other organs and potentially death. (*Id.* at 740:3-10 and 772:14-24 [Krumholz]; 1641:24-1642:15 [Gordon]).

In addition, Plaintiff provided evidence that safer alternative designs which were a marketable reality and technologically feasible existed at the time the Celect was manufactured; as noted previously, such designs included Cook's own Tulip filter and the addition of leg extenders to the Celect. Dr. McMeeking could not quantify precisely how much adding leg extenders to the Celect would decrease the rate of perforation; however, he assessed, based on his mathematical calculations, that "it would reduce it [the rate of perforation] substantially." (*Id.* at 2299:13-2300:3). Dr. McMeeking further testified that although the Tulip and the Celect had "pretty equal propensity to perforate," once

perforation starts, the legs of the Celect perforate farther outside the walls of the vena cava than the legs of the Tulip.[7] (*Id.* at 2280:21-24, 2262:3-7, 2327:25-2328:7). This is because "the [Tulip's] loops and the petal[s] spread the area of contact out and reduce the pressure which the filter is transmitting to the wall of the vena cava. And that makes it harder for the leg to continue to perforate through the wall of the vena cava." (*Id.* at 2166:4-8). The difference in the extent of perforation is important because the further a leg extends outside the wall of the vena cava, the more likely it is to fracture. (*Id.* at 2287:2-2288:9; 2328:5-7).

Plaintiff also submitted evidence that the Celect does perforate and fracture more often than the Tulip. (*See id*. at 372:14-16 [Krumholz]; 2366:25-2368:13 [Iversen]). Moreover, as compared to other filters, Dr. Krumholz testified there was no evidence that the Celect actually saves lives by reducing the likelihood of pulmonary embolism. (*Id.* at 689:1-690:1). He described the Celect as a "higher-risk filter" and testified that "in clinical studies and in clinical reports and in a wide variety of testing, [the Celect] is a device that has a higher risk of safety issues." (*Id.* at 771:18-21).

Thus, Plaintiff offered evidence that safer, alternative designs existed when Cook manufactured the Celect at issue here; that the Celect's design posed a serious risk of

[7] Cook's Director of Research, Arne Molgaard-Nielsen, understood the Tulip's "petals" acted as perforation limiters. (*Id.* at 390:8-25; PX 1569; *see also id.* at 395:8-9; PX 1524). During the development of the Celect, he was concerned that if the "petals" were taken off and replaced by "shoulders," there could be issues with perforation of the filter struts. (*Id.* at 390:8-25; PX 1569; *see also id.* at 395:8-9; PX 1524). According to Molgaard-Nielsen, "[t]he Tulip leaves are in a shape to avoid too-far penetration/perforation of the hook legs. If we make these straight, we must find another way to prove safety." (*Id.* at 395:8-10; PX 1524).

danger to the patient; and that this danger could have been prevented or minimized without impairing the usefulness of the filter or making it significantly more expensive to purchase. *Banks*, 450 S.E. 2d at 675. Based on this evidence, a reasonable jury could have found that the Celect as designed is defective.

C. Conclusion

Plaintiff has presented sufficient evidence for a reasonable jury to find in her favor on her strict liability and negligence design defect claims. Accordingly, Cook's Motion for Judgment as a Matter of Law is **DENIED**.

III. Motion for New Trial

A. Standard of Review

A court may grant a new trial under Rule 59 where "'the verdict is against the weight of the evidence, the damages are excessive [or insufficient], or if for other reasons the trial was not fair to the moving party.'" *Shick v. Illinois Dep't of Human Servs.*, 307 F.3d 605, 611 (7th Cir. 2002) (quoting *Briggs v. Marshall*, 93 F.3d 355, 360 (7th Cir. 1996)). A new trial may be granted based on an error in the admission of evidence "if the improperly admitted evidence had 'a substantial influence on the jury,' and the result reached was 'inconsistent with substantial justice.'" *Id.* (quoting *Agushi v. Duerr*, 196 F.3d 754, 759 (7th Cir. 1997)). "'[E]videntiary errors satisfy this standard only if a significant chance exists that they affected the outcome of the trial.'" *Id.* (quoting *Hasham v. Cal. State Bd. of Equalization*, 200 F.3d 1035, 1048 (7th Cir. 2000)).

B. Discussion

Cook argues it is entitled to a new trial for multiple reasons. Briefly, it argues:

(1) the court erred in admitting Plaintiff's trial exhibit 1913 ("PX-1913"); (2) the court erred in admitting the opinions of Dr. Gordon; (3) the court erred in admitting the opinions of Dr. Krumholz; (4) the court erred in admitting evidence concerning Plaintiff's fear of future damages and in permitting the jury to award damages based on future fear; and (5) Plaintiff's counsel engaged in misconduct by asking questions related to failure-to-warn, which was not at issue, and by injecting references to other lawsuits in violation of Cook's motion in limine. The court begins and ends with its analysis of PX-1913.

PX-1913 consists of an email chain involving Cook employees Dr. James Gardner, Dr. Jennifer Brown, John Kaufman, and Sara Sherman. Attached to the email is a document entitled "Complaint summary: Deaths associated with Cook IVC filters arising from complaints received between October 1, 2008 and June 10, 2016." In the last email located at the top of the page, Dr. Gardner described the document as follows:

> Attached is a table that provides some additional detail on the 27 deaths weive [sic] become aware of between October 2008 and June 2016. Complaint data is sometimes sparse, but this information does provide some insights into what happened.

As noted in the email, the attached complaint summary is in table form, with columns including: (1) the patient identification number; (2) the type of Cook IVC filter implanted—BNF (Bird's Nest[8] filter), Tulip, Celect, and Celect PT (Celect Platinum)—(3) the trend code; (4) the cause of death; and (5) the description of the event.

[8] The Bird's Nest and Tulip filters were predecessors of the Celect; the Celect Platinum is the successor to the Celect.

Prior to its admission during the testimony of Dr. Krumholz, a bench conference was held during which Cook objected to the document on three grounds: (1) there was no foundation that patient deaths were substantially similar to Plaintiff's experience with the Celect filter; (2) the document was "riddled with hearsay within hearsay"; and (3) the document was unfairly prejudicial to Cook under Federal Rule of Evidence 403. (Tr. at 494:12-495:9). The court ultimately admitted the exhibit, finding "it's prejudicial" but "[i]t's probative on the issue of risk utility" and that Cook's objections "go[] to [its] weight and not [its] admissibility." (*Id.* at 496:18-20, 502:25-503:8).

Although PX-1913 was redacted to exclude complaints related to the Bird's Nest, Tulip, and Celect Platinum filters before the exhibits were given to the jury at the conclusion of the trial, it was shown to the jury during the trial unredacted (except for the reference to "MDL").

1. Substantial Similarity

"Evidence of other accidents in products liability cases is relevant to show notice to the defendant of the danger, to show existence of the danger, and to show the cause of the accident." *Nachtsheim v. Beech Aircraft Corp.*, 847 F.2d 1261, 1268 (7th Cir. 1988). To ensure probative value and to prevent unfair prejudice from dissimilar accidents, a party seeking to offer evidence of other accidents involving a product must establish foundation and relevance by demonstrating that the other accidents are substantially similar to the accident at issue. *See, e.g.*, *id.* at 1268 (for evidence of other accidents to be admissible, "the proponent must show that the other accidents occurred under substantially similar circumstances"). As explained by the *Nachtsheim* Court:

> The foundational requirement that the proponent of similar accidents evidence must establish substantial similarity before the evidence will be admitted is especially important in cases such as this where the evidence is proffered to show the existence of a dangerous condition or causation. The rationale for this rule is simple. In such cases, the jury is invited to infer from the presence of other accidents (1) that a dangerous condition existed (2) which caused the accident. As the circumstances and conditions of the other accidents become less similar to the accident under consideration, the probative force of such evidence decreases. At the same time, the danger that the evidence will be unfairly prejudicial remains. The jury might infer from evidence of the prior accident alone that ultra-hazardous conditions existed ... and were the cause of the later accident without those issues ever having been proved.

Id. at 1268-69 (internal citations and quotation marks omitted).

Plaintiff argues she need not show that the circumstances of the complaints described in PX-1913 were substantially similar to her own experiences with the Celect because she "merely used it to show the gravity and severity of the Celect perforations." (Pl.'s Resp. at 8). Based on a review of the trial transcript, the court finds she did use PX-1913 to show notice of a problem with the Celect:

> [Dr. Krumholz:] My takeaway from this [PX-1913] was that there are many deaths here that are *highly suspicious, bell ringing*. . . . It demands more information about what happened and whether it's – this is *continuing bell ringing about safety.*

(Tr. at 504:2-504:8) (emphasis added). Likewise, Plaintiff did use PX-1913 to suggest causation:

> [Plaintiff's closing argument:] We know [death is] a serious problem because Dr. Gardner, in an email, had 18 different deaths, some of which, there's no doubt, were caused by the Celect filter. This is Plaintiff's Exhibit 1913. There were retroperitoneal bleeds resulting in open surgery to clip the filter legs, causing death. And you'll have this – this back in the jury room, but I'll read a description of one of them that shows that *there's no doubt that this filter was causing deaths*.

(*Id.* at 4287:2-11) (emphasis added).

"In any case," Plaintiff argues, she "spent the majority of the time in regard to PX-1913 questioning witnesses about the two deaths caused by perforations, substantially similar to the perforation that injured [her]." (Pl.'s Resp. at 8). These patients are noted on the exhibit as patient 65484 and patient 104779. Patient 65484 died from a retroperitoneal hemorrhage allegedly caused by perforation of one of the filter struts. (PX-1913 at 4) ("An autopsy was performed and the pathologist found IVC perforation from one of the filter struts as the cause of the retroperitoneal hemorrhage."). Patient 104779 died "due to perforation of cava." (*Id.*).

Plaintiff's experience with the Celect filter is not substantially similar to the experience of patients 65484 or 104779. She was implanted with a Celect prior to a complicated five-hour spinal fusion surgery. Although the Celect perforated her IVC, she did not suffer a retroperitoneal hemorrhage or a hemorrhage of any kind, and she did not die. Instead, the Celect fractured and the struts migrated to her thigh, psoas muscle, and to an area near her spine. The court therefore erred in admitting PX-1913.

2. Hearsay

Cook personnel drafted the complaint summary set forth in PX-1913 based on information from third parties. (*See, e.g.*, Tr. at 497:18-498:5, 498:25-499:4). PX-1913 does not identify who provided the information (*e.g.*, doctor, hospital, relative, or other third party) or whether the person submitting the information had firsthand knowledge of the events reported. It is also silent as to when the complaint was made relative to the events reported.

Cook argues PX-1913 is classic hearsay—*i.e.*, it contains out-of-court statements that Plaintiff offered for their truth. Plaintiff disagrees; she argues the complaints set forth in the summary were not offered for their truth because "the cause of death could not be determined for some, the Celect did not cause the death in others and the Celect did cause some deaths." (Pl.'s Resp. at 8). Instead, she continues, the summary was offered to show "that Celect perforation posed a severe danger—death." (*Id.*). To the extent this was Plaintiff's purpose in offering the exhibit, that purpose would not avoid a hearsay problem. PX-1913 could only show that Celect perforation "posed a severe danger—death" if the statements in the exhibit associating Celect filters with the risk of death were true.

Plaintiff also invokes Rule 801(d)(2)(D) to argue that the statements in PX-1913 are not hearsay because they were statements made by Cook employees in the course and scope of their employment. A "statement" under Rule 801 "means a person's . . . written assertion . . . if the person intended it as an assertion." Fed. R. Evid. 801(a). To be an assertion, an utterance must "be offered with the intent to state that some factual proposition is true." *State v. Land*, 34 S.W.3d 516, 526 (Tenn. Crim. App. 2000); *see also State v. Leonard*, 818 N.E.2d 229, 255 (Ohio 2004) ("An 'assertion' for hearsay purposes 'simply means to say that something is so'"). Here, Cook was not "asserting" that the information in PX-1913 was true; indeed, it is undisputed that the employees were merely recording information provided by third parties. (Tr. at 497:14-498:3). As such, the contents of PX-1913 were not "statements" of a "party's agent or employee," and thus fall outside the scope of Rule 801(d)(2)(D).

Next, Plaintiff argues the exhibit's statements were statements against Cook's interest and therefore fall within the exception to hearsay under Rule 804(b)(3)(A). (Pl.'s Resp. at 9 (explaining "[t]hey were against Cook's interest because they have so great a tendency to expose Cook to civil liability.")). Again, the statements in the document were not statements made by Cook.

Lastly, Plaintiff argues that the exhibit's statements are not hearsay under Rule 801(d)(2)(B) because they were statements that Cook "manifested that it adopted or believe to be true." (Pl.'s Resp. at 9). As stated previously, Cook gathered this information from others—hospitals, doctors, and other sources—and the information was often incomplete. (*See* Tr. at 497:14-501:11 [Dr. Krumholz]: "there's no question you would want more information"). There is nothing in the record to suggest Cook was adopting the information as true.

The court finds PX-1913 contained hearsay and that none of the exceptions to the hearsay rule apply. This is yet another ground on which the court erred.

3. Rule 403

Lastly, Cook invokes Rule 403 to argue the prejudicial effect of PX-1913 substantially outweighed its probative effect. Plaintiff disagrees; she argues the jury was not misled by the admission of the exhibit and, in any event, "PX-1913 constituted a mere side note about gravity and severity for at most 10 to 20 minutes out of a three-week trial." (Pl.'s Resp. at 10).

The patient deaths set forth in PX-1913 are not substantially similar to Plaintiff's experience with the filter and the document is replete with hearsay; therefore, the

probative value of the complaint summary is minimal. In contrast, the prejudicial effect of its admission and related testimony was substantial. For example, although the exhibit noted that the cause of death for some of the patients was unknown or unrelated to the filter, Dr. Krumholz testified that the complaint summary set off "bell ringing about safety" because virtually all of the deaths were "highly suspicious." (Tr. at 504:2-9). He continued:

> So, for example, you know, we only get information the patient died due to perforation of the cava – the inferior vena cava. But it could be that that was contributory. It could be that that was dominant. It's hard to know, just to be fair. But these *are all seemingly catastrophic*, and they all are lacking the kind of information that you would want in order to really understand – really understand what had gone on.
>
> ***
>
> So, again, my point was none of this is reassuring. It continues the drumbeat of concern from the outset.

(*Id.* at 506:9-16, 506:23-24) (emphasis added).

During cross-examination of Mr. Breedlove, Plaintiff's counsel questioned him at length about PX-1913 even though he had no contemporaneous first-hand knowledge[9] of the document. Counsel suggested that Cook determined the listed causes of death when the complaint summary said no such thing:

> Q: And what they do is they have some columns. They have a trend code, right? So y'all give that a number, and you give a description, correct?

[9] Plaintiff's counsel raised the issue of patient deaths with Dr. William Voorhees, Vice President of Cook subsidiary MED Institute. (Tr. at 2737:10-2738:2; 2739:14-23; 2742:2-27-2745:18). He also attempted to ask questions specifically related to PX-1913 even though he was not on the email chain and had never seen the document before. (*Id.* at 2740:13-20). Cook's objection based on lack of foundation was sustained. (*Id.* at 2740:21-2741:11).

A: Correct.

Q: And then you have what *you* determine to be the cause of death. See that column?

A: Yeah. *I don't know if it's us or who – who determines that.*

Q: Well –

A: I see the column, yes.

Q: Complaint summary. Deaths associated with Cook IVC filters. We're talking about the Celect here. See that?

A: Yes.

(*Id*. at 3010:3-15). Counsel then proceeded to read passages from the exhibit, and ask Mr. Breedlove to confirm that he (counsel) had read the passage correctly:

Q: So let's just go through these real quick and just make sure we've got these on the record. Celect, 16845. Migration was the code, the trend code. Okay? So the filter migrated. And it says, "Cause of death, migration to the heart." See that?

A: I'm trying to find the page you're on.

***

Q: Next, Celect. Implant. Code, migration. Cause of death, migration to the heart. See that?

A: I do see that.

Q: Next, Celect. Wire broken. Fracture. Migration to the lung. See that?

A: I do see that.

Q: Another one. Wire broken. Well, that one says suicide. So that's different. Next one, dissection, perforation of the vessel. Bleeding is the cause of death, right? You tracking with me here?

A: I am, yes. Unfortunately, there's no additional information.

(*Id.* at 3013:16-17; 3015:1). This line of questioning continued despite Cook's objection that it was cumulative and prejudicial. (*Id.* at 3016:13-21).

Lastly, in closing argument, Plaintiff's counsel referred to death and dying a multitude of times and referred to patient deaths associated with the Celect in both their initial closing and rebuttal arguments. (*Id.* at 4287:1-15 ("And you'll have [PX-1913] – this back in the jury room, but I'll read a description of one of them that shows that there's no doubt that this filter was causing deaths"); *id.* at 4371:16-19 ("Please look at Plaintiff's Exhibit 1913. So here's the thing – here's the thing. Before this product ever made it to the market, it had two deaths confirmed by Harvard that it had killed people.")). In sum, Counsel's reliance on PX-1913 linking patient death with the Celect was inappropriate and prejudicial.

C. Conclusion

An error in the admission of evidence does not necessarily require a new trial. As noted previously, a new trial is warranted "only if the error has a substantial and injurious or influence on determining the jury verdict." *Bintz v. Bertrand*, 403 F.3d 859, 869 (7th Cir. 2005). This "is a tough hurdle to cross [but] it is not impossible." *Cerabio LLC v. Wright Medical Tech., Inc.*, 410 F.3d 981, 994 (7th Cir. 2005).

In this case, the court finds the erroneous admission of PX-1913 successfully crossed the hurdle from harmless error to prejudicial error. The court does not come to this conclusion lightly. It has thoroughly reviewed the 4,000-page trial transcript and the parties' memorandums of law. The lack of substantial similarity between the patients'

experiences with the Celect described in PX-1913 and the perforation and fracture in Plaintiff's case undercut the jury's ability to infer, based on the events described in PX-1913, that the Celect was either dangerous or that its design caused Plaintiff's injuries. Complicating matters, the information in PX-1913's complaint summary came from unknown parties, raising a concern about the accuracy of the information, and the summaries provided little detail about the circumstances surrounding the patients' cause of death. Even Dr. Krumholz agreed that PX-1913 contained "a very light amount of information about these patients [and] [he] would definitely want more." (Tr. at 500:12-14).

Plaintiff's repeated efforts to connect the Celect to inadmissible patient deaths had a substantial effect on the jury's verdict. Plaintiff did not have overwhelming evidence to show the filter was defective or that a defect in the filter caused her injuries. Although there was enough to withstand a sufficiency challenge, a jury could have just as easily found in Cook's favor. A trial this close is more likely to have been affected by errors. Accordingly, Cook's Motion for New Trial (Filing No. 10292) is **GRANTED**.

SO ORDERED this 6th day of January 2020.

RICHARD L. YOUNG, JUDGE
United States District Court
Southern District of Indiana

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