No. 128841

In the Illinois Supreme Court

CHARLES MUHAMMAD and ANGIE MUHAMMAD, as parents of C.M., a minor, and C.M., individually, *Plaintiffs-Appellees,* v. ABBOTT LABORATORIES INC. and ABBVIE INC., *Defendants-Appellants.*	Rule 315 Petition for Leave to Appeal from the Appellate Court of Illinois, First Judicial District, No. 1-21-0478 There Heard on Appeal from the Circuit Court of Cook County, Illinois, County Department, Law Division, No. 19-L-6254 The Honorable Brendan A. O'Brien, Judge Presiding

BRIEF OF *AMICUS CURIAE* THE ILLINOIS CHAMBER OF COMMERCE IN SUPPORT OF DEFENDANTS-APPELLANTS

Joshua G. Vincent
Paris B. Glazer
HINSHAW & CULBERTSON LLP
151 North Franklin Street, Suite 2500
Chicago, IL 60606
Tel. 312-704-3000
jvincent@hinshawlaw.com
pglazer@hinshawlaw.com

Counsel for Amicus Curiae
The Illinois Chamber of Commerce

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INTEREST OF THE AMICUS CURIAE

The Illinois Chamber of Commerce (the "Chamber") is an association that focuses on improving Illinois' business climate. Since 1919, the Chamber has been the unifying voice for Illinois industry, advocating for an environment that allows Illinois businesses to thrive and its Citizens to have abundant job opportunities to provide for their families. The Chamber's membership is diverse and broad, with over 1,800 members. It includes pharmaceutical and medical device companies, manufacturers, wholesalers, retailers, healthcare providers, insurers, and construction companies.

The Chamber's members, the Illinois business community as a whole, and the millions of Citizens they employ, rely on this Court to bring clarity, certainty and reason to the constellation of regulations and laws they must navigate daily with precision – and almost *zero* margin for error – in order to avoid costly lawsuits and onerous legal liability.

Given the Chamber's long history of business advocacy and its status as a unifying voice for the Illinois business community, it can assist the Court in exploring and appreciating the impact of the Court's rulings on Illinois businesses. This unique perspective has been recognized multiple times by the Court in other cases, when the Court has permitted the Chamber to serve as *amicus curiae* in matters that will affect Illinois businesses. *See, e.g., Illinois Road & Transportation Builders Ass'n v. County of Cook*, 2022 IL 127126, ¶ 8; *Rosenbach*

v. Six Flags Ent. Corp., 2019 IL 123186, ¶ 16; *Hertz Corp. v. City of Chicago*, 2017 IL 119945, ¶ 10; *Carney v. Union Pac. R. Co.*, 2016 IL 118984, ¶ 15.

Although this appeal involves a rather discrete issue that concerns the application of the learned intermediary doctrine, the appellate court's decision will have troubling consequences for Illinois product liability law if it is not reversed. As detailed in this brief, the appellate court replaced the longstanding proximate cause analysis for failure-to-warn liability of pharmaceutical companies with a novel standard that turns on the supposed negligence of physicians and other professionals those pharmaceutical companies neither employ, supervise or control. In doing so, the decision improperly expands and dramatically alters the scope of longstanding product liability jurisprudence in Illinois, not only for Illinois' vibrant pharmaceutical industry, but for many other industries, as well.

Under the appellate court's reimagined liability rubric, it will be all but impossible, as a practical matter, for manufacturer-defendants to extricate themselves from costly litigation over failure-to-warn claims that lack the evidentiary support necessary to overcome summary judgment. Given the litigation costs and risks associated with jury trials, this is of paramount concern to Illinois' manufacturing industry.

Thus, the Chamber and its members have a substantial and direct interest in this case because the novel basis for strict liability the appellate court has thrust upon pharmaceutical companies can be easily extended to those who

make and sell construction materials and equipment, automotive equipment, industrial machinery, and other products used by professionals throughout Illinois. They all face significantly expanded litigation and liability risk under this newly-minted tort regime.

INTRODUCTION

The appellate court based its proximate cause analysis on the opinions of a controlled expert witness the plaintiffs hired who claimed that the decision making of the plaintiffs' (actual) treating physicians was "contrary to the standard of care." *Muhammad v. Abbott Lab'ys, Inc.*, 2022 IL App (1st) 210478, ¶¶ 18, 45. That is a professional negligence analysis. But this is not a medical malpractice claim against plaintiffs' treating physicians. This is a failure-to-warn product liability suit against prescription drug manufacturers.

The question before the appellate court was not whether plaintiffs' treating physicians were negligent, that is, whether they deviated from the standard of care, as determined by what a hypothetical "reasonable" physician should have done. Instead, the question was whether or not an allegedly inadequate prescription drug warning proximately caused plaintiffs' injuries, as required to impose strict product liability on a manufacturer.

If Illinois' proximate cause now depends on a third-party's negligence (the physicians' purported deviation from the standard of care), then a defendant-manufacturer is now, *de facto*, liable for that third-party's negligence.

That is because the strict product liability doctrine does not require a showing that the manufacturer was independently negligent – or negligent at all.

This newly-minted standard is akin to vicarious liability (*respondeat superior*), because it imputes liability to one party based on the negligence of another. But vicarious liability is limited to select relationships, such as employer-employee, principal-agent, and master-servant. There is no evidence in the record that any such relationship existed between the defendants and plaintiffs' treating physicians.

If the appellate court's decision is not reversed, this distortion of Illinois law will not be limited in its effect to litigation against drug and medical device manufacturers. The proximate cause standard at issue can be extended well beyond that context. The appellate court's reformulation of the law threatens manufacturers of all manner of equipment and materials used by professionals, including engineers, architects, fabricators and mechanics, whether they injure themselves or a third party.

Under this new rule, any manufacturer of equipment or materials used by professionals now faces the risk of what is essentially vicarious liability for the negligent acts of thousands of professionals they neither employ, supervise nor control, who may cause injury to themselves or another, even where the professional was not *actually* influenced by the manufacturer's warnings or lack thereof. Under the appellate court's rationale, liability could be imposed simply because a paid expert says a theoretical "reasonable" professional should have

acted differently, assuming the equipment's warnings were different in some respect. That standard is inapposite in the product liability context, where causation depends upon how an actual real-life individual's conduct was affected or influenced by the manufacturer's warning – *if at all* – and not the warning's effect on some hypothetical "reasonable" being. The appellate court's decision not only alters longstanding principles of product liability law by shifting the analysis away from the conduct of the actual professional to a hypothetical one; it also effectively transforms that professional into the manufacturer's agent for purposes of imposing liability in those instances where a third party has been injured.

Applying a professional malpractice standard in a product liability case also has enormous implications for claims involving ordinary consumers and end users, not just professionals. The plaintiff-consumer in a failure-to-warn case could always defeat the manufacturer's summary judgment motion merely by hiring an expert to say another plaintiff would have acted more reasonably than the actual plaintiff if a different warning had been given. *Muhammad v. Abbot* stands the law of product liability on its head – to the extreme detriment of Illinois' manufacturing industry.

The *amicus curiae* respectfully request that this Court correct this error. The proximate cause requirement for product liability must be judiciously safeguarded and enforced. It is the crucial link that connects a manufacturer's warning label to the plaintiff's injury, since strict product liability relieves the

plaintiff of the burden to show that the manufacturer was at fault. Without a rigorous proximate cause standard and analysis, non-meritorious claims will be able to proceed where there is the mere *coincidence* of an allegedly inadequate warning and an injury, rather than an unbroken chain of causation between the two. The *Muhammad v. Abbott* decision has gutted that critical proximate cause requirement.

Indeed, the record below is bereft of facts capable of showing that the defendants' allegedly inadequate drug warning proximately caused plaintiffs' injuries, as required for a failure-to-warn claim. Yet, the appellate court reversed the circuit court's entry of summary judgment. In doing so, it incorrectly grafted a medical malpractice liability standard onto the body of Illinois product liability law.

The correct proximate cause analysis for a failure-to-warn claim is a case-specific inquiry into whether there is a causal connection between the manufacturer's warning, the physician's decision-making process (or, in non-medical contexts, the product user's), and the plaintiffs' injury. That causal connection turns on whether and how the manufacturer's warning actually influenced the user's conduct to produce the complained-of injury. Indeed, a warning – text on a piece of paper or packaging – cannot, itself, directly cause physical injury to a human being any more than this brief. Rather, a person must act or fail to act based on that warning language. There is always a human element in the chain of causation. The correct proximate cause analysis grounds

product liability in the *actual* facts and actions of the individuals personally involved in the events that took place, not what a hypothetical actor might or should have done.

In the drug and medical device context, the proper analysis considers whether the treating physician would have changed her patient's course of care if she had been warned differently by the drug or device manufacturer. If the physician would have done nothing differently, the chain of causation is severed between the product's warning and the plaintiff's injuries. The latter simply had no impact on the course of care that ultimately led to the injury.

In contrast to examining what the treating physician "would have" done differently, the medical malpractice standard applied by the appellate court erroneously focused on what a hypothetical reasonable physician "should have" done; that is, whether the actual treating physician's deviation from the professional standard of care proximately caused the plaintiffs' injuries.

The difference between "would have" and "should have" is not mere verbiage. For example, a person who has been warned that smoking causes cancer ***should*** quit. That is what a "reasonable" smoker should do. But would that person quit? Maybe. But maybe not. There are still millions of smokers. Expert testimony as to what a "reasonable" smoker should have done would not resolve whether a warning about the hazards of smoking cigarettes was proper and effective.

The purpose of this brief is not to rehash the parties' arguments on the learned intermediary doctrine. Rather, the Chamber seeks to provide broader context on why the appellate court's decision must be reversed to prevent an unjustified, inapposite liability regime from being thrust onto not only pharmaceutical companies, but manufacturers of other types of equipment and materials used by professionals and even by ordinary consumers. Accordingly, the Chamber respectfully requests that this Court reverse the decision of the appellate court and affirm the circuit court's entry of summary judgment in favor of the defendants, Abbott Laboratories Inc. and AbbVie Inc.

ARGUMENT

I. LONGSTANDING FAILURE-TO-WARN PRODUCT LIABILITY LAW

It is well understood that the mere fact that a product's warning fails to sufficiently warn of a risk of injury is not, by itself, sufficient to impose liability on the manufacturer. See *Kirk v. Michael Reese Hospital & Medical Cente*r, 117 Ill. 2d 507, 525 (1987). Rather, the product's inadequate warning must proximately cause the plaintiff injury. *Id*.

Because words themselves cannot directly cause physical injury, there is necessarily a human element to the chain of causation. That human element can be the learned-intermediary physician in the drug and device context, the plaintiff's coworker or employer in an industrial setting, or the plaintiff herself in other contexts. A person must act, or fail to act, in response to the product's

warning before any alleged deficiency in the warning can be connected to an injury.

That human element can also sever the chain of causation, entitling the manufacturer to judgment in its favor, notwithstanding an allegedly deficient warning. This is true not only for claims involving medical or professional services, but for claims involving ordinary consumers, as a line of cases from the First District itself explains.

For example, in *Kane v. R.D. Werner Co., Inc.*, 275 Ill. App. 3d 1035 (1st Dist. 1995), the plaintiff fell from a ladder. He subsequently brought suit against the manufacturer claiming that the warnings on the ladder were inadequate. *Id.* at 1035-36. However, the plaintiff never read the warnings that were affixed to the ladder. *Id.* at 1035-36. The *Kane* court held that a plaintiff who does not read an allegedly inadequate warning cannot maintain a failure-to-warn action unless the nature of the alleged inadequacy is such that it prevents him from reading it (an exception not at issue here). *Id.* at 1037. Summary judgment was affirmed for the defendant. *Id.* at 1037.

Similarly, in *Murray v. Chicago Youth Center*, 352 Ill. App. 3d 95 (1st Dist. 2004)[1], an eighth-grade student sustained injuries resulting in quadriplegia

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[1] Reversed on other grounds, 224 Ill. 2d 213 (2007). Specifically, this Court reversed summary judgment for the distributor's codefendant, which had been granted based on the Local Governmental and Governmental Employees Tort Immunity Act (745 ILCS 10/3-109). *Id.* at 216-17. But the appellate court's affirmance of summary judgment for the trampoline's distributor, based on a

while using a mini-trampoline. The student's claims included failure-to-warn liability against the trampoline's distributor based on inadequate warnings affixed to the trampoline. *Id*. at 95. But it was admitted in pleadings that the student did not read the warnings. *Id*. at 95. Accordingly, the appellate court affirmed summary judgment for the distributor. *Id*. at 95.

Broussard v. Houdaille Industries, Inc., 183 Ill. App. 3d 739 (1st Dist. 1989) concerned an allegedly deficient warning for specialized industrial machinery. The appellate court found no evidence in the record that either the plaintiff or his coworker "would have acted any differently if they had had the manual" for the machinery on which the plaintiff was injured. *Id*. at 744. Thus, the appellate court reversed the jury's verdict and ordered that judgment be entered as a matter of law for the machinery manufacturer. *Id*. at 746.

These cases employed the proper standard for determining liability in a failure-to-warn case based on the plaintiff's actual conduct, and implicitly recognized that the mere *coincidence* of an inadequate warning and an injury cannot support liability. Rather, the allegedly inadequate warning must actually *cause* the injury. See *Kirk*, 117 Ill. 2d at 525. Thus, the proximate cause analysis considers whether the inadequate warning (*e.g.*, omitted or incorrect information) actually affected the course of human conduct which led to the

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lack of proximate cause, was not challenged on appeal or reversed. See *id*. at 218.

injury. *Kane*, 275 Ill. App. 3d 1037; *Teran v. Coloplast Corp.*, No. 19 C 6351, 2022 WL 4604198, 2022 U.S. Dist. LEXIS 178838, at *19-20 (N.D. Ill. Sep. 30, 2022) (entering summary judgment for the manufacturer because the medical device's warning was neither read nor relied on by the plaintiff's physician) (collecting cases), copy attached as **A1**; *Vaughn v. Ethicon, Inc.*, No. 20-cv-562-JPG, 2020 U.S. Dist. LEXIS 180240, at *10-11 (S.D. Ill. Sep. 30, 2020) (same), copy attached as **A2**.

Stated another way, the plaintiff must be able to prove "that the presence of adequate warnings ***would have*** prevented the plaintiff's injuries." *Broussard*, 183 Ill. App. 3d at 744 (emphasis added). The "would have" inquiry focuses on the actual individual who acted or failed to act in regard to the product's warning – a subjective standard. *Id*.

Under the appellate court's standard adopted in this case, the plaintiffs in *Kane*, *Murray* and *Broussard* could have defeated the defendants' summary judgment motions merely by hiring an expert to testify that another person would have heeded a better warning and avoided injury. As a practical matter, summary judgment would no longer be available in a failure-to-warn case – ever – and every case would have to go to trial.

II. LONGSTANDING MEDICAL & PROFESSIONAL NEGLIGENCE LIABILITY LAW

While the proximate cause analysis for product failure-to-warn claims focuses on what the physician or professional actually involved ***would*** have done differently if warned differently (a subjective standard), the medical

malpractice analysis focus on what a hypothetical doctor ***should*** have done differently (an objective standard).

To answer the "should have done" question, the physician or professional's own decision-making process and actions are compared to that of a hypothetical "ordinarily careful professional." See *Jones v. Chicago HMO Ltd. of Illinois*, 191 Ill. 2d 278, 295 (2000) (quoting *Advincula v. United Blood Services*, 176 Ill. 2d 1, 23 (1996)). This objective standard of care is used in both medical and non-medical professional liability cases. *Jones*, 191 Ill. 2d at 296 (citing *Advincula*, 176 Ill. 2d at 23-24).

Generally speaking, expert testimony is used to establish what an ordinarily careful professional should have done in a particular situation "because jurors are not skilled in the practice of medicine and would find it difficult without the help of medical evidence to determine any lack of necessary scientific skill on the part of the physician." *Johnson v. Armstrong*, 2022 IL 127942, ¶ 52 (quoting *Walski v. Tiesenga*, 72 Ill. 2d 249, 256 (1978)); *Thompson v. Gordon*, 241 Ill. 2d 428, 444-45 (2011).

Once the standard of care is established, expert testimony also is generally required to establish that the defendant deviated from the standard of care (*i.e.*, breached their duty to the plaintiff). *Jones*, 191 Ill. 2d at 295; *Johnson*, 2022 IL 127942, ¶ 53. Finally, the plaintiff must prove that he was injured and that the injury was proximately caused by the defendant's breach of duty. *Johnson*, 2022 IL 127942, ¶ 53.

Thus, the proximate cause analysis for medical and other professional liability cases incorporates the standard of care, such that the two are intertwined, because proximate cause considers whether a breach of the standard of care was the cause of the plaintiff's injury. See *Buck v. Charletta*, 2013 IL App (1st) 122144, ¶ 59 ("It is the plaintiff's burden to present expert testimony that shows both that: (1) the defendant "deviated from the standard of care" and (2) "that *that deviation* was the proximate cause of the plaintiff's injury.") (quoting *Snelson v. Kamm*, 204 Ill. 2d 1, 46 (2003)) (emphasis in original).

Finally, in the event that the negligence of a physician or other professional has proximately caused injury to the plaintiff, other parties, such as hospitals, medical groups and employers, may be vicariously liable for that negligence based on agency principles. *Wilson v. Edward Hospital*, 2012 IL 112898, ¶ 18. Such vicarious liability requires a showing that "(1) a principal/agent, master/servant, or employer/employee relationship existed; (2) the principal controlled or had the right to control the conduct of the alleged employee or agent; and (3) the alleged conduct of the agent or employee fell within the scope of the agency or employment." *Id*. Importantly, though, the plaintiff need not establish the principal or employer was at fault based on its own independent negligent act. *See Sperl v. Henry*, 2018 IL 123132, ¶¶ 26-27.

In that regard, vicarious liability bears a striking resemblance to strict product liability, in that they both impose liability without a showing of independent negligence on the part of the principal or manufacturer. See *Frazer*

v. A.F. Munsterman, Inc., 123 Ill. 2d 245, 255-59 (1988); *Jinwoong, Inc. v. Jinwoong, Inc.*, 310 F.3d 962, 965 (7th Cir. 2002) (*respondeat superior* and strict product liability are "legal principle[s] that impose[] liability regardless of fault."); *Gaston v. Ghosh*, 920 F.3d 493, 497 (7th Cir. 2019) ("From the employer-defendant's point of view, vicarious liability is strict liability, since he is liable without personal fault.").

III. THE APPELLATE COURT'S DECISION IN *MUHAMMAD V. ABBOTT*

In the instant case, Ms. Muhammad's treating physicians "testified that they would not have acted differently if they had been informed that Depakote posed a greater risk of birth defects"[2] beyond the 1% to 2% risk of spina bifida listed in the drug's warning. *Muhammad v. Abbott Lab'ys, Inc.*, 2022 IL App (1st) 210478, ¶ 46. Absent contrary facts to show that an enhanced warning of the total 10% to 17% risk of birth defects would have caused these particular physicians to have changed the treatment they prescribed for Ms. Muhammad, the proximate cause analysis should have ended there. The circuit court's entry of summary judgment for the defendants should have been affirmed.

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[2] Curiously, the appellate court's decision does not explain how defendants' failure to warn of this 10% to 17% risk of unspecified "birth defects" is at all relevant or casually related to the injuries of C.M., the plaintiffs' child. The decision states only that "C.M. was born neural tube defect spina bifida", ***which Depakote already warned of***. *Muhammad*, 2022 IL App (1st) 210478, ¶¶ 1, 45. The appellate court addressed no other birth defects that C.M. suffered so as to justify liability based on the failure to disclose their risk.

Yet, the appellate court did not end there. Although its decision cites ***no*** fact witness testimony or other medical (or even non-medical) evidence to contradict or impeach the veracity of the sworn testimony of Ms. Muhammad's own treating physicians that they would have done nothing differently if warned differently, the appellate court relied on opinions of a controlled expert witness hired by plaintiffs' counsel.

Plaintiffs' expert opined that, "if Abbott's labeling and warnings had disclosed a 10% to 17% risk of birth defects, a reasonably careful psychiatrist adhering to the standard of care would not have prescribed Depakote" for Ms. Muhammad. *Muhammad*, 2022 IL App (1st) 210478, ¶¶ 15, 45. Thus, in that expert's opinion, the testimony from Ms. Muhammad's actual treating physicians that "they would have prescribed Depakote for [her] regardless of the level of risk is contrary to the standard of care". *Id.* ¶ 18.

However, the appellate court overlooked that the testimony of plaintiffs' expert about what a physician ***should*** have done could not competently contradict the testimony of the treating physicians about their *own* decision-making process – that they ***would*** have done nothing different had a different warning been given by the defendants.

The appellate court then concluded, based solely on the expert's opinion, that there was "conflicting" evidence as to whether or not the conduct of Ms. Muhammad's treating physicians "conform[ed] to the standard of care." *Id.* ¶ 46. Based on its analysis of whether there was a deviation from that standard of

care, the appellate court determined that there was a question of fact precluding summary judgment on whether the Depakote warning proximately caused C.M.'s spina bifida. *Id*. ¶ 46. Respectfully, that was incorrect.

IV. THE APPELLATE COURT'S DECISION MUST BE REVERSED

As a general matter, it is quite common for courts to consider expert testimony on medical care, when called for. Jurors, lawyers, and judges are not trained healthcare practitioners. If this were a medical malpractice case, it would be entirely proper for the appellate court to consider testimony from a qualified expert on whether Ms. Muhammad's treating physicians deviated from the standard of care in a manner that proximately caused injury. See *Johnson*, 2022 IL 127942, ¶ 52. In other words, opinion testimony on what the treating physicians "should have" done.

But this is not a medical malpractice claim. It is a product liability action. Indeed, the issue of whether Ms. Muhammad's treating physicians deviated from the standard of care and proximately caused C.M.'s spina bifida by prescribing Depakote has been adjudicated by a jury in a separate action. *Muhammad*, 2022 IL App (1st) 210478, ¶ 1. That jury already considered what the treating physicians "should have" done. Plaintiffs obtained a judgment of $18.5 million in that medical malpractice action. *Id*., ¶ 1.

The plaintiffs should not be permitted to recover a second time for those same treating physicians' medical malpractice, by imposing liability on the defendant manufacturers, especially in a case where it is wholly irrelevant

whether those physicians objectively breached the standard of care – as distinct from their actual and subjective decision-making process. Indeed, the appellate court acknowledged in *Muhammad* that a physician's breach of the standard of care (medical malpractice) is different than a drug manufacturer's liability. *Muhammad*, 2022 IL App (1st) 210478, ¶ 33 ("This court has recognized that a prescribing physician's malpractice does not necessarily relieve a drug manufacturer from liability for failure to provide adequate warnings of a drug's risks.") (citing *Mahr v. G.D. Searle & Co.*, 72 Ill. App. 3d 540, 566 (1st Dist. 1979)).

Yet, the appellate court based its proximate cause analysis on whether Ms. Muhammad's treating physicians were negligent (deviated from the standard of care), not whether they actually would have acted differently if a different warning had been given. If the question of whether a business proximately caused a plaintiff's injuries is determined by whether the negligence of a third party proximately caused those same injuries, the analysis is eerily similar to vicarious liability.

When it is imposed, vicarious liability is premised on specific public policy considerations in specific kinds of cases. See *Bennett v. Chicago C. R. Co.*, 243 Ill. 420, 429 (1909). It is "founded on the expediency of placing the risk upon those who can ***best guard against it***." *Id*. (emphasis added). Generally speaking, a stranger is not in a position to best guard against the actions of another. Thus, to hold a defendant vicariously liable for the actions of another person, requires, *inter alia*, that (1) the there be a principal-agent, employer-employee or master-

servant relationship between the defendant and that at-fault individual; and (2) the defendant control or have the right to control that individual, such as an employer's control over the manner of its employee's work. See *Bogenberger v. Pi Kappa Alpha Corp.*, 2018 IL 120951, ¶¶ 28, 33. Where there is no such relationship or control, vicarious liability cannot be imposed. *Id*. That is, the liability for one person's wrongs cannot be imposed onto another.

But defendants were not the employers, principals or masters of Ms. Muhammad's treating physicians. Defendants did not train them, supervise them, or control them. That is critical. Control – whether the defendant controlled or had the right to control the individual who caused the injury – is a "significant factor" in the vicarious liability analysis. *Reed v. Bascon*, 124 Ill. 2d 386, 396-97 (1988). There is no evidence in the record that drug and device manufacturers, such as the defendants in this case, control Ms. Muhammad's doctors or any of the thousands of physicians who prescribe and use their products throughout the world on a daily basis. To the extent those physicians may deviate from the standard of care, and thereby cause injuries, their patients can seek relief under medical malpractice principles – just as plaintiffs did here. But those legal doctrines cannot be stretched to also impose liability in product liability cases brought against manufacturers, in the absence of the required principal-agent relationship and control.

Accordingly, there are simply no facts that could justify the imposition of vicarious liability on Abbott and AbbVie for the treating physicians'

purported deviation from the standard of care. See *id*. ("Dr. Bascon [a general practitioner] was not even present when the surgery was performed. Thus, it is clear from the record that Dr. Bascon did not have control over or the right to control the surgery or the selection of the surgical procedure…. We conclude therefore that the trial court was correct in holding that Dr. Bascon could not be vicariously liable for any negligence on the part of [the surgeon] on the basis of the doctrine of *respondeat superior* or agency."). To hold otherwise is contrary to a century of Illinois agency law. *See, e.g.*, *Jefferson v. Chapman*, 127 Ill. 438, 444 (1889) ("The general rule is[] that the principle of *respondeat superior* does not extend to cases … where the party … is not the immediate superior of those guilty of the wrongful act, and has no choice in the selection of workmen, and no control over the manner of doing the work …").

Moreover, defendants did not participate in the examination, diagnosis or treatment of Ms. Muhammad. They were not in the "best position" to guard against her physicians negligently prescribing Depakote. *Bennett*, 243 Ill. at 429. Instead, as this Court has explained in adopting the learned intermediary doctrine, "it is the physician who is in the best position to decide when to use and how and when to inform his patient regarding risks and benefits pertaining to drug therapy." *Kirk*, 117 Ill. 2d at 523. Thus, the appellate court's imposition of vicarious-style liability on the drug manufacturers based on the negligence of Ms. Muhammad's prescribing physicians is wholly incompatible with the foundations of the learned intermediary doctrine.

Additionally, vicarious liability based on the negligence of physicians is a form of upstream indemnity. See *Sperl*, 2018 IL 123132, ¶ 26. But this Court has repeatedly recognized that product liability law was never intended to make the manufacturer an "absolute insurer" (indemnitor) of its product. *Dixon v. Chicago & North Western Transportation Co.*, 151 Ill. 2d 108, 124-25 (1992). Thus, the appellate court's decision is out-of-step with longstanding precedent in that respect as well.

The proper proximate cause analysis for failure to warn asks whether the product's warning proximately cause a person to act or fail to act in a manner that injured the plaintiff. In other words, ***would*** Ms. Muhammad's treating physicians have declined to prescribe Depakote if they had been provided an enhanced warning on birth defect risk.

Muhammad jettisoned this "would have" analysis for a "should have" analysis borrowed from medical malpractice jurisprudence that rests on entirely different principles of law and policy. The former considers what the individuals personally involved actually did, or did not do, or would have done. Conversely, what they should have done is a judgment call for paid experts to make. The difference between "would have" and "should have" is not gossamer. There is a large gulf.

For example, if your friend warns that traffic is heavy, ***should*** you leave early for the Bulls game? Of course. Any reasonable fan should. But ***would*** you? Maybe. But maybe not. Perhaps, you think that you can take a different route,

or are not worried about missing the tip off. It is the last quarter of the game that counts anyway.

Or, what if your spouse warned you that it would rain today? Should you have grabbed an umbrella on the way out the door? A "reasonable" commuter should. But would *you* have done so? Perhaps. But perhaps you do not mind a little sprinkle or thought you could get home before the storm hit. Expert testimony as to what you should have done cannot answer the question of what you would have done. Only you know that answer.

The appellate court has cast aside a proximate case analysis centered on the actual events and individuals, and replaced it with a novel (in this area) and hypothetical inquiry based on the opinions of paid experts. The *amicus curiae* respectfully request that this Court redirect the analysis back to the facts on which *Kirk* and its progeny focus.

The proximate cause analysis at issue here transcends this case and affects industries other than pharmaceutical products and medical devices. Throughout failure-to-warn product liability law, the question in Illinois has been, and must remain: Would the actual product user have acted differently if warned differently? Not "should" they, or some hypothetical user, have acted differently. Of course, any plaintiff can hire an "expert" to say they *should* have. If the appellate court's decision is not reversed, the jury's inquiry into the causal consequences of the manufacturer's warning will be supplanted by an analysis of the negligence of others – not the defendant manufacturers themselves.

Finally, the appellate court's reformulation of the proximate cause standard will, as practical matter, divorce it from the summary judgment analysis. It is difficult, if not impossible, to conceive of a realistic scenario in which an expert could not be paid to opine that a so-called reasonable physician "should have" done something differently, when a patient was injured during a course of treatment. Indeed, various courts have recognized that summary judgment is rare – to put it mildly – when the analysis depends on whether a professional deviated from the standard of care (*i.e.*, what they should have done). See, *e.g.*, *Demoney v. Kaufman*, 2019 MT 195N, ¶ 9 ("Because expert testimony is required to establish negligence in medical malpractice cases, summary judgment is rarely proper. In this case, each party presented expert testimony regarding the standard of care … the District Court properly found that genuine issues of material fact precluded summary judgment…"); *Yarborough v. Springhill Memorial Hospital*, 545 So. 2d 32, 34 (Ala. 1989); *Smith v. Dermatology Associates of Fort Wayne, P.C.*, 977 N.E.2d 1, 5 (Ind. Ct. App. 2012).

Without a *bona fide* proximate cause requirement focused on the actual decision-making process and course of action, plaintiffs will be able to bypass the important gatekeeping stage of summary judgment, just so long as there is some metaphysical inadequacy in a product's warning. But, again, an inadequate warning, by itself, is not enough to impose liability on a manufacturer if a different warning would not have changed how the product

was used; and, accordingly, it should be insufficient to withstand summary judgment.

If *Muhammad* is allowed to set a new proximate cause standard, manufacturers will be wise to avoid the Illinois market. That would be a loss for the economy, for workers, and for consumers.

CONCLUSION

The Chamber respectfully requests that this Court reverse the appellate court's decision and affirm summary judgment in favor of the defendants, Abbott Laboratories Inc. and AbbVie Inc.

Date: March 8, 2023

Respectfully submitted,

By: /s/ *Paris B. Glazer*

HINSHAW & CULBERTSON, LLP
151 North Franklin Street
Suite 2500
Chicago, IL 60606
312-704-3000
Paris B. Glazer
ARDC No. 6309089
pglazer@hinshawlaw.com

Counsel for Amicus Curiae
The Illinois Chamber of Commerce

By: /s/ *Joshua G. Vincent*

HINSHAW & CULBERTSON, LLP
151 North Franklin Street
Suite 2500
Chicago, IL 60606
312-704-3000
Joshua G. Vincent
ARDC No. 6186197
jvincent@hinshawlaw.com

Counsel for Amicus Curiae
The Illinois Chamber of Commerce

CERTIFICATION OF COMPLIANCE

I certify that this brief conforms to the requirements of Rules 341(a) and (b). The length of the brief, excluding the pages containing the Rule 341(d) cover, the Rule 341(h)(1) statement of points and authorities, the Rule 341(c) certificate of compliance, the certificate of service, and those matters to be appended to the brief under Rule 342(a) is 23 pages.

/s/ Paris B. Glazer

CERTIFICATE OF SERVICE

I, Paris Glazer, one of the attorneys for *amicus curiae*, The Illinois Chamber of Commerce, certify that I electronically filed the foregoing Brief of *Amicus Curiae* The Illinois Chamber of Commerce in Support of Defendants-Appellants with the Clerk of the Illinois Supreme Court on the 8th day of March, 2023, via Odyssey eFile IL.

The undersigned further certifies that on the 8th day of March, 2023, an electronic copy of the foregoing Brief of Amicus Curiae is being served via Odyssey eFile IL.

In addition, I have served counsel of record by sending a copy thereof by email on the 8th day of March, 2023, before 5:00 p.m., at the following email address:

Milo W. Lundblad
Brustin & Lundblad, Ltd.
10 N. Dearborn Street
Suite 350
Chicago, IL 60602
mlundblad@mablawltd.com

Dan H. Ball
Stefani L. Wittenauer
Bryan Cave Leighton Paisner LLP
211 N. Broadway
Suite 3600
St. Louis, MO 63102
dhball@bclplaw.com
stefani.wittenauer@bclplaw.com

Lauren J. Caisman
Bryan Cave Leighton Paisner LLP
161 North Clark Street
Suite 4300
Chicago, Illinois 60601
Lauren.caisman@bclplaw.com

Under penalties as provided by law pursuant to § 1-109 of the Code of Civil Procedure (735 ILCS 5/1-109), the undersigned certifies that the statements set forth in this instrument are true and correct.

/s/ Paris B. Glazer

Appendix

Teran v. Coloplast Corp.

United States District Court for the Northern District of Illinois, Eastern Division

September 30, 2022, Decided; September 30, 2022, Filed

No. 19 C 6351

Reporter
2022 U.S. Dist. LEXIS 178838 *; __ F.Supp.3d __; 2022 WL 4604198

Nidia Teran, Plaintiff, v. Coloplast Corp. Defendant.

Counsel: [*1] For Nidia Teran, Plaintiff: Thomas G. Siracusa, LEAD ATTORNEY, Powers, Rogers & Smith, Chicago, IL.

For Coloplast Corp., Defendant: Jade R. Lambert, LEAD ATTORNEY, Abigail Hoverman Terry, King & Spalding LLP, Chicago, IL; Lana K Varney, LEAD ATTORNEY, King & Spalding LLP, Austin, TX; Andrew Jacob Chinsky, Gregory Arthur Ruehlmann, Jr., King & Spalding LLP, Atlanta, GA; Donald F. Zimmer, Jr., PRO HAC VICE, King & Spalding LLP, San Francisco, CA; Oliver Peter Thoma, King & Spalding LLP, PRO HAC VICE, Austin, TX; Zachary Thomas Fardon, King & Spalding, Chicago, IL.

Judges: Elaine E. Bucklo, United States District Judge.

Opinion by: Elaine E. Bucklo

Opinion

Memorandum Opinion and Order

After the birth of her third child, plaintiff Nidia Teran sought medical treatment for pelvic pain, recurrent urinary tract infections, and incontinence. Her primary care doctor referred her to urologist Alan Sadah, who diagnosed her with Grade IV cystocele with cervical/uterine prolapse—the most severe stage of pelvic organ prolapse ("POP") characterized by herniations of the bladder and uterus. In March of 2014, Dr. Sadah performed a pelvic floor reconstructive surgery called a sacrohysteropexy using a polypropylene "Restorelle Y" surgical **[*2]** mesh implant—a product manufactured by defendant Coloplast—to repair her condition. But plaintiff's pelvic pain only worsened, and in June of 2015, she underwent a second surgery to remove her uterus and to explant the Restorelle Y mesh. During that procedure, a cystotomy occurred, i.e., a surgical instrument sliced a hole in plaintiff's bladder, necessitating further surgical repairs and ultimately bladder reconstruction. Since then, plaintiff has undergone numerous additional surgeries and procedures to repair recurrent vesicovaginal fistulas and remove bladder stones, and she continues to suffer from chronic pelvic pain, urinary tract infections, urinary frequency, urgency, incontinence, bladder spasms and a need for catheterization.

On March 31, 2016, plaintiff filed this lawsuit in the multi-district litigation ("MDL") pending in the U.S. District Court for the Southern District of West Virginia, identifying eighteen counts for

injuries she claims were caused by defendant's Restorelle Y surgical mesh and defendant's failure to warn her adequately of the risks associated with implantation of that product. After the case was transferred here following discovery, defendant moved for **[*3]** summary judgment of all of plaintiff's claims. In conjunction with that motion, defendant filed motions to exclude testimony proffered by plaintiff's experts, Drs. Ostergard, Chughtai, and Mays. Plaintiff's opposition to summary judgment is likewise accompanied by *Daubert* motions seeking to exclude the testimony of defendant's experts, Drs. Culligan, Cole, Molavi, and Becker.

For the reasons explained below, I grant defendant's summary judgment motion in part, and resolve the remaining motions as follows.

I.

Summary judgment is appropriate "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)*. My role at this juncture is not to "weigh the evidence and determine the truth of the matter" but rather to determine if "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, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986)*. Accordingly, I credit plaintiff's admissible evidence and draw all reasonable inferences in her favor. *Id. at 255*.

Expert testimony is admissible under *Rule 702 of the Federal Rules of Evidence* and *Daubert v. Merrill Dow Pharmaceuticals, 509 U.S. 579, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993)*, if the expert is qualified and the testimony is reliable and relevant. In my role as gatekeeper, I must determine whether: (1) the witness **[*4]** is qualified in the relevant field; (2) the expert's methodology is scientifically reliable; and (3) the expert's testimony will assist the trier of fact in understanding the evidence or determining a fact in issue. *Gopalratnam v. Hewlett-Packard Co., 877 F.3d 771, 779 (7th Cir. 2017)*. Importantly, "the key to the gate is not the ultimate correctness of the expert's conclusions. Instead, it is the soundness and care with which the expert arrived at her opinion[.]" *Schultz v. Akzo Nobel Paints, LLC, 721 F.3d 426, 431 (7th Cir. 2013)*. Accordingly, my analysis does not "take the place of the jury to decide ultimate issues of credibility and accuracy." *Lapsley v. Xtek, Inc., 689 F.3d 802, 805 (7th Cir. 2012)*. And because "the admissibility determination is not intended to supplant the adversarial process...even 'shaky' testimony may be admissible." *Ortiz v. City of Chicago, 656 F.3d 523, 536 (7th Cir. 2011)*. *See also Walker v. Ethicon, Inc., No. 12-CV-1801, 2017 U.S. Dist. LEXIS 112738, 2017 WL 2992301, at *2 (N.D. Ill. June 22, 2017)* (if expert testimony is reliable and relevant, "the accuracy of the actual evidence is to be tested before the jury with the familiar tools of vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.").

II.

Although plaintiff's complaint asserts eighteen counts for claims sounding in products liability, fraud, breach of warranty, consumer protection, and various other theories of liability, she tacitly concedes by her silence in response to several of defendant's arguments **[*5]** that she lacks evidence sufficient to take certain of her claims to trial. Accordingly, I grant defendant's motion as unopposed insofar as it seeks judgment on: plaintiff's claims under consumer protection laws (Count XIII); her warranty-based claims (Counts XI and XII); her unjust enrichment claim (Count

XV); her gross negligence claim (Count XIV), her loss of consortium claim (Count XVI), and her claim captioned "Discovery Rule and Tolling" (Count XVIII).[1] What remains in dispute is whether the admissible evidence entitles plaintiff to a jury trial on her claims of negligence (Count I), strict liability-manufacturing defect (Count II), strict liability — failure to warn (Count III), strict liability — defective product (Count IV), strict liability — design defect (Count V), common law fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), negligent misrepresentation (Count IX), negligent infliction of emotional distress (Count X), and punitive damages (Count XVII).

A. Expert Testimony - Causation

Defendant's broadest summary judgment argument is that plaintiff lacks admissible evidence that her injuries were proximately caused by her mesh implant. Under **[*6]** Illinois law, "proximate cause can only be established when there is a reasonable certainty that the defendant's acts caused the injury," *Wintz By & Through Wintz v. Northrop Corp., 110 F.3d 508, 515 (7th Cir. 1997)* (quoting *Schultz v. Hennessy Industries, 222 Ill. App. 3d 532, 584 N.E.2d 235, 241, 165 Ill. Dec. 56 (Ill. App. Ct. 1991)*), and products liability cases require expert testimony to establish causation, *Wheeler v. C.R. Bard, Inc., No. 19-CV-08273, 2022 U.S. Dist. LEXIS 61118, 2022 WL 971394, at *4 (N.D. Ill. Mar. 31, 2022)* (citation omitted).

Defendants contend that neither Dr. Ostergard nor Dr. Chughtai can testify competently that defendant's product proximately caused her injuries. Because I agree that plaintiff cannot survive summary judgment without these witnesses' causation testimony, I begin by determining whether the testimony they seek to provide satisfies the *Daubert* standard.

Donald R. Ostergard

Plaintiff has designated Dr. Ostergard to offer opinions related to injury causation and the allegedly defective design and manufacture of Restorelle Y mesh. Dr. Ostergard is a retired urogynecologist who has published hundreds of peer-reviewed articles on the topic of urogynecology and has performed thousands of pelvic organ prolapse surgeries using polypropylene mesh and other materials. He has held several academic positions in the fields of obstetrics, gynecology, and women's health, and he has been qualified to provide testimony in a number of cases in this MDL. See, e.g., *Waltman v. Bos. Sci. Corp., No. 2:12-CV-691, 2016 U.S. Dist. LEXIS 74593, 2016 WL 3198322, at *13 (S.D.W. Va. June 8, 2016)* **[*7]** ; *Tyree v. Boston Scientific, 54 F. Supp. 3d 501, 549-53 (S.D. W. Va. 2014.)*. Nevertheless, defendant contends that Dr. Ostergard is unqualified to offer the opinions set forth in his expert report because he has never performed any surgery involving the Restorelle Y mesh, has never performed a robotic-assisted sacrohysteropexy with a surgical mesh implant, and has not treated patients or performed any surgery in the past decade. But there is no serious question that Dr. Ostergard is highly qualified "by knowledge, skill, experience, training, [and] education"

[1] This count does not appear to state an independent claim but rather a theory relating to the timeliness of her remaining claims. In any event, because defendant does not raise the issue of timeliness, and nothing in plaintiff's submissions suggests that this count raises any substantive right to relief, summary judgment is appropriate.

in the medical fields relevant to his testimony. Accordingly, the issues defendant raises are better analyzed through the lens of *Daubert*'s reliability and relevance prongs.

With respect to the first of these prongs, defendant argues that Dr. Ostergard's causation opinions are unreliable because he failed to consider likely alternative causes of plaintiff's injury. Dr. Ostergard's causation analysis proceeds through the process of differential diagnosis, which is "a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Eghnayem v. Bos. Sci. Corp., 57 F. Supp. 3d 658, 669 (S.D.W. Va. 2014)*. Generally speaking, differential diagnosis (or, more accurately **[*8]** in this context, "differential etiology") is an "accepted and valid methodology." *Myers v. Ill. Cent. R.R. Co., 629 F.3d 639, 644 (7th Cir. 2010)*. To survive *Daubert* scrutiny, a differential etiology must reflect "scientifically valid decisions as to which potential causes should be 'ruled in' and 'ruled out.'" *Ervin v. Johnson & Johnson, Inc., 492 F.3d 901, 904 (7th Cir. 2007)* (citation omitted).

In defendant's view, Dr. Ostergard failed to account adequately for likely alternative causes of plaintiff's injuries, including, most significantly, Dr. Sadah's mesh implantation procedure, which the jury in a malpractice suit plaintiff filed against him found to be negligent and to have caused plaintiff millions of dollars in damages.[2] Setting aside that Dr. Ostergard *did* consider whether Dr. Sadah performed plaintiff's mesh implantation procedure within the standard of care—his view merely differs from the jury's—plaintiff need not exclude Dr. Sadah's negligence as a cause of her injuries to prevail in her claim that she was injured by defendant's defective mesh. *See Sherer-Smith v. C.R. Bard, Inc., No. 19-CV-903-JDP, 2020 U.S. Dist. LEXIS 52439, 2020 WL 1470962, at *4 (W.D. Wis. Mar. 26, 2020)* ("[t]o be considered a 'cause,' the defect need not be the sole cause or even the primary cause; it is sufficient to show that the defect was a substantial factor in causing the injury.").[3] Moreover, Dr. Ostergard "need not testify with complete certainty about **[*9]** the cause of an injury; rather he may testify that one factor could have been a contributing factor to a given outcome." *Gayton v. McCoy, 593 F.3d 610, 619 (7th Cir. 2010)*. At bottom, Dr. Ostergard's testimony is sufficiently reliable if he "consider[s] alternative causes" to "show why a particular alternative explanation is not, in [his] view, the *sole* cause" of her injuries. *Schultz v. Akzo Nobel Paints, LLC, 721 F.3d 426, 434 (7th Cir. 2013)* (emphasis in original). I conclude that his report and deposition testimony satisfy this standard.

In his supplemental report, Dr. Ostergard identifies and excludes a number of potential alternative causes. Ostergard Supp. Rep., ECF 142-2 ¶¶ 84-93. While I agree that he gives many of these cursory attention, defendant will have ample opportunity to expose this weakness in his analysis through cross-examination. *See Enborg v. Ethicon, Inc., No. 220CV02477AWIBAK, 2022 U.S. Dist. LEXIS 47313, 2022 WL 800879, at *11 (E.D. Cal. Mar. 16, 2022)* (acknowledging that "many of [Dr. Ostergard's] determinations [concerning alternative causes] strike the Court as conclusory, unclear and unconvincing," but declining to exclude his

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[2] *See* Order, *Nidia Teran v. Alan Y. Sadah, M.D., et al.*, No. 17-L-004790 (Cir. Ct. of Cook Cty. Mar. 2, 2022)(awarding plaintiff $7,535,459.76 in damages), ECF 155-3; verdict form itemizing plaintiff's damages in plaintiff's malpractice case, ECF 155-3.

[3] Although the *Sherer-Smith* court applied Wisconsin law, Illinois law similarly recognizes that injuries can have more than one proximate cause. *See Mack v. Ford Motor Co., 283 Ill. App. 3d 52, 669 N.E.2d 608, 613, 218 Ill. Dec. 465 (Ill. App. Ct. 1996)* (citing *Bentley v. Saunemin Township, 83 Ill. 2d 10, 413 N.E.2d 1242, 1246, 46 Ill. Dec. 129 (Ill. 1980)*).

testimony, reasoning that he nevertheless "proffered relevant testimony putatively based on a relevant data set" and performed a differential diagnosis, and that "whatever defects there may be in Dr. Ostergard's work go **[*10]** to the weight of his testimony and become f@@@@ for cross-examination."). The same goes for other potential causes that Dr. Ostergard did not discuss. *See* *Wheeler v. C.R. Bard, Inc., No. 19-CV-08273, 2022 U.S. Dist. LEXIS 61118, 2022 WL 971394, at *12 (N.D. Ill. Mar. 31, 2022)* (declining to bar causation witness even though she "did not mention" certain potential causes in her differential diagnosis). Indeed, Dr. Ostergard "is not required to rule out every alternative cause" of plaintiff's injuries to survive *Daubert* scrutiny. *Schultz, 721 F.3d at 434*. In short, I decline to exclude Dr. Ostergard's causation opinions on the basis that the methodology he used was insufficiently reliable.

I agree with defendant, however, that Dr. Ostergard may not testify that defendant's products are likely to cause plaintiff future injuries attributable to degradation of her mesh implant or to the ongoing presence of mesh in her body, as Dr. Ostergard acknowledged that there is no evidence of either in her medical records. *See* Ostergard Dep., ECF 124-2 at 66-68 (acknowledging that "there is nothing in...the medical records of this patient to indicate that degradation has occurred," nor "any indication in the records that the entire Restorelle mesh device was not removed"). *See* *Leavitt v. Ethicon, Inc., No. 2:20-CV-00176, 2021 U.S. Dist. LEXIS 156852, 2021 WL 3674067, at *2 (D. Vt. Aug. 19, 2021)* (excluding Dr. Ostergard's **[*11]** opinions concerning mesh degradation and risk of future injury because they were "not case-specific and...not helpful in evaluating the risks Plaintiff...is reasonably likely to face in the future"). For similar reasons, Dr. Ostergard may not testify about polypropylene's general propensity to degrade in vivo or about injuries he believes such degradation can cause.

Bilal Chughtai

Plaintiff has disclosed Dr. Chughtai, a urologist specializing in Female Pelvic Medicine and Reconstructive Surgery, and an Associate Professor in the Department of Obstetrics and Gynecology at Weill Cornell Medicine, to testify "about the cause, nature and extent of injuries suffered by Ms. Teran because of defendant's pelvic mesh and the need for its removal." Pl.'s Resp., ECF 141, at 1. Dr. Chughtai's opinions in this connection are stated in a single paragraph of his seventeen-page report, the bulk of which—pages four through sixteen—is devoted to a list of Dr. Chughtai's extensive publications in the fields of urology, gynecology, and pelvic surgery. (Pages one through three of his report comprise a brief introduction and a summary of plaintiff's medical history drawn from the records Dr. Chughtai reviewed.) **[*12]**

The substance of Dr. Chughtai's opinion is set forth in the following excerpt:

> Dr. Chughtai will testify, to a reasonable degree of medical certainty, that Nidia Teran's continuing symptoms are most probably related to her initial mesh surgery and subsequent removal. The subsequent surgical intervention was necessary because of pelvic pain and incontinence. It is probable that the multiple procedures and the complex nature of mesh removal are the causes of Ms. Teran's chronic lower urinary tract symptoms, multiple surgical interventions, and continued pelvic pain.

Chughtai Rep., ECF 141-6 at 8. This opinion—which offers no analysis or discussion of any particular element of plaintiff's complex medical history, nor does it address the role any aspect

of that history may have played in her injuries or ongoing symptoms—is a classic example of expert *ipse dixit*. As the Seventh Circuit has often reiterated, an expert "cannot waltz into the courtroom and render opinions unless those opinions are based upon some recognized scientific method[.]" *Clark v. Takata Corp., 192 F.3d 750, 759 (7th Cir. 1999)*. Nor can an expert offer merely a bottom line, as doing so supplies nothing of value to the judicial process. *Burns v. The Sherwin-Williams Company, No. 19-CV-5258, 2022 U.S. Dist. LEXIS 168122, 2022 WL 4329417, at *26 (N.D. Ill. Sept. 18, 2022)*. Dr. Chughtai's one-paragraph statement **[*13]** of his opinions putatively based on the totality of records he reviewed offers just this type of unhelpful "bottom line."

In response to defendant's observation that Dr. Chughtai's opinions are not based on any discernable methodology, plaintiff points to his qualifications and suggests that because Dr. Chughtai "based his opinions on the medical records of the treating physicians, all of which include detailed descriptions of plaintiff's prior medical history," his approach amounts to a reliable differential diagnosis. Pl.'s Resp., ECF 141 at 9. But that is plainly wrong: to conduct a valid differential diagnosis, "an expert must systematically 'rule in' and 'rule out' potential causes in arriving at her ultimate conclusion." *Higgins v. Koch Dev. Corp., 794 F.3d 697, 705 (7th Cir. 2015)*. *See also James v. Coloplast Corp. & Coloplast Manufacturing US, LLC, No. CV 20-654 (JRT/TNL), 2022 U.S. Dist. LEXIS 173766, 2022 WL 4465956, at *5 (D. Minn. Sept. 26, 2022)* (excluding expert opinion as *ipse dixit* based on expert's failure to "delineat[e] **any** connections between his causation opinion and the records he purports to have reviewed") (emphasis in original). Because there is no evidence that Dr. Chughtai "ruled in" or "ruled out" any of the potential alternative causes documented in her extensive medical history, his testimony does not satisfy *Daubert* standards and will be excluded.

The upshot of the foregoing discussion **[*14]** is that defendant is not entitled to summary judgment of plaintiff's claims in their entirety on the ground that she lacks admissible expert evidence of causation. Although plaintiff may not call Dr. Chughtai to testify, she may offer at least the testimony of Dr. Ostergard to support her causation theory.[4]

Barring global judgment in its favor for lack of evidence that plaintiff's Restorelle Y mesh caused any of her injuries, defendant offers a host of arguments for summary judgment as to each of plaintiff's individual claims. I resolve these as set forth below.

B. Products Liability

"An injured plaintiff may allege one of two types of products liability claims: a strict liability claim or a negligence claim." *Africano v. Atrium Med. Corp., No. 17-CV-7238, 2021 U.S. Dist. LEXIS 108950, 2021 WL 2375994, at *6 (N.D. Ill. June 10, 2021)* (quoting *Salerno v. Innovative Surveillance Tech., Inc., 402 Ill. App. 3d 490, 497, 932 N.E.2d 101, 108, 342 Ill. Dec. 210 (1st Dist. 2010)*). "The key distinction between the two types of claims lies in the concept of fault. In a strict liability claim, the focus of the inquiry is on the condition of the product itself. A negligence

[4] I say "at least" because plaintiff asserts that the postoperative reports of her treating physicians also include evidence of causation. While treating physicians may offer opinion testimony only if they are properly disclosed as witnesses, defendant has not argued that plaintiff may not rely on the additional evidence to which she points.

claim accounts for a defendant's fault as well as the product's condition." *Id.* Both theories require evidence of proximate causation. *Thornton v. M7 Aerospace LP, 796 F.3d 757, 770 (7th Cir. 2015)* ("[u]nder Illinois law, in a products liability action, whether based on strict liability or negligence, the plaintiff must demonstrate a causal **[*15]** relationship between the injury and the manufacturer's product."). *See also Salerno, 932 N.E. 2d at 109, 111* (identifying proximate causation as an element under each standard).

The Supreme Court of Illinois "has recognized three theories of strict product liability: manufacturing defect, design defect, and failure to warn." *Mikolajczyk v. Ford Motor Co., 231 Ill. 2d 516, 901 N.E.2d 329, 348, 327 Ill. Dec. 1 (Ill. 2008)*, opinion modified on denial of reh'g (Dec. 18, 2008).

Design Defect

As evidence of a design defect, plaintiff points to the testimony of Dr. Sondra Summers, the gynecologist who performed her hysterectomy, who testified that during the procedure, she observed that the mesh was "kind of balled up" and "encased in scar tissue." Summers Dep., ECF 146-6 at 130. In Dr. Ostergard's view, the "balled up" condition of the mesh is the result of its tendency to shrink or contract—a defect that he opines makes it "unreasonably dangerous," an element plaintiff must establish to prevail on her claim. *Mikolajczyk 901 N.E.2d at 345*.

Defendant argues that plaintiff has not raised a triable issue as to this element under what is known as the "risk-utility" test, one of two approaches Illinois courts use to determine whether a product is unreasonably dangerous. *See Bensenberg v. FCA US LLC, 31 F.4th 529, 535 (7th Cir. 2022)*. In defendant's view, Dr. Chughtai's deposition testimony referring to POP repair **[*16]** using polypropylene mesh as the "gold standard" and stating that he would use Coloplast mesh if it were stocked at the hospital at which he were performing surgery, and Dr. Sadah's testimony that he continues to use Restorelle Y mesh, undermine any argument that the risks of Restorelle Y outweigh its utility. But defendant fails to explain why this testimony disposes of the risk-utility analysis. Even assuming Dr. Chughtai's testimony were not excluded, plaintiff is entitled to have a jury weigh whatever inferences it might draw from his and Dr. Sadah's statements against evidence such as Dr. Ostergard's testimony concerning the physical properties of the mesh and its tendency to shrink or contract, both of which, he opines, render the product unreasonably dangerous.[5]

Defendant's sweeping assertion that plaintiff has "failed to offer any evidence or expert testimony that any purported design defect was a cause" of her injuries is incorrect. This argument presumably rests on the assumption that Dr. Ostergard's causation opinions will be

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[5] I am mindful of defendant's objection to Dr. Ostergard's testimony concerning the pore size of the mesh based on his "visual inspection." While I agree that visual inspection is not a reliable method for determining the size of pores that are measured in microns, it seems to me that the more important question is not the size of the mesh's pores prior to implantation, but rather whether the mesh's design allowed for shrinkage or contracture post-operatively in a way that made the mesh unreasonably dangerous. There is no dispute that Dr. Ostergard cited studies showing that polypropylene mesh in general is subject to shrinkage. The fact that these studies were not performed on Restorelle mesh specifically goes to the weight, not the reliability, of Dr. Ostergard's testimony, and a jury could construe Dr. Summers's observation that plaintiff's mesh was "balled up" as evidence that the product at issue here in fact contracted in vivo.

excluded. Having denied this aspect of defendant's *Daubert* motion targeting Dr. Ostergard's opinions, I need not address defendant's argument further. I deny **[*17]** defendant's summary judgment motion to the extent it targets plaintiff's design defect claim.

Failure to Warn

Defendant raises several arguments in connection with plaintiff's failure to warn claim, but one is dispositive: Plaintiff offers no evidence to establish, as she must, that inadequate warnings played any causal role in her injuries. *See* *Vaughn v. Ethicon, Inc., No. 20-CV-562-JPG, 2020 U.S. Dist. LEXIS 180240, 2020 WL 5816740, at *4 (S.D. Ill. Sept. 30, 2020)* ("[u]nder Illinois law, a plaintiff must show 'that the presence of adequate warnings would have prevented the plaintiff's injuries.'" (quoting *Broussard v. Houdaille Indus., Inc., 183 Ill. App. 3d 739, 539 N.E.2d 360, 363, 132 Ill. Dec. 50 (Ill. App. Ct. 1989)*). Indeed, plaintiff acknowledges that she relied entirely on Dr. Sadah's advice when deciding to receive the Restorelle Y mesh implant, and there is no evidence that Dr. Sadah read or relied upon the Instructions For Use ("IFU") accompanying the Restorelle Y mesh when formulating his recommendation. Asked at his deposition whether he "rel[ied] on" the IFU that accompanied the mesh he implanted in plaintiff,[6] Dr. Sadah provided this answer:

> So this was not my first to-do so, I mean, initially when I embark on doing something for the first time, whether it's a new instrument, whether it's a new device, whether it's a new implant, including mesh of course, I will be **[*18]** informed about it. Either I would have read about it or I would have attended a course about it or whether it's a technique that we have to learn more the -- if you will, the basic science of how that material works as it compares to other competitor ones. In addition, the rep, when he or she brings the item for a first time, will essentially give everyone sort of an in-service information, not just -- not so much to me but also to the staff, intraoperatively how to process that mesh, how it's handled and so forth, so that if they do drop it on the floor, they have a replacement, et cetera. So once that takes place the first time, we don't go through that as a routine.

Sadah Dep., ECF 146-3 at 99-100. *See also* Pl.'s Resp. to Def.'s *L.R. 56.1* Statement, ECF 146 at ¶ 10 (admitting that "Dr. Sadah relied on his training, experience, and guidance from his colleagues and peers to inform his decision to use the Restorelle Y, including using Restorelle Y to treat in March 2014."). In short, the evidence shows that Dr. Sadah learned about the product and how to use it from various sources, but none of them was the IFU.

Moreover, plaintiff acknowledges that Dr. Sadah continued to perform surgeries **[*19]** using Restorelle Y even after he learned of her injuries, and that he continued to consider sacrocolpopexy surgery with mesh as the "gold standard" for treating POP. ECF 146 at ¶¶ 13-14. These admissions foil any inference that different warnings alerting Dr. Sadah to the specific risks that ultimately materialized in plaintiff's case would have caused him not to use the product. Meanwhile, plaintiff never saw the Restorelle Y IFU herself, nor did she see marketing

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[6] Actually the question was, "Did you rely on the Instructions For Use that accompanied the Altis sling?" ECF 146-3 at 99:17-19, but Dr. Sadah testified that his answer would be the same for the IFU accompanying the Restorelle Y. *Id.* at 101:4-7.

materials or other representations by Coloplast about the product. Pl.'s Resp. to Def.'s L.R. 56.1 Statement, ECF 146 at PP 16-17. On these facts, I need not resolve the parties' dispute over the role of the "learned intermediary" doctrine; since neither plaintiff nor Dr. Sadah read or relied upon the IFU, no reasonable jury could conclude that different warnings might have prevented plaintiff's injuries.[7] *See* Aquino v. C.R. Bard, Inc., 413 F. Supp. 3d 770, 790 (N.D. Ill. 2019) (to prevail on failure to warn claim under Illinois law, plaintiff "must allege that if there had been a proper warning, her surgeon would have declined to use the product") (citing In re Zimmer, NexGen Knee Implant Prods. Liab. Litig., 884 F.3d 746, 752 (7th Cir. 2018) ("[a] plaintiff who has established both a duty and a failure to warn must also establish causation by showing that, if properly warned, he or **[*20]** she would have altered behavior and avoided injury.") (Wisconsin law); N. Tr. Co. v. Upjohn Co., 213 Ill. App. 3d 390, 572 N.E.2d 1030, 1037, 157 Ill. Dec. 566 (Ill. App. 1991) (to prevail on failure to warn claim, "plaintiff was required to show that the omission of such information made the warning inadequate...and that this defect was the proximate cause of plaintiff's injuries."). For the foregoing reasons, defendant's motion for summary judgment is granted as to this claim.

Manufacturing Defect

Defendant is entitled to summary judgment of this claim as well, as plaintiff offers no evidence that her Restorelle Y mesh "depart[ed] from its intended design[.]" Blue v. Env't Eng'g, Inc., 215 Ill. 2d 78, 828 N.E.2d 1128, 1139, 293 Ill. Dec. 630 (Ill. 2005). "A manufacturing defect and design defect are '*different* theories of liability.'" Africano v. Atrium Med. Corp., No. 17-CV-7238, 2021 U.S. Dist. LEXIS 108950, 2021 WL 2375994, at *8 (N.D. Ill. June 10, 2021) (quoting Salerno v. Innovative Surveillance Tech., Inc., 402 Ill. App. 3d 490, 932 N.E.2d 101, 108, 342 Ill. Dec. 210 (Ill. App. 2010) (emphasis in Africano). As the Salerno court explained, "[a] manufacturing defect occurs when one unit in a product line is defective, whereas a design defect occurs when the specific unit conforms to the intended design but the intended design itself renders the product unreasonably dangerous." 932 N.E.2d at 108. Plaintiff's response brief suggests that she fails to perceive the difference between these two theories. For example, she points to Dr. Ostergard's testimony concerning "general defects in the weight of Restorelle mesh, which vary from design **[*21]** parameters" and "deviations in mesh dimensional results, including its width" as evidence of a manufacturing defect. Pl.'s Resp., ECF 147 at 8. But what matters in connection with this theory of liability is the condition of plaintiff's "specific unit," and Dr. Ostergard concedes that neither he nor anyone else examined plaintiff's mesh to determine whether it conformed to the product's intended design. Without such evidence, plaintiff cannot proceed to trial on her claim of manufacturing defect.

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[7] Indeed, plaintiff's insistence that the doctrine "does not apply" in this case, Pl.'s SJ Resp., ECF 147 at 7, 10, does not advance her argument. If the doctrine is inapplicable, that means only that defendant cannot stand on adequate warnings to plaintiff's surgeon as a defense to the argument that defendant breached its duty to warn her. *See* Watts v. Medicis Pharm. Corp., 239 Ariz. 19, 365 P.3d 944, 951 (Ariz. 2016) ("the doctrine provides a means by which a manufacturer may satisfy its duty to warn the end user."). The shortcoming in plaintiff's evidence is one of causation. Regardless of whether the learned intermediary doctrine applies, plaintiff must offer some evidence to suggest that different, better warnings *to someone* would have prevented her injury. *See* Aquino v. C.R. Bard, Inc., 413 F. Supp. 3d 770, 790 (N.D. Ill. 2019) The record contains no such evidence.

C. Fraud-based Claims

Plaintiff fails to raise a triable issue on her fraud-based claims (common law fraud, fraudulent concealment, constructive fraud, and negligent misrepresentation) for substantially the reasons she cannot proceed on her failure to warn claim: She offers no evidence to suggest that she would not have gone forward with her implantation surgery if she (or Dr. Sadah) had been advised of the risks she faults defendant for omitting from the Restorelle Y IFU. In response to defendant's motion targeting her fraud-based claims, plaintiff reiterates the view that the learned intermediary doctrine does not bar these claims because the Restorelle Y IFU failed to "specify for any of **[*22]** the adverse events listed therein the expected time of onset, the anticipated duration of the event, the likely intensity of symptoms, or that the product could degrade after implantation." Pl.'s SJ Resp., ECF 147 at 9. But regardless of whether the learned intermediary doctrine applies, plaintiff points to nothing in the record to suggest that Dr. Sadah would not have recommended, or that she would not have consented to, implantation with Restorelle Y mesh if she had known the omitted information. *Cf.* *Corder v. Ethicon, Inc., 473 F. Supp. 3d 749, 758 (E.D. Ky. 2020)* (acknowledging that plaintiff "has the burden on proximate cause, and any warning defect, to support relief, must have caused her injury," and concluding that the plaintiff's attestation that "if she were apprised of all alleged complications stemming from Defendants' products, she would not have elected implantation" raised a factual dispute precluding summary judgment of her fraud-based claims).

D. Negligent Infliction of Emotional Distress ("NIED")

Defendant argues that plaintiff's NIED claim fails because it requires proof of a physical injury proximately caused by defendant's negligence, and the record does not support a finding that the Restorelle Y mesh caused any of her injuries. **[*23]** This argument does not warrant summary judgment in light of my conclusion above that plaintiff has presented sufficient evidence to allow a jury to conclude that her injuries were proximately caused by the mesh's defective design. Nevertheless, plaintiff's response falls short of identifying evidence sufficient to raise a triable issue as to each element she must prove to prevail on this claim. Plaintiff's four-line argument asserts that defendant's motion fails to address testimony in which she "identified the conditions she suffers and the impact that her injuries continue to have on her life." *See* Pl.'s SJ Resp., ECF 147 at 10. But the deposition testimony to which plaintiff points describes symptoms she experienced "before Dr. Sadah's surgery." Teran Dep., ECF 146-1 at 72:3-4. Nothing about that testimony suggests that she suffered emotional distress *as a result of* her implantation with defendant's mesh, much less does it support "the traditional elements of negligence: duty, breach, causation, and damages." *Schweihs v. Chase Home Fin., LLC, 2016 IL 120041, 412 Ill. Dec. 882, 77 N.E.3d 50, 58 (Ill. 2016)* (identifying elements of NIED claim). For these reasons, defendant's motion is granted as to plaintiff's NIED claim.

E. Punitive Damages

Defendant seeks summary judgment with **[*24]** respect to plaintiff's claim for punitive damages on the ground that a request for punitive damages is "merely a type of remedy," rather than an independent claim. *Vincent v. Alden-Park Strathmoor, Inc., 241 Ill. 2d 495, 948 N.E.2d 610, 615, 350 Ill. Dec. 330 (Ill. 2011)*. Defendant argues further that plaintiff cannot prove an entitlement to punitive damages, since she lacks evidence of the type of willful and wanton or outrageous conduct that would support such relief. While it may be that Illinois law does not treat a prayer for punitive damages as a "claim," the issue is academic, since plaintiff's ability to recover punitive damages does not turn on how her request is characterized. Moreover, I am not persuaded that no reasonable jury could award punitive damages on the record here. Defendant's motion is denied in this respect.

F. Expert Testimony — Remaining Issues

Although not dispositive of defendant's summary judgment motion, resolution of issues raised in the parties' remaining *Daubert* motions will shape the course of proceedings as the parties head towards trial. Accordingly, I address these issues below.

Ostergard's Additional Opinions

In addition to Dr. Ostergard's causation opinions, which I addressed in a previous section, defendant seeks to limit various other aspects of his proposed **[*25]** testimony. Most saliently, defendant seeks to preclude Dr. Ostergard from testifying about "safer alternative designs" on the ground that what he really describes are alternative treatments or procedures, rather than alternative designs for the Restorelle Y device. It is true that some courts have barred this aspect of Dr. Ostergard's testimony on that ground. *See, e.g., Leavitt v. Ethicon, Inc., No. 2:20-CV-00176, 2021 U.S. Dist. LEXIS 156852, 2021 WL 3674067, at *4 (D. Vt. Aug. 19, 2021)* ("a safer alternative treatment or procedure that does not include a safer alternative design of the product in question yields no relevant information regarding whether a safer alternative design was feasible."); *In re Ethicon, Inc. Pelvic Repair Sys. Prods. Liab. Litig., No. MDL 2327, 2017 U.S. Dist. LEXIS 46235, 2017 WL 1264620, at *3 (S.D. W. Va. Mar. 29, 2017)* (same). Other courts, however, have concluded that Dr. Ostergard's criticism of the materials or specifications used in the manufacture of vaginal mesh is admissible evidence of the existence of safer alternatives. *See Arruda v. C.R. Bard, Inc., No. 619CV1523TJMATB, 2020 U.S. Dist. LEXIS 141129, 2020 WL 4569436, at *18 (N.D.N.Y. Aug. 6, 2020)* ("Dr. Ostergard does not propose abandoning the sling device for some other procedure or treatment. He instead criticizes the material from which Defendant constructed the sling. He suggests that another material would be safer in serving the same function. That amounts to an argument for a safer alternative design, just as arguing that using aluminum instead of steel in a bike frame would **[*26]** make the frame stronger, lighter, and more durable, and thus safer."). Yet other courts have concluded that because alternative procedures may be relevant, for example, to rebut a defendant's claim that surgical repair using its product was the "gold standard" for treatment of a plaintiff's condition—an argument defendant appears poised to make in this case—the admissibility of opinions concerning such alternatives is best decided at trial. *See, e.g., McBroom v. Ethicon, Inc., No. CV-20-02127-PHX-DGC, 2021 U.S. Dist. LEXIS 123510, 2021 WL 2709292, at *19 (D.*

Ariz. July 1, 2021); *Heinrich v. Ethicon, Inc., No. 220CV00166APGVCF, 2021 U.S. Dist. LEXIS 105251, 2021 WL 2290996, at *3 (D. Nev. June 4, 2021)*. This last course strikes me as sensible, so I deny defendant's motion in this respect.

To the extent plaintiff intends to solicit testimony from Dr. Ostergard concerning defendant's corporate knowledge or state of mind, however, I agree that such opinions are not appropriate subjects of expert testimony. *See* *Wise v. C.R. Bard, Inc., No. 2:12-CV-01378, 2015 U.S. Dist. LEXIS 14869, 2015 WL 521202, at *3 (S.D.W. Va. Feb. 7, 2015)* ("[a]lthough an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will **[*27]** not assist the jury.").

Lastly, Dr. Ostergard will not be permitted to testify about informed consent or the adequacy of the Restorelle Y IFU because his opinions on these questions are relevant, if at all, to plaintiff's failure to warn claim, which is no longer at issue.

Jimmy W. Mays

Plaintiff has designated Dr. Mays, Distinguished Professor of Chemistry at the University of Tennessee, as an expert to offer opinions concerning the suitability of defendant's polypropylene mesh products for permanent implantation in the human body. Specifically, Dr. Mays opines that defendant's products are susceptible to degradation *in vivo*, and that such degradation causes adverse effects on the human body. The parties hotly dispute the reliability of Dr. Mays's opinions, and indeed, courts around the country have considered the question in a number of suits in this MDL and have come to varying conclusion. *Compare*, e.g., *Nunez v. Coloplast Corp., No. 19-CV-24000, 2020 U.S. Dist. LEXIS 83836, 2020 WL 2315077, at *4 (S.D. Fla. May 11, 2020)* (denying motion to exclude Mays's testimony); *Tyree v. Bos. Sci. Corp., 54 F. Supp. 3d 501, 538 (S.D.W. Va. 2014)*, as amended (Oct. 29, 2014) (permitting Dr. Mays "to testify generally about polypropylene degradation based on his experience and review of the literature"); and *Cantrell v. Coloplast Corp., No. 20-CV-0672 (WMW/JFD), 2022 U.S. Dist. LEXIS 126383, 2022 WL 2806390, at *4 (D. Minn. July 18, 2022)* (allowing Dr. Mays to testify "as to the general process of mesh degradation" **[*28]** but excluding as unreliable his opinions "about the specific properties of Coloplast's mesh"), *with* *Martinez v. Coloplast Corp. & Coloplast Mfg. US, LLC, No. 2:18-CV-220, 2022 U.S. Dist. LEXIS 23992, 2022 WL 409638, at *4 (N.D. Ind. Feb. 10, 2022)* (finding that Dr. Mays failed to "apply the same 'intellectual rigor' to his litigation opinions as he did to his 400 published articles" and excluding his opinions in their entirety).

Ultimately, however, this case does not compel me to take sides on the reliability of Dr. Mays's methodology, since his opinions about polypropylene's tendency to degrade have no place in this case. As noted above, there is no evidence that plaintiff's mesh degraded, or that any of her injuries was caused by mesh degradation. For that reason, Dr. Mays's opinions are more likely to confuse than to help the jury decide the issues before it. His testimony will be excluded. *See Hammock v. Coloplast Corp*. et. al, No. 3:19-cv-01041-RJD, at 3 (S.D. Ill. Mar. 29, 2021) (slip

op.) (declining to interpret evidence that the defendant's product "rolled on itself" to mean that the product "degraded" and excluding Dr. Mays's opinions as irrelevant as they concerned oxidative degradation).

Emily Cole

Dr. Cole is another repeat player in this MDL, and the sadmissibility of her opinions regarding the safety and design of **[*29]** mesh products used to repair POP and SUI, including Restorelle Y, has been considered by several courts. *See* *Martinez v. Coloplast Corp. & Coloplast Mfg. US, LLC, No. 2:18-CV-220, 2022 U.S. Dist. LEXIS 25827, 2022 WL 444281 (N.D. Ind. Feb. 14, 2022)* (denying motion to exclude Dr. Cole's opinions); *Nunez v. Coloplast Corp., No. 19-CV-24000, 2020 U.S. Dist. LEXIS 83836, 2020 WL 2315077, at *5 (S.D. Fla. May 11, 2020)* (same); *Bayless v. Bos. Sci. Corp., No. 620CV831ORL37GJK, 2020 U.S. Dist. LEXIS 256069, 2020 WL 10058191, at *6 (M.D. Fla. Dec. 7, 2020)* (permitting Dr. Cole to testify "as to what she found in the literature regarding mesh outcomes—and whether those findings are consistent with her own clinical experience" but precluding her from testifying "that her experiences are representative of all clinical experiences (outside of a discussion of the scientific literature) or that the product is or is not defective, whether its physical properties change in vivo, or other aspects of the mesh's material properties that go beyond her clinical experience and her expertise as a medical doctor.").

Dr. Cole's qualifications are beyond reasonable dispute. As the *Martinez* court recently observed:

> Dr. Cole is clearly an experienced female pelvic health surgeon. She has performed over 1,500 pelvic floor surgeries in the last ten years, with five involving Restorelle Y. She currently serves as the Chief Urologist and Director of the Female Pelvic Health Center at Sharp Ress-Stealy Medical Group where she maintains an active surgical practice that specializes in using mesh implants **[*30]** to treat female POP and urinary incontinence conditions.

*Martinez, 2022 U.S. Dist. LEXIS 25827, 2022 WL 444281, at *3*. Nothing in plaintiff's motion provides a reason to doubt Dr. Cole's ability to testify competently about the safety and design of Restorelle Y mesh.

As for the reliability of the specific opinions she proposes to offer in this case—which, in short, are that: 1) all pelvicf-loor surgeries have risks and benefits, and that Restorelle Y should not be deemed defective based on adverse outcomes experienced by certain patients; and 2) the medical literature and her personal experience indicate that Restorelle Y is safe and effective for implantation in appropriately selected patients—I conclude that her methodology of observing complication rates in her own practice and reviewing relevant medical literature provides a sound basis for her conclusions. *See* Cole Rep., ECF 113-1 at 12. Plaintiff's argument that Dr. Cole cannot opine that the Restorelle Y mesh is not defective because she is not an expert in "how a company designs medical devices" and has not "assisted with the design [of] any medical products" is misplaced. Dr. Cole does not purport to offer opinions about the design *process*. Instead, she describes certain of the product's **[*31]** design features and offers

opinions about its functionality and safety based on outcomes she has observed personally and has reviewed in the literature. Because I am satisfied that Dr. Cole's methodology satisfies *Daubert* standards, plaintiff's motion to preclude her testimony is denied.[8]

Patrick Culligan

Dr. Culligan is a urogynecologist who is board certified both in General Obstetrics and Gynecology and in Female Pelvic Medicine and Reconstructive Pelvic Surgery. Defendant has designated Dr. Culligan to offer causation opinions related to polypropylene products generally and defendant's Restorelle Y mesh in particular. Plaintiff moves to exclude various aspects of Dr. Culligan's testimony, including his opinions about Dr. Sadah's surgical technique and his testimony concerning mesh shrinkage and degradation. Plaintiff also seeks to preclude Dr. Culligan from offering opinions about "the FDA or regulatory issues." Mot., ECF 123 at 4.

Having reviewed the parties' motions and accompanying materials, I conclude first that Dr. Culligan may testify to his opinion that Dr. Sadah's surgical technique was "unconventional," as that testimony is not based exclusively on his own experience, as plaintiff **[*32]** asserts, but also on his "rather extensive knowledge of the field of urogynecology," which includes researching and teaching in the field of pelvic reconstructive surgery. *See generally* Culligan CV, ECF 140-7.

As for Dr. Culligan's opinions concerning mesh shrinkage, plaintiff argues that his opinions are unreliable because they "ignore contrary studies." Pl.'s Mem., ECF 123 at 3. Defendant disputes the factual basis for this argument, pointing to the wide body of literature Dr. Culligan cites. At all events, however, plaintiff will have ample opportunity at trial to cross-examine Dr. Culligan concerning the studies she believes he failed to consider. Accordingly, her motion is denied insofar as it relates to Dr. Culligan's opinions about mesh shrinkage. For reasons explained elsewhere in this opinion, however, Dr. Culligan will not be permitted to testify about mesh degradation.

To the extent plaintiff challenges Dr. Culligan's opinions concerning defendant's compliance with FDA regulatory processes, her motion is granted. Judge Goodwin, who presided over the MDL in which this case originated, has "repeatedly and thoroughly considered the admissibility of the FDA's 510(k) process," **[*33]** and has consistently excluded expert testimony on the subject because "the 510(k) process does not relate to safety or efficacy." *Eghnayem v. Bos. Sci. Corp., 57 F. Supp. 3d 658, 725 (S.D.W. Va. 2014)* (citing cases). The Seventh Circuit agrees. *See Kaiser v. Johnson & Johnson, 947 F.3d 996, 1018 (7th Cir. 2020)* (concluding that because "*§ 510(k)* clearance is remote from FDA safety review," evidence of the clearance process was only minimally probative of product safety and probative value was outweighed by likelihood of prejudice). Because I see no compelling basis for departing from these rulings, Dr. Culligan will not be permitted to testify about FDA regulatory processes, regardless of whether he is qualified to do so.

[8] I note that plaintiff filed no reply in support of her motion, which may indicate that she concedes defendant's arguments in response to her motion.

Karen Becker

For similar reasons, and consistently with other courts that have considered the admissibility of her opinions on the subject, I grant plaintiff's motion to exclude the testimony of Karen Becker concerning medical device industry practices and the FDA's regulation of medical devices. *See, e.g.,* *Martinez v. Coloplast Corp., No. 2:18-CV-220, 2022 U.S. Dist. LEXIS 30551, 2022 WL 571398, at *1 (N.D. Ind. Feb. 23, 2022)* (excluding "Dr. Becker's opinions regarding the FDA in general as well as its regulatory process as it pertains to labeling, adverse event reporting system, and the *§ 510(k)* clearance process."); *Wood v. Am. Med. Sys. Inc., No. 120CV00441DDDKLM, 2021 U.S. Dist. LEXIS 63960, 2021 WL 1178547, at *3 (D. Colo. Mar. 26, 2021)* (same). Additionally, to the extent Dr. Becker's testimony addresses **[*34]** FDA regulation of product labeling, her testimony is irrelevant given that I have granted summary judgment on plaintiff's failure to warn claim.

Diana Molavi

Defendant offers the opinions of Dr. Molavi, a board-certified anatomic and clinical pathologist who serves as Chief of Pathology at Sinai Hospital in Baltimore, Maryland, to rebut the causation opinions offered by Drs. Ostergard and Chughtai. The opinions she articulates concern the human body's response to polypropylene mesh, the limited value of existing studies of the pathologic response to mesh, and the limitations of histologic examinations. Plaintiff asserts that Dr. Molavi "is not qualified to testify regarding the ability of polypropylene mesh to cause pain in patients," and that her methodology is unreliable because she "fails to use any scientific method" in reaching her conclusions. These arguments do not survive scrutiny.

As to the first, I agree with the observation of the court in *Nunez v. Coloplast Corp., No. 19-CV-24000, 2020 U.S. Dist. LEXIS 83836, 2020 WL 2315077, at *5 (S.D. Fla. May 11, 2020)*, that "no serious argument can be made about Dr. Molavi's qualifications."[9] In addition to the credentials mentioned above, Dr. Molavi "is the author of an academic textbook on the topic of surgical pathology, the diagnostic process, and **[*35]** female anatomy [and] has numerous peer-reviewed articles" in the relevant field. *Id.* Having reviewed her CV and deposition testimony, I find that Dr. Molavi is amply qualified "to assess and interpret scientific literature that analyzes whether histopathology findings (such as the presence of macrophages, foreign body giant cells, fibrosis or chronic inflammation) correlate with a patient's reported symptoms, including pain, following surgery with polypropylene surgical mesh." Def.'s Resp., ECF 137 at 6.

As to the reliability of Dr. Molavi's opinions, plaintiff suggests that because she has not performed independent "research on how transvaginal mesh implants react in the human body," her conclusions are not the product of "a reliable scientific method." Pl.'s Mem. ECF 115 at 4. But independent research is not the only means of arriving at scientifically reliable opinions. As

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[9] I am mindful that the *Nunez* court went on to exclude Dr. Molavi's testimony on the ground that her own deposition testimony called into question the reliability of her opinions. For reasons explained below, I conclude that the opinions she offers in this case are based on a reliable methodology, and that plaintiff may address the deposition testimony that "bothered" the *Nunez* court through cross-examination. *Nunez, 2020 U.S. Dist. LEXIS 83836, 2020 WL 2315077, at *6*.

Dr. Molavi explained in her deposition, a microscope is a pathologist's "tool" for evaluating the human body's response to the presence of a foreign body such as polypropylene mesh, and she analyzes thousands of histological slides through a microscope each year. Molavi Dep., ECF 137-20 at 104, 22. ECF. Dr. Molavi's **[*36]** report addresses the tissue responses she expects to see, based on her twelve years of experience, when polypropylene mesh is present. She then addresses the scientific literature concerning the relationship between those responses and patient symptoms and concludes that "there is poor correlation between symptoms and pathology." I am satisfied that Dr. Molavi's approach is appropriately grounded in the tools and methods of her profession. Plaintiff's objection that she "ignored" literature that does not support her conclusions is, as I noted above in conjunction with my analysis of Dr. Culligan's testimony, a criticism that is best evaluated through cross-examination.

III.

For the foregoing reasons, I grant defendant's motion for summary judgment with respect to plaintiff's claims of strict liability-manufacturing defect (Count II), strict liability — failure to warn (Count III), common law fraud (Count VI), fraudulent concealment (Count VII), constructive fraud (Count VIII), negligent misrepresentation (Count IX), and negligent infliction of emotional distress (Count X) only. In addition, I grant defendant's motions to exclude the testimony of Drs. Bilal Chughtai and Jimmy Mays, and **[*37]** I grant plaintiff's motion to exclude the testimony of Dr. Karen Becker. I deny plaintiff's motions to exclude the testimony of Drs. Emily Cole and Diana Molavi. Finally, I grant in part and deny in part defendant's motion to preclude the testimony of Dr. Ostergard and plaintiff's motion to preclude the testimony of Dr. Culligan.

ENTER ORDER:

/s/ Elaine E. Bucklo

Elaine E. Bucklo

United States District Judge

Dated: September 30, 2022

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Vaughn v. Ethicon, Inc.

United States District Court for the Southern District of Illinois

September 30, 2020, Decided; September 30, 2020, Filed

Case No. 20-cv-562-JPG

Reporter
2020 U.S. Dist. LEXIS 180240 *

CARRIE VAUGHN, Plaintiffs, v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants.

Prior History: *In re : Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig., 2012 U.S. Dist. LEXIS 121523 (J.P.M.L., Aug. 27, 2012)*

Counsel: [*1] For Carrie Vaughn, Plaintiff: Christopher A. Gomez, Eleanor O. Aldous, LEAD ATTORNEYS, Kline & Specter, PC, Philadelphia, PA; Lee B. Balefsky, LEAD ATTORNEY, PRO HAC VICE, Kline & Specter, PC, Philadelphia, PA; Michelle L. Tiger, LEAD ATTORNEY, PRO HAC VICE, KLINE & SPECTER, Philadelphia, PA.

For Ethicon, Inc., Johnson & Johnson, Defendants: Sherry A. Knutson, LEAD ATTORNEY, Tucker Ellis LLP-Chicago, Chicago, IL; Amy M. Pepke, Butler Snow LLP - Memphis, Memphis, TN.

Judges: J. PHIL GILBERT, DISTRICT JUDGE.

Opinion by: J. PHIL GILBERT

Opinion

MEMORANDUM AND ORDER

This matter comes before the Court on the motion for partial summary judgment filed by defendants Ethicon, Inc. and Johnson & Johnson (Docs. 19 & 20). Plaintiff Carrie Vaughn has responded to the motion (Docs. 21 & 22).

The plaintiff brought this products liability case after she underwent surgery in February 2012 for implantation of one of the defendants' medical devices. The case was consolidated for pretrial purposes in multi-district litigation ("MDL") proceedings—*In re: Ethicon Inc., Pelvic Repair System Products Liability Litigation*, MDL No. 2327—and has been remanded to this Court for trial. The defendants' motion for partial summary judgment, filed in **[*2]** the MDL proceeding, remains pending.

I. Summary Judgment Standard

Summary judgment must be granted "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); *see* Celotex Corp. v. Catrett, 477 U.S. 317, 322, 106 S. Ct. 2548, 91 L. Ed. 2d 265 (1986); Spath v. Hayes Wheels Int'l-Ind., Inc., 211 F.3d 392, 396 (7th Cir. 2000). The court must construe the evidence in the light most favorable to the nonmoving party and draw all reasonable inferences in favor of that party. *See* Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986); Chelios v. Heavener, 520 F.3d 678, 685 (7th Cir. 2008); Spath, 211 F.3d at 396. Nevertheless, the "favor toward the nonmoving party does not extend to drawing inferences that are supported by only speculation or conjecture." Monroe v. Ind. Dep't of Transp., 871 F.3d 495, 503 (7th Cir. 2017) (internal quotations and citations omitted).

The initial summary judgment burden of production is on the moving party to show the Court that there is no reason to have a trial. Celotex, 477 U.S. at 323; Modrowski v. Pigatto, 712 F.3d 1166, 1168 (7th Cir. 2013). Where the nonmoving party carries the burden of proof at trial, the moving party may satisfy its burden of production in one of two ways. It may present evidence that affirmatively negates an essential element of the nonmoving party's case, *see* Fed. R. Civ. P. 56(c)(1)(A), or it may point to an absence of evidence to support an essential element of the nonmoving party's case without actually submitting any evidence, *see* Fed. R. Civ. P. 56(c)(1)(B). Celotex, 477 U.S. at 322-25; Modrowski, 712 F.3d at 1169. Where the moving party fails to meet its strict burden, a court cannot **[*3]** enter summary judgment for the moving party even if the opposing party fails to present relevant evidence in response to the motion. Cooper v. Lane, 969 F.2d 368, 371 (7th Cir. 1992).

In responding to a summary judgment motion, the nonmoving party may not simply rest upon the allegations contained in the pleadings but must present specific facts to show that a genuine issue of material fact exists. Celotex, 477 U.S. at 322-26; Anderson, 477 U.S. at 256-57; Modrowski, 712 F.3d at 1168. A genuine issue of material fact is not demonstrated by the mere existence of "some alleged factual dispute between the parties," Anderson, 477 U.S. at 247, or by "some metaphysical doubt as to the material facts," Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986). Rather, a genuine issue of material fact exists only if "a fair-minded jury could return a verdict for the [nonmoving party] on the evidence presented." Anderson, 477 U.S. at 252.

II. Facts

Viewed in the light most favorable to the plaintiff, the evidence establishes the following relevant facts.

A. Implantation of the Device

On February 8, 2012, Vaughn, 41 years old and an Illinois resident at the time, underwent a surgical procedure for partial hysterectomy and implantation of a transvaginal polypropylene mesh medical device—a TVT-Obdurator ("TVT-O"). The device was manufactured by Ethicon, a subsidiary of Johnson & Johnson. The surgery took place at Memorial Hospital **[*4]** in Belleville, Illinois, and was performed by Sekou Kelsey, M.D.

Prior to her surgery, Vaughn had been diagnosed with stress urinary incontinence, and the implantation of the TVT-O was aimed at addressing that issue. Dr. Kelsey recommended the TVT-O and discussed with her the potential complications of which he knew. However, he never discussed with her the permanency, frequency or severity of the risks or complications she actually experienced following surgery. Specifically, Dr. Kelsey never advised her that she could have permanent or severe pain with intercourse, chronic pelvic pain, painful urination and urinary problems, vaginal and urinary tract infections, worsening incontinence, or that she might never be able to have sex again, or might need multiple corrective surgeries to treat complications from the mesh. If he had so advised her, she would have chosen not to have the surgery. Without this information, Vaughn chose to have the surgery. Dr. Kelsey implanted the device correctly, in accordance with Ethicon's instructions and the applicable standard of care.

Vaughn moved from Illinois to Missouri in May 2013. About a year later, in mid-2014, Vaughn started having problems connected **[*5]** with the TVT-O. She suffered vaginal pain and dyspareunia due to a mesh erosion as well as anxiety and embarrassment. On October 2, 2015, she had to undergo additional surgery to remove exposed mesh. The procedure was performed by Siobhan Hyland, M.D. at Boone Hospital Center in Columbia, Missouri. Dr. Hyland was not able to remove all of the TVT-O during the corrective surgery, and Vaughn continues to suffer complications.

B. Dr. Kelsey 's Knowledge About the Device

When Dr. Kelsey first began implanting the TVT-O in patients in 2004, he read the Instructions for Use ("IFU")—essentially, a device reference manual for physicians—but stopped reviewing them in 2007, years before Vaughn's surgery, because he had become familiar with the procedure. Different warnings in the IFU before Vaughn's surgery would not have caused Dr. Kelsey to change his recommendation that Vaughn use the TVT-O because he would not have read those different warnings. Additionally, even knowing what he does today, Dr. Kelsey still believes the TVT-O was a safe and effective treatment for Vaughn, although there was always a risk that the surgery would need to be redone.

C. Procedural History

Vaugh filed this lawsuit **[*6]** in the United States District Court for the Southern District of West Virginia in July 2015 as part of MDL No. 2327. She asserts 17 claims under various legal theories. The case emerged from the MDL proceeding earlier this year and was remanded to this Court for trial. Pending at the time of remand was the defendants' motion for partial summary judgment.

The defendants seek summary judgment on the plaintiffs' claims for negligence (Count I), strict liability — manufacturing defect (Count II); strict liability — failure to warn (Count III); common law fraud (Count VI); fraudulent concealment (Count VII); constructive fraud (Count VIII); negligent misrepresentation (Count IX); negligent infliction of emotional distress (Count X); breach of express warranty (Count XI); breach of implied warranty (Count XII); violation of consumer protection laws (Count XIII); gross negligence (Count XIV); and unjust enrichment (Count XV). The plaintiff makes no argument in opposition to the request to the extent it concerns Counts II and VI-XV and merely respond that she will not be pursuing these counts at trial. The plaintiff further states she will not be pursuing Count IV either. Accordingly, the

Court **[*7]** will grant the defendants' motion as to Counts II and VI-XV and will dismiss Count IV pursuant to *Federal Rule of Civil Procedure 41(b)* for failure to prosecute. The Court turns now to the remaining requests for summary judgment. Only two claims remain at issue in this motion: (1) negligence based on the defendants' failure to warn (part of Count I) and (2) strict products liability for failure to warn (Count III).

III. Analysis

The defendants contend that they are entitled to summary judgment on Vaughn's failure to warn claims because Dr. Kelsey's deposition testimony shows that he would not have changed his conduct if he had received a different warning from Ethicon before recommending the TVT-O to Vaughn. In response, Vaughn argues that she would not have chosen to have a TVT-O implanted if she had been better informed of the potential risks and complications.

The Court first addresses the question of what state's substantive law applies. In this suit heard under the Court's diversity jurisdiction, the Court applies the choice of law rules of the state in which it sits—for this Court, Illinois—to determine the applicable substantive law. *McCoy v. Iberdrola Renewables, Inc., 760 F.3d 674, 684 (7th Cir. 2014)* (citing *Felder v. Casey, 487 U.S. 131, 151, 108 S. Ct. 2302, 101 L. Ed. 2d 123 (1988))*. For tort claims, Illinois generally follows the most-significant-contacts **[*8]** approach of *§ 145 of the Restatement (Second) of Conflict of Laws*. *Cont'l Vineyard, LLC v. Vinifera Wine Co., LLC, No. 19-2089, 973 F.3d 747, 2020 U.S. App. LEXIS 27942, 2020 WL 5229402, at *9 (7th Cir. Sept. 2, 2020)* (citing *Wreglesworth v. Arctco, Inc., 316 Ill. App. 3d 1023, 738 N.E.2d 964, 971, 250 Ill. Dec. 495 (Ill. App. Ct. 2000))*. Illinois law presumes in personal injury cases that the applicable law is the law of the state in which the injury occurred unless Illinois has a more significant relationship with the occurrence and the parties. *Townsend v. Sears, Roebuck & Co., 227 Ill. 2d 147, 879 N.E.2d 893, 903, 316 Ill. Dec. 505 (Ill. 2007)*; *Ingersoll v. Klein, 46 Ill. 2d 42, 262 N.E.2d 593, 595 (Ill. 1970)*; *Kolchinsky v. W. Dairy Transp., LLC, 949 F.3d 1010, 1013 n.2 (7th Cir. 2020))*. Other factors to consider that may overcome the presumption include: the place where the conduct causing the injury occurred, the domiciles of the parties, and the place where the parties' relationship is centered. *Ingersoll, 262 N.E.2d at 596*; *Restatement (Second) of Conflict of Laws § 145* (1971).

The defendants argue that Missouri law applies because Vaughn first began suffering symptoms from the allegedly defective TVT-O about a year after she moved from Illinois to Missouri and then received treatment for her injuries in Missouri. In support, it cites a case in which the implantation surgery and subsequent symptoms occurred in the same state. *Bellew v. Ethicon, Inc., No. 2:13-CV-22473, 2014 U.S. Dist. LEXIS 164428, 2014 WL 6886129, at *3 (S.D.W. Va. Nov. 24, 2014)*. *Bellew* is not helpful to the Court because it does not address the question of, in a failure to warn claim, which state has the most significant relationship where the surgery and subsequent symptoms caused by an allegedly defective implanted medical device occur in different states.

On the other hand, the plaintiff cites no law **[*9]** whatsoever and baldly states Illinois substantive law applies "based on the decisions of this Court." It does not attach or cite any relevant decision.

The Court finds that it does not matter which law applies to the failure to warn claims because both states' laws require proof of causation. Under Illinois law, a plaintiff must show "that the presence of adequate warnings would have prevented the plaintiff's injuries." *Broussard v. Houdaille Indus., Inc., 183 Ill. App. 3d 739, 539 N.E.2d 360, 363, 132 Ill. Dec. 50 (Ill. App. Ct. 1989)*; *compare Kane v. R.D. Werner Co., 275 Ill. App. 3d 1035, 657 N.E.2d 37, 39, 212 Ill. Dec. 342 (Ill. App. Ct. 1995)* ("However, since plaintiff failed to read the warning labels, the alleged inadequate content of those warnings could not have proximately caused his injuries. . . ."). Stated another way, the plaintiff must be able to prove that if there had been a proper warning, the learned intermediary—Dr. Kelsey, in this case—would have declined to prescribe or recommend the product. *N. Trust Co. v. Upjohn Co., 213 Ill. App. 3d 390, 572 N.E.2d 1030, 1037, 157 Ill. Dec. 566 (Ill. App. Ct. 1991)*.

Causation is also required under Missouri law. To prevail in a failure to warn products liability case under Missouri law, a plaintiff must show, among other things that a warning would have changed the behavior of the individuals involved in the incident. *Moore v. Ford Motor Co., 332 S.W. 3d 749, 762 (Mo. 2011)* (*en banc*); *Tune v. Synergy Gas Corp., 883 S.W.2d 10, 14 (Mo. 1994)*; *Campbell v. Am. Crane Corp., 60 F.3d 1329, 1331 (8th Cir. 1995)*. Like Illinois law, Missouri law requires a plaintiff to prove that a warning would have caused the learned intermediary **[*10]** to alter his recommendation for the allegedly defective product. *Madsen v. Am. Home Prods. Corp., 477 F. Supp. 2d 1025, 1035 (E.D. Mo. 2007)* (citing *In re Norplant Contraceptive Prods. Liab. Litig., 215 F. Supp. 2d 795, 821 (E.D. Tex. 2002))*. "[T]he causal link between a patient's injury and the alleged failure to warn is broken when evidence is presented that the prescribing physician would have continued to prescribe the [product] for the patient even if he had been provided with adequate warnings." *Madsen, 477 F. Supp. 2d at 1035*. In Missouri, there is a presumption that the learned intermediary would have heeded warnings about risks about which he did not already know, but that presumption can be overcome by evidence that an adequate warning would have been futile because it would not have been read by the person to be warned. *Bachtel v. TASER Int'l, Inc., 747 F.3d 965, 971 (8th Cir. 2014)*.

The defendants are entitled to summary judgment under either Illinois or Missouri law. They have presented uncontroverted evidence that Dr. Kelsey did not consult the IFU in deciding whether to recommend the TVT-O for Vaughn, so any new or different warnings in the IFU could not have changed his advice. Furthermore, even allowing for a presumption that Dr. Kelsey would have heeded different warnings—had he read them—the evidence clearly shows his recommendation would not have changed. Dr. Kelsey testified that even today he believes the TVT-O was a **[*11]** safe and appropriate device for Vaughn. And while it is true that, if there is an issue of fact regarding whether a learned intermediary would have acted differently with different warnings, summary judgment should not be granted, *see Huskey v. Ethicon, Inc., No. 2:12-cv-05201, 2015 U.S. Dist. LEXIS 109454, 2015 WL 4944339, at *9 (S.D.W. Va. Aug. 19, 2015)*, *aff'd*, *848 F.3d 151 (4th Cir. 2017)*; *Giles v. Wyeth, Inc., 500 F. Supp. 2d 1063, 1070 (S.D. Ill. 2007)*, *aff'd*, *556 F.3d 596 (7th Cir. 2009)*, there is no such issue of fact in this case. There is simply no evidence from which a reasonable jury could conclude that the lack of warnings played a causal role in Vaughn's injuries.

IV. Conclusion

For the foregoing reasons, the Court **GRANTS** the defendants' motion for partial summary judgment (Doc. 19) as to the following counts:

- Count I to the extent it relies on a negligent failure to warn theory;
- Count III, a strict liability failure to warn theory; and
- Counts II and VI-XV.

The Court **DISMISSES** Count IV pursuant to *Federal Rule of Civil Procedure 41(b)* **with prejudice** for failure to prosecute.

The Court **DIRECTS** the Clerk of Court to enter judgment accordingly at the close of the case. The remaining claims in this case are Count I except to the extent it relies on a negligent failure to warn theory and Counts V, XVI, XVII, and XVIII in their entirety. Should the parties believe any other claim can be disposed of by agreement **[*12]** prior to trial, they are encouraged to notify the Court a soon as possible.

IT IS SO ORDERED.

DATED: September 30, 2020

/s/ J. Phil Gilbert

J. PHIL GILBERT

DISTRICT JUDGE

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