No. 128841

In the Illinois Supreme Court

CHARLES MUHAMMAD and ANGIE MUHAMMAD, as parents of C.M, a minor, and C.M., individually,	)	On Appeal from the Appellate Court of Illinois, First Judicial District No. 1-21-0478
Appellees	)	
v.	)	On Appeal from the Circuit Court of Cook County, Illinois – Law Division
ABBOTT LABORATORIES INC. and ABBVIE INC.,	)	Case No. 2019-L-6254 Hon. Brendan A. O'Brien
Appellants	)	

APPELLANTS' REPLY BRIEF

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Oral Argument Requested

POINTS AND AUTHORITIES

INTRODUCTION

Plaintiffs' brief ignores the central legal question on which this Court granted review: Whether, as a matter of law, a defendant prescription drug manufacturer is entitled to summary judgment on a failure-to-warn claim where, as here, the prescribing physicians proffer uncontroverted testimony that a different warning would not have caused them to act differently. As a matter of *law*, principles of causation and the learned intermediary doctrine answer that question yes. Accordingly, this Court should reverse with instructions to enter judgment for Abbott. That outcome ensures that Illinois remains among the judicial mainstream that adopt and follow the learned intermediary rule in this context.

Seeking to avoid that straightforward result, Plaintiffs' brief focuses on factual and legal questions not relevant to this appeal. First, Plaintiffs attempt to muddle the record by incorrectly casting this legal issue as a fact question, suggesting contested facts where none exist. Plaintiffs' eleventh-hour submission of Dr. Nasr's affidavit speculating what a hypothetical reasonable physician would have done is one prime example of this. Second, Plaintiffs attack a straw man, judicial estoppel, an argument that Abbott has not raised here. While judicial estoppel was at issue below, before this Court, Abbott asks only for resolution of the legal question articulated in its Petition for Leave to Appeal. That the doctor and hospital in this matter were separately found liable under a medical malpractice theory in another case simply demonstrates

the fairness of Abbott's proposed outcome on the failure-to-warn claim in this case. As explained in Abbott's opening brief, faithful application of the learned intermediary rule in this context does *not* leave plaintiffs like these without recourse for their injuries on the theory that a reasonable physician should have made a different choice, as Plaintiffs' separate, multi-million dollar verdict and settlement against other actors demonstrates.

The issue in this appeal is a simple one: Mrs. Muhammad's prescribing physicians, her "learned intermediaries," testified that they would *not* have changed their subjective prescribing decision even if they had received the warnings Plaintiffs claim were required. Without evidence of any such change, Plaintiffs cannot establish that the alleged failure to warn caused their injuries, and summary judgment is required.

ARGUMENT

I. AS A MATTER OF LAW, THE LEARNED INTERMEDIARY DOCTRINE APPLIES AND REQUIRES SUMMARY JUDGMENT WHERE THE UNCONTROVERTED EVIDENCE FROM PRESCRIBING DOCTORS NEGATES PROXIMATE CAUSATION.

A. The Court Can And Should Resolve This Appeal As A Matter Of Law On Proximate Causation And Thereby Keep Illinois Aligned With The Majority Of States.

The learned intermediary doctrine stems from this Court's recognition that manufacturers of prescription drugs like Depakote have "no duty to directly warn the user of a drug of possible adverse effects." *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 117 Ill. 2d 507, 519 (1987). Rather, manufacturers have a duty to warn prescribing physicians, and those physicians, "using *their* medical judgment, have a duty to convey the warnings to their patients." *Id.*

at 517 (emphasis added). Thus, to prove proximate cause for a failure-to-warn claim against a manufacturer, 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, 744 (1st Dist. 1989).

The learned intermediary doctrine has been Illinois law for nearly forty years. *Kirk*, 117 Ill. 2d at 517. And when that doctrine is applied to a failure-to-warn claim, proximate causation asks whether the treating doctor would have altered his prescribing decision with respect to the plaintiff-patient in light of an additional warning. *See, e.g.*, *Vaughn v. Ethicon, Inc.*, 2020 WL 5816740, at *4 (S.D. Ill. Sept. 30, 2020) ("[T]he plaintiff must be able to prove that if there had been a proper warning, the learned intermediary . . . would have declined to prescribe or recommend the product."). The question is not what a *hypothetical* doctor would have done; nor is it what this doctor *should have* done.[1] The inquiry is personal to the plaintiff-patient and the treating physician and, as a matter of law, is evaluated subjectively.

While Plaintiffs concede that Abbott's duty to warn "is defined by the 'learned intermediary' doctrine," and "a drug company is only obligated to 'warn prescribing physicians of the drug's known dangerous propensities,'" Opp. at 3 (quoting A.20, ¶ 43), Plaintiffs confuse the straightforward causation

[1] As Abbott explained in its opening brief, the question what the treating physician *should have done* is relevant in a *medical malpractice* claim against the treating physician, but is irrelevant in a failure-to-warn claim against the prescription drug manufacturer. The First District below blurred that key distinction, and Plaintiffs repeat the error in their brief here.

analysis that follows. First, they challenge the question itself, suggesting that this Court "has not weighed in on" how the learned intermediary doctrine impacts proximate cause analysis. Opp. at 5. But that is precisely why this Court granted review of that critical question.

Then, they confuse the answer. This Court should hold that the learned intermediary doctrine applies in Illinois the same way it applies in the overwhelming number of states catalogued in Abbott's opening brief. Because the undisputed evidence at summary judgment makes clear that *these doctors* treating *this patient* would not have done anything differently even if presented with Plaintiffs' preferred warnings, Plaintiffs have failed as a matter of law to meet their burden on proximate causation. *See* Abbott Br. at 7, 19; A.9, 28, 35 (treating physicians' testimony that Mrs. Muhammad's psychotic episodes were so severe that she was in significant danger of hurting herself or others, and because they believed she was using effective birth control, they would not have changed their prescribing decisions). Plaintiffs proffered no contradictory evidence from Mrs. Muhammad's physicians, instead pointing to Dr. Nasr's late-in-the-game affidavit speculating about what a hypothetical reasonable doctor would have done. But that analysis is wholly irrelevant to the question what Mrs. Muhammad's prescribing physicians in fact would have done here. Speculation about a hypothetical doctor from someone who had no relationship with the patient does not contradict unwavering testimony from the patient's own treating physicians about what their subjective

judgment would have been for their patient. The physicians' testimony, then, breaks the chain of causation between any alleged failure to warn and Plaintiffs' injuries. *See* Abbott Br. at 31-33; *Motus v. Pfizer Inc.,* 196 F. Supp. 2d 984, 997-98 (C.D. Cal. 2001) (collecting cases), *aff'd*, 358 F.3d 659 (9th Cir. 2004); *In re Zyprexa Prods. Liab. Litig.*, 727 F. Supp. 2d 101, 114 (E.D.N.Y. 2010) (collecting cases); *Cooper v. Bristol-Myers Squibb Co.*, 2013 WL 85291, at *6 (D.N.J. Jan. 7, 2013); *Vaughn,* 2020 WL 5816740, at *4. Despite Plaintiffs' arguments to the contrary, that is the end of the issue.

That outcome aligns Illinois with a majority of other states that (1) adopt the learned intermediary rule; and (2) hold that the chain of causation is broken when a different warning would not have altered the prescribing physician's decision. *See* Abbott Br. at 16-18.

B. The Learned Intermediary Doctrine Applies And Negates Proximate Causation.

Plaintiffs disingenuously claim that Abbott "concedes" "that its warnings were inadequate," Opp. at 4, and contend that, as a result of the purported admission, the learned intermediary doctrine does not apply. That argument is factually and legally wrong. The learned intermediary doctrine applies *and* is fatal to Plaintiffs' claims.

As a matter of fact, Abbott has never conceded that its warnings—which included an FDA-mandated Black Box Warning about spina bifida (the most

stringent warning available), among other birth defect warnings[2]—were inadequate. *See, e.g.,* C357 n.2. Plaintiffs mischaracterize the undisputed facts regarding Depakote's label. *See* Opp. at 1. To clarify: At the time Mrs. Muhammad became pregnant, the Depakote label warned, in a Black Box Warning, of a 1-2% risk of spina bifida (the injury C.M. ultimately experienced). Plaintiffs do not dispute the accuracy of this number. *See* C259. The label *also* explicitly warned of the risk of other birth defects "compatible and incompatible with life," though it did not quantify those risks. *Id.* Plaintiffs' complaint is that the label should have quantified the *total* risk of *all* birth defects in addition to quantifying the risk of spina bifida.[3]

Regardless, as a matter of law, the adequacy of the warning is not relevant to the issue in this appeal. That is because the legal question here turns on *causation*, and the uncontroverted facts show that the chain of causation has been broken. *Even if* Mrs. Muhammad's physicians were given

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[2] "Black Box Warnings, also called 'boxed warnings,' are the FDA's most stringent warnings for drugs and medical devices in marketplace. Black Box Warnings are intended to alert the public and health care providers that certain medications carry serious adverse reactions, such as injury or death." *Solomon v. Ctr. for Comprehensive Servs., Inc.*, 2023 IL App (5th) 210391, ¶ 7 n.2 (describing Depakote labeling).

[3] If anything, it was *Plaintiffs* who conceded that Abbott's warnings were *adequate*. Plaintiffs failed to disclose any expert to testify regarding the adequacy of the warning, notwithstanding that Illinois law requires expert testimony to create a genuine issue of fact on that issue and in this context. *See Stephens v. CVS Pharmacy*, 2009 WL 1916402, at *2 (N.D. Ill. June 11, 2009) ("[A] party attempting to create a genuine dispute that the warning was inadequate must offer expert testimony in support.") (citing *N. Tr. Co. v. Upjohn Co.*, 213 Ill. App. 3d 390, 404-05 (1st Dist. 1991)). *See, e.g.,* C333 n.2.

the different warning that Plaintiffs claim was required—that is, even if the label included everything Plaintiffs want—Mrs. Muhammad's physicians would not have changed their course of treatment. This breaks the chain of causation between the manufacturer and the patient as a matter of law.

Plaintiffs seek to avoid this outcome by tossing aside the learned intermediary doctrine entirely, claiming that it "does not apply" in this case. Opp. at 4. But it squarely does. Indeed, the doctrine—which is well-established in Illinois and throughout the country—is rooted in the rationale that the treating physician is best positioned to "weigh[] the benefits of any medication against its potential dangers" and make an "individualized medical judgment bottomed on a knowledge of both patient and palliative." *Kirk* 117 Ill. 2d at 518 (quoting *Stone v. Smith, Kline & French Labs.*, 731 F.2d 1575, 1579-80 (11th Cir. 1984)). In other words, it is designed to apply precisely to this type of case.

The learned intermediary doctrine necessarily impacts the proximate cause analysis in a failure-to-warn case like this one. It is a core tenet of causation that plaintiffs are required to show that a different warning, if given, would have prevented their injuries. This is true both in the prescription drug context and elsewhere: A failure to read warnings given, for example, is an intervening cause that negates proximate cause. *See* Abbott Br. 23-24; *Kane v. R.D. Werner Co.*, 275 Ill. App. 3d 1035, 1037 (1st Dist. 1995) (affirming grant of summary judgment where "alleged inadequate content" of a warning "could

not have proximately caused [the plaintiff's] injuries"). In the pharmaceutical failure-to-warn context, the prescribing physician's independent medical judgment and decision-making provide an additional gloss on causation, because the learned intermediary's medical expertise stands between the manufacturer's warning and the patient taking the medicine. The presence of a physician's independent medical decision is both the reason for the doctrine and a key part of the chain of causation. Thus, "the plaintiff must be able to prove that if there had been a proper warning, the learned intermediary . . . would have declined to prescribe or recommend the product." *Vaughn*, 2020 WL 5816740, at *4.

Plaintiffs' assertion that the learned intermediary doctrine does not apply rests on a single non-binding case, *Giles v. Wyeth Inc.*, 500 F. Supp. 2d 1063 (S.D. Ill. 2007). But that decision can be read consistently with Abbott's position. *Giles* states (correctly): "In failure to warn cases, courts regularly grant summary judgment when the physician's testimony shows unequivocally that s/he knew at the relevant time *all* the information which would have been included in a proper warning." *Id.* at 1066 n.3 (internal quotation marks omitted). But the facts in *Giles* included physician testimony that a different warning *would have changed his prescribing behavior*, *id.* at 1069-70, so application of the learned intermediary doctrine simply did not preclude liability on those facts. The law is the same. *Giles* applies exactly the test that Abbott proposes. Only the facts are different, with the physicians here, unlike

Giles, testifying that Plaintiffs' additional warning would *not* have changed their decision to prescribe Depakote. Applying the rule that Abbott proposes would not have changed the outcome in *Giles*.

Plaintiffs also raise *Hansen v. Baxter Healthcare Corporation*, 198 Ill. 2d 420 (2002), which *Giles* cites, to argue that Mrs. Muhammad's treating physicians were not learned intermediaries. Particularly, Plaintiffs claim that "doctors who receive insufficient warnings 'cannot be considered learned intermediaries.'" *Giles*, 500 F. Supp. 2d at 1066 (quoting *Hansen*, 198 Ill. 2d at 432). Plaintiffs use this statement to argue that, where a warning is inadequate, the learned intermediary doctrine does not apply to any aspect of a failure-to-warn claim. Opp. at 4.

But *Hansen*'s statement addressed whether the medical community as a whole had sufficient knowledge of the risks associated with a medical device to conclude that the "manufacturer need not provide a warning of risks already known to the medical community." 198 Ill. 2d at 430. The question in *Hansen* was whether the manufacturer was relieved of its duty to provide any warning at all, because the risks were known throughout the medical community. That duty question is distinct from the issue of proximate cause here—something the *Hansen* court recognized when it determined it did not need to even address proximate cause in that case. *Id.* at 429. Indeed, Plaintiffs' argument that the learned intermediary doctrine does not apply where the prescribers allegedly received "insufficient warnings" would negate the doctrine entirely, because

the doctrine applies in failure-to-warn cases, which by definition involve allegations that the warnings were inadequate.

Misapplying *Giles* and *Hansen*, Plaintiffs argue that the factual question of what the doctors would have done had they received the allegedly adequate warning would do is irrelevant. Opp. at 4. That eviscerates the element of causation, which requires a plaintiff to show "that the presence of adequate warnings would have prevented the plaintiff's injuries." *Broussard*, 183 Ill. App. 3d at 744.

Aside from their misreading of *Giles* and *Hansen*, Plaintiffs offer no legal support for their position. They make no attempt to address the numerous cases cited in Abbott's opening brief, in which courts have granted summary judgment on proximate cause where the adequacy of the warning either was not at issue or where the court expressly assumed the warnings were inadequate. Abbott Br. at 16-18; *see e.g.*, *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 212 (5th Cir. 2008) (declining to decide if there was a genuine dispute as to whether a label was misleading where doctor testified unequivocally his treatment "would not have changed . . . even had the warning been stronger"); *Vaughn*, 2020 WL 5816740, at *4 ("[T]he plaintiff must be able to prove that *if there had been a proper warning*, the learned intermediary. . . would have declined to prescribe or recommend the product.") (emphasis added); *In re Plavix Mktg., Sales Pracs. & Prods. Liab. Litig. (No. II)*, 2017 WL 3531684, at *7 (D.N.J. Aug. 17, 2017) (granting summary judgment where there was no

evidence "to suggest that a different warning would have led his doctor to alter the treatment for [p]laintiff" even when defendant did not challenge plaintiffs' contention that label was inadequate). Plaintiffs' argument ignores the vast weight of the case law, and it should be rejected.

C. Plaintiffs Cannot Defeat Summary Judgment By Arguing That The Jury May Not Find The Treating Physicians' Testimony Credible.

To survive summary judgment on causation, Plaintiffs had to demonstrate a genuine factual dispute about whether *Mrs. Muhammad's physicians* would have prescribed Depakote if given an additional warning. They failed to do so. The unequivocal testimony from Mrs. Muhammad's physicians is that they would not have made a different prescribing decision, even if Abbott had provided the warnings Plaintiffs claim were required.

Seeking to create a fact dispute where none exists, Plaintiffs argue—for the first time in this appeal—that they can survive summary judgment simply because a jury might not believe the doctors' testimony. As a threshold matter, the Court need not consider this argument because it was forfeited when it was not raised before the trial and appellate courts below. *See Dineen v. City of Chi.*, 125 Ill. 2d 248, 266 (1988) (declining "to consider . . . an argument that was not presented in the proceedings below"); *Cholipski v. Bovis Lend Lease, Inc.*, 2014 IL App (1st) 132842, ¶ 57 (party forfeited argument "by failing to raise it below").

But even considered, this argument does not create a genuine issue of material fact, because Plaintiffs have no contradictory evidence supporting

proximate cause. Plaintiffs' brief spends several pages manufacturing "inconsistencies" in the physicians' testimonies, which Plaintiffs claim support that "a jury *could* conclude that their assertions are unbelievable." Opp. at 8-12 (emphasis added). But poking holes is not enough at this stage. Summary judgment requires contested *facts*: ""To survive a motion for summary judgment, the nonmoving party *must come forward with evidentiary material* that establishes a genuine issue of fact.' The nonmoving party cannot simply deny the moving party's factual allegations." *Goodrich Corp. v. Clark*, 361 Ill. App. 3d 1033, 1044 (4th Dist. 2005) (emphasis added) (citations omitted); *see also Prince v. Wolf*, 93 Ill. App. 3d 505, 509 (1st Dist. 1981) ("Even if the complaint and answer purport to raise an issue of fact, summary judgment is, nevertheless, appropriate if such issues are not further supported by evidentiary facts through affidavits or other proper materials.").

A challenge to the credibility of a witness does not a contested question of fact make—or, stated more colorfully, "a party cannot create a genuine issue of material fact by arguing that a witness is not credible. . . . Trials don't happen based on 'liar liar pants on fire.'" *Gonzalez v. Scaletta*, 2021 WL 4192065, at *13 (N.D. Ill. Sept. 15, 2021). "[W]hen challenges to witness' credibility are *all* that a plaintiff relies on, and he has shown no independent facts—no proof—to support his claims, summary judgment in favor of the defendant is proper." *Springer v. Durflinger*, 518 F.3d 479, 484 (7th Cir. 2008).

Summary judgment is how other courts have resolved this argument in failure-to-warn cases. For example, in *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360 (S.D. Fla. 2007), the plaintiff argued that a genuine issue of fact existed as to causation because the treating physician was "misled by [a medical device manufacturer] into believing that the product worked better than it actually did," which plaintiff claimed caused his injuries. *Id.* at 1370. The court rejected this because the treating physician testified unequivocally that "none of [the manufacturer's] marketing materials influenced his decisions in any fashion," and the plaintiff did not produce "any evidence in the record to create an issue of material fact." *Id.* "Speculation and hypothesizing" without concrete evidence could not and did not "suffice to create a genuine issue of fact." *Id.* at 1371*; see also Miller v. Pfizer Inc.*, 196 F. Supp. 2d 1095, 1123 (D. Kan. 2002), *aff'd*, 356 F.3d 1326 (10th Cir. 2004) ("Plaintiffs' hope . . . that the jury will disbelieve [the treating physician], is insufficient to survive summary judgment.").

Multiple courts have rejected the exact line of cases Plaintiffs cite, *Golod v. Hoffman La Roche*, 964 F. Supp. 841 (S.D.N.Y. 1997) and *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71 (2d Cir. 1993), both of which held that a drug or medical device manufacturer could be liable for failure to warn even where a learned intermediary testified he would not have changed his prescribing decision. The courts have done so because a plaintiff is required "to refute [the treating physician's] testimony, not just undermine its credibility." *Garrison*

v. Novartis Pharms. Corp., 30 F. Supp. 3d 1325, 1337 (M.D. Ala. 2014). As one court explained, both *Golod* and *Bravman* misapplied precedent in determining a doctor's testimony can only support summary judgment where it is "self-disserving." But the principle that only self-disserving testimony is trustworthy applies *where the doctor is a defendant*. *In re Plavix*, 2017 WL 3531684, at **7-8. That is precisely the error this Court should avoid (and which the appellate court made below, when it held that it "makes no difference" that this was a failure to warn case, not a medical malpractice case (A22, ¶ 47)).

Golod and *Bravman* erred in applying this principle to a failure-to-warn claim "without explaining why the credibility of a disinterested witness should be questioned simply because the doctor treated the plaintiff." *In re Plavix*, 2017 WL 3531684, at *8. As that court explained, such a rule would mean "summary judgment would never be granted in these types of cases, because a third-party prescriber's testimony would always be subject to doubt, unless the prescriber testified he or she would not have prescribed the drug." *Id.* "Such a one-sided result for a disinterested physician's testimony cannot be correct." *Id.* This Court should similarly reject Plaintiffs' attempt to impose the *Bravman* and *Golod* rationale.[4]

[4] Plaintiffs' cases are also readily distinguishable on important facts. For example, in *Golod*, the treating physician's testimony was not unequivocal, it was "ambiguous" and did not "amount to an assertion that he would have prescribed the drug to [plaintiff] in the face of a risk of blindness." 964 F. Supp. at 857. And in *In re Prempro Products Liability Litigation,* which Plaintiffs

D. Plaintiffs' Attacks On The Prescribing Physicians' Credibility Do Not Change The Legal Analysis.

At bottom, Plaintiffs' discussions of Dr. Allen's and Dr. Stepansky's testimony boils down to nothing more than mere "[s]peculation and hypothesizing," *Beale*, 492 F. Supp. 2d at 1371, about how the physicians *should have* acted. These arguments about what prescribing physicians should have done belong in a medical malpractice suit, and are ultimately irrelevant to resolving this *failure to warn* case against Abbott. Abbott addresses Plaintiffs' manufactured inconsistencies to make clear they do not impact the legal analysis in this case.

Plaintiffs claim that Dr. Allen's testimony is not material because he did not physically evaluate or personally discuss the prescription with Mrs. Muhammad. Opp. at 9. Notwithstanding that Dr. Allen was the *supervising* physician, this criticism is irrelevant to whether Dr. Allen's prescribing decision (as the supervising physician) would have changed with an additional warning. Plaintiffs do not dispute that Dr. Allen would have still approved the Depakote prescription even with an additional warning because Mrs. Muhammad was taking reliable birth control.

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also cite, there was a material disputed question whether one of the physicians would "have prescribed [the medication] to [p]laintiff in the same amount, and for the same length of time—both key points." 2006 WL 1981902, at *2 (E.D. Ark. July 13, 2006). Further, the *Prempro* physician actually testified that her understanding of appropriate dosages and duration for the medicine at issue had changed in the time since she prescribed the medicine to the plaintiff. *Id.*

The same is true for Plaintiffs' attempts to undermine Dr. Stepansky's testimony. Plaintiffs insinuate that Dr. Stepansky testified inconsistently between this case and his deposition in the *Northwestern* medical malpractice case. Plaintiffs suggest that this inconsistency creates a genuine dispute of material fact. Opp. at 10-11; *see* Appellees' Appendix at A007-039. There is no such inconsistency. This and the *Northwestern* case involved different issues, and Dr. Stepansky was asked different and additional questions in his deposition in each. *Compare* Appellees' Appendix at A022, *with* A.28. The additional details Dr. Stepansky provided do not contradict his prior testimony on the issue and cannot carry Plaintiffs' burden to produce actual evidence establishing a genuine dispute of fact. *See Dunn v. Menard, Inc.*, 880 F.3d 899, 911 (7th Cir. 2018) (determining additional details regarding scene of accident provided in affidavit did not contradict previous deposition testimony).

Nor can Plaintiffs' broadside attack on the doctors' credibility save their claims.[5] *See* Opp. at 9-12. While these grievances regarding Dr. Stepansky's

[5] Plaintiffs are wrong that the physicians' testimony that they would not have changed their prescribing decision is not credible in the first place. It is undisputed that Mrs. Muhammad's psychiatric symptoms were severe, and that she was at risk of harming herself and others. It is further undisputed that they in fact prescribed the medicine despite a Black Box Warning that Plaintiffs effectively concede was accurate concerning the risk of spina bifida—the primary birth defect at issue. Her prescribing physicians understood that she was using reliable birth control, which was being monitored by Mrs. Muhammad's treatment team, and they believed that negated any birth defect risk. Consequently, it is not incredible to believe that there was no difference in the physicians' mind between levels of overall birth defect risk. Given these realities, a birth defect risk of any amount would not have changed the prescribing decision.

decision-making process may be relevant to a medical malpractice case (which Plaintiffs already brought and won), they have no relevance in evaluating whether Dr. Stepansky would have acted differently had he received a different warning. There is no ambiguity or dispute as to what Dr. Stepansky would have done with an additional warning. He provided unequivocal testimony answering that very question.

E. Plaintiffs' Expert Affidavit Does Not Rebut The Treating Physicians' Testimony As A Matter Of Law.

Plaintiffs spend remarkably little time defending the grounds on which the First District actually held in their favor: that their purported expert's affidavit, which Plaintiffs submitted at the eleventh-hour with their opposition to Abbott's summary judgment motion, created a material fact question. This argument suffers the same basic problem as Plaintiffs' other fact-based attacks: it ignores the central legal issue. Dr. Nasr's opinion (as to what a hypothetical reasonable physician should have done) is irrelevant to the operative legal question of what *Mrs. Muhammad's treating physicians* actually *would have* done with different warnings, and thus cannot create a genuine issue of material fact on proximate cause. Abbott Br. at 20-24. This case is about what actually happened, *not* what the physicians should have done.

Expert opinion regarding what a putative "reasonable physician would do" does not "create[] a triable issue as to proximate cause" in a pharmaceutical failure-to-warn case because "[t]he question in the learned intermediary

context is not what an objective physician would decide, but rather what *[the] plaintiff's doctor* would determine based on *his* knowledge of the drug in question and the plaintiff's risk factors." *Stafford v. Wyeth,* 411 F. Supp. 2d 1318, 1322 (W.D. Okla. 2006) (emphasis added); *see also* Abbott Br. at 21-22 (collecting cases). This is consistent with this Court's case law applying the learned intermediary doctrine, because a plaintiff's prescribing physician is responsible for making an "individualized medical judgment" in weighing the benefits and risks of a particular drug. *Kirk*, 117 Ill. 2d at 518.

Plaintiffs do not even attempt to address the overwhelming precedent Abbott has cited holding that an expert opinion does not create a genuine issue of material fact in causation-related circumstances nearly identical to these. *See* Abbott Br. at 20-24. Instead, like the First District below, Plaintiffs rely exclusively on medical malpractice cases which, of course, address a different (and, in this context, irrelevant) legal question. Medical malpractice cases apply a different standard. *See* Abbott Br. 24-28. Those cases ask whether a hypothetical "reasonable physician," applying professional standards of care, would have acted in the same way that the plaintiff's physician did; failure-to-warn cases, by contrast, ask whether the plaintiff's physician would have in fact made a different decision if given a different warning. That is why medical malpractice cases *require* expert testimony on this point—because "a lay juror is not skilled in the profession and thus is not equipped to determine what constitutes reasonable care in professional conduct without the help of expert

testimony." *Snelson v. Kamm*, 204 Ill. 2d 1, 42 (2003). The same is not true for the inherently subjective question what this treating physician would have done for this patient if given a different warning.

Plaintiffs' opposition relies heavily on *Snelson*, Opp. at 14-15, which the court below did not even cite. But *Snelson* is also a medical malpractice case. 204 Ill. 2d at 43-44 ("[E]xpert testimony is necessary *in professional negligence* cases to establish the standard of care and that its breach was the proximate cause of the plaintiff's injury.") (emphasis added). *Snelson* says nothing about the effect (or lack thereof) of expert testimony on the issue of proximate cause in a pharmaceutical failure-to-warn case. The same is true for the other cases Plaintiffs cite—*Buck v. Charletta*, 2013 IL App (1st) 122144, and *Shicheng Guo v. Kamal*, 2020 IL App (1st) 190090—which are both medical malpractice cases that address what the defendant physician *should have* done, not what a third-party physician actually *would have* done with a different warning.[6]

Indeed, the policy reason informing the medical malpractice standard—that a doctor may give self-serving testimony in a case in which he is a defendant, *see* Opp. at 15-16—does not apply here, where the treating physicians are not defendants. *See* Abbott Br. at 26-27; *In re Plavix*, 2017 WL 3531684, at *8.

[6] Plaintiffs do not even acknowledge Abbott's arguments that they greatly overread both *Buck* and *Schicheng Guo*, let alone rebut them. As explained in Abbott's opening brief, both cases involved a dispute of factual evidence and did not rely on expert testimony alone to establish a genuine dispute existed on the essential element of proximate cause. *See* Abbott Br. 27-30.

Plaintiffs' cases thus stand only for the proposition that a plaintiff can "present expert testimony as to what a reasonably qualified physician would do" to "discredit" the defendant-physician's testimony regarding his decision-making *when determining whether the treating physician or hospital were professionally negligent* because such expert testimony is *required* to establish the elements of a professional negligence claim. *Snelson*, 204 Ill. 2d at 46. Plaintiffs have already recovered for what they actually claim caused their harm—a course of treatment that departed from what a "reasonable physician" should have done—in the separate *Northwestern* suit. *See* Abbott Br. at 36-39.

The court below erred in exactly the way that Plaintiffs' brief does here, by suggesting that the causation standard applicable to medical malpractice claims could be grafted onto failure-to-warn claims because the type of claim "makes no difference." A.22, ¶ 47. The type of claim at issue makes a fundamental difference. The question what Mrs. Muhammad's physicians would have actually done is borne out by their own unequivocal testimony. This Court should reverse the First District's decision.

F. The Heeding Presumption Does Not Apply Or Change The Result.

The Court need not and should not address or adopt the heeding presumption. *See* Abbott Br. at 33-35. Plaintiffs concede that the presumption does not help their case, and they all but abandon any argument supporting it. After spending several pages of their briefing explaining the heeding presumption, Plaintiffs concede that this Court "has not adopted the heeding

presumption theory," Opp. at 5, and therefore has no obligation to apply it. Plaintiffs also acknowledge that even if the presumption applied, it is rebuttable "through testimony of the prescribing physician that he or she would have not taken a different course of action even if there had been stronger warning." *Id.* In other words, the presumption can and would be rebutted through the precise testimony here. *See* Abbott Br. at 35-36. It is no surprise, then, that Plaintiffs ultimately relinquish the argument altogether, saying that this Court need not reach this issue. Opp. at 6.

The heeding presumption was not a basis for the decision below. Abbott Br. at 33. And application of the presumption creates thorny issues better resolved for the first time by a lower court. For example, it is not even clear what it means for a prescribing physician to "heed" a proposed warning, especially when significant warnings regarding the same risk were already in place. *See* Abbott Br. at 34-35. Further, even if the Court were inclined to consider the issue and adopt the heeding presumption for the first time—an endeavor both parties agree is unnecessary—any presumption is rebutted here by the physicians' testimony that a different warning would not have changed their treatment decisions. *See Eck v. Parke, Davis & Co.*, 256 F.3d 1013, 1021 (10th Cir. 2001) (heeding presumption rebutted by prescriber testimony "that even if she knew [plaintiff] was taking a drug with a more frequent [risk], *she would have still prescribed*" the drug).

II. JUDICIAL ESTOPPEL IS NOT AT ISSUE IN THIS APPEAL, AND REVERSAL IS THE EQUITABLE RESULT.

Seeking to further confuse the simple legal question presented by this appeal, Plaintiffs attack a straw man that Abbott has not raised. While judicial estoppel was litigated below, it was *not* an issue in Abbott's Petition for Leave to Appeal or opening brief. Rather, Abbott argued only that the result it proposes—maintaining the distinction between medical malpractice cases, which ask the objective question what the treating physician *should have done*, and failure to warn cases, which ask the subjective question whether the treating physician *would have changed course*—is equitable. *See* Abbott Br. at 36-39. That is because, as here, clearly defining the separate causation inquiries in these two types of torts does *not* leave injured plaintiffs without recourse.

The application of the subjective learned intermediary standard to failure to warn cases, and application of the objective professional negligence standard in medical malpractice cases, ensure that the right defendants are held to account based on the information and decisions they actually control. That is not an argument for judicial estoppel, but for fundamental fairness. Plaintiffs' separate medical malpractice case makes clear that Abbott's proposed outcome is both the right one *and* the fair one.

CONCLUSION

For the foregoing reasons, the Court should reverse the decision of the First District Appellate Court.

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Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

I, Lauren J. Caisman, an attorney for Appellants Abbott Laboratories Inc. and Abbvie Inc., hereby certify that this Brief conforms to the form and length requirements of Rule 341. The length of this Brief, excluding the pages containing the Rule 341(d) cover, 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 5,699 words.

/s/ *Lauren J. Caisman*
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NOTICE OF FILING/CERTIFICATE OF SERVICE

The undersigned hereby certifies that on the 5th day of July, 2023, I electronically submitted a true and correct copy of the foregoing *Appellants' Reply Brief* to the Clerk of Court using the Court's approved electronic filing service provider.

The undersigned hereby further certifies that one copy of the *Appellants' Reply Brief* were served via electronic mail and U.S. Mail on the 5th day of July, 2023, to the following counsel/parties of record to this appeal:

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Under penalties as provided by law pursuant to Section 1-109 of the Code of Civil Procedure, the undersigned certifies that the statements set forth in this Notice of Filing/Certificate of Service are true and correct.

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