No. 128841

IN THE SUPREME COURT OF ILLINOIS

CHARLES MUHAMMAD AND ANGIE MUHAMMAD, AS PARENTS OF C.M., a minor, and C.M., Individually,

Respondent-Appellee,

v.

ABBOT LABORATORIES INC. and ABBVIE INC.,

Petitioners-Appellants.

On Grant of Petition to Appeal from the Appellate Court of Illinois, First Judicial District No. 1-21-0478

There on appeal from the Circuit Court of Cook County No. 2019-L-6254

The Honorable Brendan A. O'Brien, Judge Presiding

BRIEF *AMICUS CURIAE* OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. IN SUPPORT OF PETITIONERS-APPELLANTS

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STATEMENT OF INTEREST OF *AMICUS CURIAE*

The Product Liability Advisory Council, Inc. ("PLAC") is a non-profit professional association of corporate members representing a broad cross-section of American and international product manufacturers.[1] These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products and those in the supply chain. PLAC's perspective is derived from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. In addition, several hundred of the leading product litigation defense attorneys are sustaining (non-voting) PLAC members. Since 1983, PLAC has filed more than 1,200 briefs as *amicus curiae* in both state and federal courts, including this Court, on behalf of its members, while presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product risk management.

BRIEF SUMMARY OF FACTS RELEVANT TO POINT ARGUED

In reversing the grant of summary judgment by the Circuit Court of Cook County, the First District Appellate Court found the following:

Ms. Muhammad suffered from bipolar and schizoaffective disorders. App. Op. ¶ 4. She was being treated for those disorders, but the antipsychotic medication she was taking was not controlling her symptoms. *Id.* In a five-month period, between January and May 2005, she was hospitalized four times with "acute psychotic symptoms, including auditory

[1] See PLAC, *Amicus Program*, available at https://plac.com/PLAC/PLAC/Amicus.aspx.

hallucinations and suicidal and homicidal ideation." *Id.* ¶ 3. At the time, she had two young children at home. *Id*. Tragically, a recent study published in JAMA Psychiatry confirms both suicidal ideation and intentional self-harm are on a significant upward trajectory among women during and following pregnancy. Admon, L., *et al.*, *Trends in Suicidality 1 Year Before and After Birth Among Commercially Insured Childbearing Individuals in the U.S.*, 2006-17, 78(2) JAMA Psychiatry, Feb. 2021, 171–76 (noting that among those with comorbid bipolar or psychotic disorders, suicidality increased from 6.9 percent per hundred in 2006 to 16.9 percent per hundred in 2017, and that overall, suicide accounts for 6.5 percent of maternal deaths).

Dr. Stepansky, a second-year psychiatric resident who was supervised by Dr. Marcia Brontman initially and then by Dr. Thomas Allen, treated Ms. Muhammad. App. Op. ¶¶ 5, 8. To ensure he accounted for any language barrier, Dr. Stepansky referred Ms. Muhammad for an assessment by a Spanish-speaking psychiatrist, Dr. Pedro Dago. *Id.* ¶ 5. Dr. Dago recommended either Depakote or lithium, and after evaluating those medications and a third option, Tegretol, Dr. Stepansky determined Depakote was the best medication for her. *Id*.

Depakote carried a "black box warning" regarding its potential to cause birth defects, including spina bifida, in its insert and in the Physician's Desk Reference. *Id*. ¶ 6.[2] A black box warning is the most strenuous warning the Food and Drug Administration requires pharmaceutical companies to include on their labels. Consistent with the black

[2] The FDA approved Depakote in early 1983 and designated it a "Pregnancy Category D" drug long before Ms. Muhammad was prescribed the medication. See *Rheinfrank v. Abbott Laboratories, Inc*., 680 F. App'x 369, 371-72 (6th Cir. 2017) (listing 2003 Black Box warning).

box warning, Dr. Stepansky warned Ms. Muhammad not to become pregnant because of the risk of birth defects with the medication he was prescribing to her. *Id*. ¶ 7. Ms. Muhammad assured her treating physician that she did not want to become pregnant and was using a contraceptive patch to keep from becoming pregnant. *Id*. ¶¶ 5, 7. Both Dr. Stepansky and the nurse could monitor compliance with the birth control patch because Ms. Muhammad was visiting the clinic weekly. *Id*. ¶¶ 4, 7.

Despite these precautions, Ms. Muhammad became pregnant, and her son was born with the warned-about birth defect, spina bifida. *Id*. ¶ 9. He also has other physical and cognitive impairments that a neurologist attributed to Depakote. *Id*. Spina bifida is a neural tube defect that itself can cause physical and intellectual disabilities. Centers for Disease Control and Prevention, *What is Spina Bifida?*, available at https://www.cdc.gov/ncbddd/spinabifida/facts.html.

In 2012, Plaintiffs sued Northwestern and Dr. Allen. While that case was preparing to go to trial, Plaintiffs filed and then dismissed without prejudice a suit against Abbott. The *Northwestern* suit went to trial in 2019, where Plaintiffs convinced a jury that the doctors had failed to satisfy the standard of medical care in their treatment of Ms. Muhammad. In this suit, in contrast, Plaintiffs claim that the birth defect should be attributed to Abbott's allegedly inadequate warning. Plaintiffs assert that two studies, one of epileptic women looking at birth defects of any type and another study showing malformations of some sort, should have been expressly reflected on the label. App. Op. ¶ 15. Plaintiffs acknowledge that the label accurately reported the risk of spina bifida, but they contend that the label's warning that "OTHER CONGENITAL ANOMALIES (EG, CRANIOFACIAL DEFECTS, CARDIOVASCULAR MALFORMATIONS AND

ANOMALIES INVOLVING VARIOUS BODY SYSTEMS), COMPATIBLE AND INCOMPATIBLE WITH LIFE, HAVE BEEN REPORTED" was not sufficiently specific. The failure to warn claim was based on an expert's opinion that placing statistics from those two studies on the label—as opposed to the 1-2 percent risk of spina bifida and the unquantified warning of other potential birth defects—would have changed the risk-benefit calculus such that Ms. Muhammad ***would not have been prescribed Depakote***.

That opinion was, however, contradicted by the factual testimony of Ms. Muhammad's treating doctors, who testified unequivocally under oath that they would have prescribed Depakote for Ms. Muhammad even if Abbott had changed its warning in the manner Plaintiffs proposed. *Id*. ¶¶ 16–17. Under well-established principles of tort and product liability law, this broke the causal chain between any allegedly deficient warnings and the alleged injury.

Seeking to change well-established principles of Illinois law, Plaintiffs' expert opined that regardless of whether the treatment decision ***would*** have changed, it ***should*** have changed, which is to say that a "reasonable" physician would have responded to the amended warning by declining to prescribe Depakote at all. *Id*. ¶ 18. Plaintiffs argued that their experts' opinion created a factual dispute about the effect of a different warning, a novel proposition with which the Court of Appeals agreed. *Id*. ¶ 47. Said differently, if this opinion were to stand, it would not matter that there is no dispute of fact as to what the treating physicians' medical judgment was and whether a different warning would have changed it. Instead, a jury would be given the task of weighing the reasonableness of the doctor's judgment and would determine whether a ***manufacturer*** was liable based on its assessment of the reasonableness of a ***doctor's*** judgment.

The learned intermediary doctrine arose because medicine is complex on multiple levels. In an average product liability case, a consumer purchases a product that he or she chose to accomplish a specific purpose and alleges that a defect in the product injured the purchaser. In contrast, the predicates for prescriptions is that a patient has sought care from doctors who are licensed and regulated by states, and the doctor will choose the prescription based on the severity of the patient's ailment and many other factors. The drugs that the doctors prescribe are in turn federally regulated. Only after the FDA has reviewed extensive research about a drug, and only subject to its continued monitoring, can a drug be prescribed at all, and then only if the label is approved by the FDA. From professional education, experience, and ongoing information from many sources—as well as the label—the doctor applies specialized knowledge and independent professional judgment to assess how to treat a specific patient's condition and circumstances, including what to prescribe.

The learned intermediary doctrine thus serves the salutary and essential function of separating the basis for liability that can be laid at the feet of a doctor from the basis of liability that can be laid at the feet of a manufacturer to reflect the reality of their respective relationships with the patient. Measuring the "reasonableness" of a doctor's judgment in order to measure the liability of a manufacturer collapses and conflates the liability analysis, and PLAC urges this Court to hold that the Court of Appeals blurred the distinction in a manner incompatible with the learned intermediary doctrine in general and as this Court has adopted, construed, and applied it.

ARGUMENT

This case involves warnings a prescription drug manufacturer included in its label. Illinois has long recognized that manufacturers of prescription drugs have no duty to warn

patients directly about the risks of such drugs. Instead, the manufacturer's label is for a treating physician to utilize in deciding how to treat—and to what extent to warn—a patient. In that regard, a treating physician stands as a learned intermediary between the manufacturer and patient. The body of law recognizing the distinct roles of manufacturer, doctor, and patient in medical treatment is called the learned intermediary doctrine.

Because the doctor is in the center of any causal chain, a plaintiff cannot establish that a change to a warning would have prevented an injury unless the different warning would have led the treating physician to make a different prescribing decision. See, *e.g.*, *Vaughn v. Ethicon*, *Inc.*, No. 20-cv-562, 2020 WL 5816740, *4 (S.D. Ill. Sept. 30, 2020) (under Illinois law, "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.").

The Court of Appeals in the decision below deviated from this longstanding rule by finding a fact issue on causation, even though the treating physicians would not have changed their prescriptions if there had been a different warning. There was no dispute of fact about that; instead, the Court of Appeals claimed that Plaintiffs' expert created a dispute of fact by opining that the treating physician ***should*** have done something different with a revised warning, even if he ***would not*** actually have done so. This makes no logical sense when the label on a prescription is at issue. By making the test of a ***manufacturer***'s liability a jury's assessment of the relative reasonableness of differing medical judgments, the court blurred the distinction between medical malpractice (***should*** the treating physician have done something different in light of the standard of care?) and prescription manufacturer product liability (***would*** the treating physician have done something different

if the drug had carried a different warning?). This Court should reverse the decision of the intermediate appellate court and reaffirm existing law.

The learned intermediary doctrine dates back nearly 75 years. At least by 1951, courts had begun to acknowledge that "[t]here is a manifest distinction between selling a medical preparation to the public, who may have no knowledge of the dangers attendant upon its use, and making available a preparation to a hospital at its request, whose physicians may be expected to have knowledge of the dangers involved in utilizing the therapeutic preparation ordered by them." *Parker ex rel. Parker v. State*, 201 Misc. 416, 422 (N.Y. Ct. Claims 1951), *aff'd*, 280 App. Div. 157 (1952). Because certain drugs and devices can be chosen and prescribed only by trained doctors—learned intermediaries—it is the doctor who needs to read a manufacturer's warning and take it into account along with all of the other details about the patient, the illness, and the pros and cons of alternative treatments. It is also the doctor who is trusted to counsel the patient, sometimes relaying only the salient part of a written warning and sometimes going far beyond a written warning's text. This results in better care than a piece of paper could provide. It also changes the way courts treat the chain of causation, because if a doctor would write the same prescription, notwithstanding the proposed modification of the warning, the suggested change would not have prevented the plaintiff's asserted injury. In the ensuing years, virtually all states have adopted or have been predicted by federal courts as likely to adopt the learned intermediary doctrine. See *Leavitt v. Ethicon, Inc.*, 524 F.Supp.3d 360, 368–69 (D. Vt. 2021) (recognizing that "48 states have adopted, or a federal court has

predicted the state's highest court would adopt, the learned intermediary doctrine" and predicting Vermont would do likewise).[3]

This Court adopted the learned intermediary doctrine over 35 years ago, in *Kirk v. Michael Reese Hospital and Medical Center*, 117 Ill.2d 507 (1987), following years of application of the doctrine by the intermediate appellate courts. *Id*. at 517–19. As the Court recognized in *Kirk*, drug manufacturers communicate warnings regarding medications to physicians, and physicians in turn exercise "medical judgment" in determining "which available drug best fits the patient's needs and [] which facts from the various warnings should be conveyed to the patient." *Id*. at 519. Indeed, because a doctor forms his or her judgment based on experience, training, and information from many sources, ***how*** a doctor comes to understand the risks of prescribing a drug or device is immaterial to the application of the learned intermediary doctrine. See, *e.g*., *Koncz v. Burroughs Wellcome Co*., No. 92-C-5797, 1994 WL 178320 (N.D. Ill. May 9, 1994). Indeed, a plaintiff must plead a doctor's reliance on a manufacturer's representations even to withstand a motion to dismiss. See *Norabuena v. Medtronic, Inc.*, 2017 IL App (1st) 162928, ¶ 38.

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[3] Although Rhode Island is cited as the other unknown state, see*, e.g.*, *Plass v. DeKalb Eye Consultants, LLC*, 2020 IL App. (2d) 190403-U, ¶ 17, the Second Circuit Court of Appeals has predicted that Rhode Island would adopt the learned intermediary doctrine as well and considers the Rhode Island Supreme Court to have impliedly recognized it. See *Greaves v. Eli Lilly & Co*., 503 F. App'x 70, 71–72 (2d Cir. 2012) (citing *Hodges v. Brannon*, 707 A.2d 1225, 1227–28 (R.I. 1998)). In *Hodges*, the Rhode Island Supreme Court recognized that a drug was not the proximate cause of a patient's death, and thus the manufacturer's "alleged failure to warn Dr. Brannon about all the potential dangers in prescribing Vasotec could not possibly have played any role" in the death. 707 A.2d at 1227–28.

Both this Court and other courts have repeatedly recognized that treating physicians can better advise patients than could cold words on product packages and inserts drafted by manufacturers. As this Court explained, the treating doctor is the one who "take[s] into account the propensities of the drug as well as the susceptibilities of his patient" and "weigh[s] the benefits of any medication against its potential dangers" "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)). A common statement of the policy rationale underlying the learned intermediary doctrine is the following:

> 1. The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor.
>
> 2. Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life.
>
> 3. It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.

Carmichael v. Reitz, 17 Cal.App.3d 958, 989 (1971) (quoting Rheingold, *Products Liability—the Ethical Drug Manufacturer's Liability*, 18 Rutgers L. Rev. 947, 987 (1964)). *Carmichael* was in turn relied on in *Mahr v. G.D. Searle & Co*., 72 Ill.App.3d 540, 639 (1979) and discussed in *Kirk*, 513 N.E. 2d at 392. The learned intermediary doctrine is thus founded in concern for the effective treatment of patients and the judicial determination of the primacy of the doctor for that purpose, particularly given the limited and remote role of the manufacturer.

When a learned intermediary stands between a manufacturer and patient, courts have recognized that the causal chain for any product liability claim necessarily runs

through the decisions of the learned intermediary. Thus, in *Kirk*, this Court discussed its earlier decision in *Greenberg v. Michael Reese Hospital* and its conclusion that the manufacturer was not liable for the plaintiff's harm. 83 Ill.2d 282, 287 (1980). In *Greenberg*, the Court reasoned that because the emphasis was not on "the defective nature of the particular X-radiation treatments in question [but] as to the appropriateness of X-radiation treatment for plaintiffs' complaints," the harm, if any, was remediable only by a negligence action against the treating physician. *Id.* at 289; see also *Kirk*, 117 Ill.2d at 522–23 (discussing *Greenberg*).

Courts in other states have employed the same approach to proximate causation in the learned intermediary context as this Court. As one New York court explained:

> Plaintiff's grievance giving rise to her viable cause of action for medical malpractice lies not with Mecta's ECT machine, but the manner of its employment by her physicians. It is their status as "responsible intermediar[ies]" that insulates Mecta from liability to plaintiff and breaks the chain of proximate cause. Any deficiency in the warnings given [to] her as to dangerous side effects of the treatment is the responsibility of these physicians, and any resulting damages are cognizable under her fifth cause of action alleging in conventional terms the absence of her informed consent to the procedure.

Andre v. Mecta Corp., 186 A.D.2d 1, 2 (N.Y. Sup. Ct., App. Div. 1992).

Under these well-established principles, Plaintiff's defective-warning claim against Abbott fails as a matter of law for lack of causation based on the testimony of the treating physicians. They testified unequivocally that even if there was a different warning about a higher incidence of birth defects, they would have prescribed Depakote for Ms. Muhammad. Depakote already had a black box warning about use during pregnancy—the strongest that the FDA requires. Moreover, Depakote was in pregnancy category "D," which prior to an FDA determination to replace letters with narratives, see 79 Fed.

Reg. 72064 (Dec. 4, 2014), meant there was "positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks." U.S. Dept. of Health & Human Services, *FDA Pregnancy Categories*, available at https://chemm.hhs.gov/pregnancycategories.htm. There was only one category (X) that was more restrictive; for those drugs, the FDA determined that the "risks involved in use of the drug in pregnant women clearly outweigh potential benefits." *Id*. Depakote's level has not changed over time. Whether it should have is, of course, for the FDA to determine, and it has not done so.

Although the Court of Appeals characterized the denial of summary judgment as necessary because of disputed ***facts*** to be resolved at trial, there is no factual dispute about the facts critical to the learned intermediary analysis. It is undisputed that Ms. Muhammad's doctor needed to make an individualized assessment whether the risks of Depakote to a woman who did not want to become pregnant, and was being actively treated and monitored to prevent pregnancy, were outweighed by the need to manage her mental illness, given the severity of her symptoms and the inferior performance of alternative medications. And there is no dispute of fact whether that happened here. The doctors knew the risks of Depakote during pregnancy, communicated to Ms. Muhammad it was important for her not to become pregnant, secured her agreement that she would not become pregnant, and discontinued Depakote's use as soon as she became pregnant. App. Op. ¶¶ 6–8, 46. The black box warning in this instance discussed both the specifically demonstrated heightened risk of spina bifida and the fact that there were also risks of

additional birth defects. *Id*. ¶ 6. That risk was already something her doctors understood and recognized as serious.

Whether other doctors would view more statistics about different birth defects on a label as tantamount to a reclassification to FDA Pregnancy Category X in their own minds does not change the fact that Depakote was and is a Pregnancy Category D drug, and ***these*** doctors undertook the risk-benefit analysis that is required for a Pregnancy Category D drug, decided Ms. Muhammad's symptoms warranted prescribing Depakote despite the risks, and would have done so based on Plaintiffs' proffered different label. A change in the manufacturer's behavior would not change the outcome here, and the ***undisputed*** facts demonstrate that Plaintiffs cannot establish proximate causation—which is why summary judgment was appropriate. If other doctors would have treated Ms. Muhammad differently on these facts, their opinions might be relevant to a malpractice suit, but not to impose liability on a manufacturer.

This Court has rejected prior attempts to eliminate the requirement of proximate causation before holding a manufacturer liable, and it should do so in this case as well. In *Smith v. Eli Lilly & Co*., 137 Ill.2d 222 (1990), for example, the Court rejected market share liability, relying in part on *Kirk*, and strongly reaffirmed that "[t]he concept that liability may be imposed based merely on a breach of duty, without causation being established, has long been rejected in American tort law." *Id*. at 266. Neither "creation of risk or breach of a duty alone" is sufficient to impose liability—and the fact that defendants are "members of the drug industry" does not excuse the requirement for causation. *Id*. The holding of the Court of Appeals poses a similar threat to the proximate causation requirement by pitting a hired expert's opinion about what a hypothetical doctor ***should***

conclude against the testimony of the treating doctor about what he or she actually ***would*** conclude, given everything that went into the original prescribing decision.

In this regard, it is instructive to look at the four other occasions on which this Court has discussed the learned intermediary doctrine, in each case careful not to allow interference in the relationship between doctor and patient. In *Frye v. Medicare-Glaser Corp*., 153 Ill.2d 26 (1992), the question was the extent of a pharmacist's obligation to warn, a responsibility this Court placed squarely upon the doctor, consistent with the learned intermediary doctrine. Four years later, the Court decided *Martin ex rel. Martin v. Ortho Pharmaceutical Corp*.,169 Ill.2d 23 (1996), where the Court was asked to carve out an exception to the learned intermediary doctrine for oral contraceptives and refused the invitation, recognizing that the question raised was one of duty. *Id*. at 239–40. The Court reiterated that "important policy considerations" undergird the learned intermediary doctrine, namely that "prescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs." *Id*. at 244.

Six-years later, the Court decided two cases, *Hansen v. Baxter Corp*., 198 Ill.2d 420 (2002) and *Happel v. Wal-Mart Stores, Inc*., 199 Ill.2d 179 (2002). In both cases, the Court concluded that the learned intermediary doctrine would not be compromised by imposing liability on the defendant. In *Hansen*, the question of manufacturer liability properly went to the jury because there were ***no*** warnings to convey that only one interconnection was appropriate in central intravenous lines, knowledge the manufacturer had, but not the medical personnel. 198 Ill.2d at 428–32.

In *Happel*, the Court found that if a pharmacy had allergy information that suggested a medication is contraindicated at the time it filled the prescription, "it has a duty to warn either the prescribing physician or the patient," which it emphasized was a "narrow duty to warn" that did not implicate the doctor's medical judgment. 199 Ill.2d at 197. Indeed, later cases in the intermediate appellate courts demonstrate that even a third party's knowledge of the ***patient*** and the ***prescription*** (neither of which the manufacturer had in this case) would not be enough to impose liability on that third party.

For example, even when a manufacturer sponsored classes about how to use a medication that discussed side effects, the Court of Appeals—and the doctor—recognized that the responsibility for warning plaintiffs about side effects rested with the doctor. *Hernandez v. Schering Corp.*, 2011 IL App (1st) 093306. Distinguishing *Happel*, the court concluded that "imposing the duty to warn of the side effects of PEG-Intron on the defendants based on the classes Schering sponsored would interject the defendants into [the patient's] relationship with Dr. Hindi." *Id*. ¶ 32. And in *Kennedy v. Medtronic, Inc*., 366 Ill.App.3d 298 (2006), a doctor violated the duty of care in the way he inserted a defect-free pacemaker lead while a representative of the manufacturer was present. The Court of Appeals emphasized that it was not the role of the representative to substitute its judgment as to where or how the surgery was performed:

> [A] central aspect of the learned intermediary doctrine, as first adopted by our supreme court in *Kirk*, is that a licensed physician, such as Dr. Salvador, has the knowledge of his patient's medical history and background, and, therefore, he is in a better position, utilizing his medical judgment, to determine a patient's needs and what medical care should be provided. It would be unreasonable, and potentially harmful, to require a clinical specialist such as Friedman to delay or prevent a medical procedure simply because she believes the setting is not appropriate or the doctor is unqualified. To hold otherwise would place a medical device manufacturer such as Medtronic in the middle of the doctor-patient relationship.

Id. at 307. What is proposed here is a more fundamental threat to the learned intermediary doctrine because Plaintiffs are arguing for liability not based on a third party's first-hand knowledge of the plaintiff—as was the case in *Happel*, *Kennedy*, and *Hernandez*—but on a hired expert's prediction of a hypothetical doctor's reaction to a hypothetical change in a manufacturer's warning in a vacuum. The more dangerous a person's symptoms are—and Ms. Muhammad included both suicidal and homicidal ideation—the more compelling identifying a prescription to treat the symptoms is. A manufacturer is not a physician. It communicates the risks of a given prescription, but if that risk materializes, that is not the fault of a label that told the doctor to exercise caution given that very risk. A primary function of the learned intermediary doctrine is to differentiate the manufacturer's liability from the doctor's. If the manufacturer can be liable for every physician's decision in the face of warned-of risk, the cost-effective choice is simply not to produce drugs with significant risks—even though those drugs might be essential to the well-being of the most severely ill. That would be unwise and contrary to Illinois law and social policy.

Illinois has already determined that manufacturers are not "insurers" of their products, *Smith*, 137 Ill.2d at 266, and that would include the risk that a doctor might mis-prescribe it. Indeed, the "mere sale of a prescription medication cannot be a representation which serves as the basis for a consumer fraud claim." *De Bouse v. Bayer AG*, 235 Ill.2d 544, 558 (2009). Instead, liability should attach to a manufacturer for its label only if a patient is injured because a doctor relied on a misrepresentation that the manufacturer made and wrote a prescription based on that reliance. Under long-established Illinois law, both the potential liability of a prescription drug or device manufacturer and the care of a patient are mediated through the knowledge and judgment of a doctor. Which is as it should be.

CONCLUSION

For the reasons set forth above, PLAC urges this Court to maintain its commitment to the learned intermediary doctrine as the best way to ensure that doctors' care for their patients is informed, independent, and patient-centered; and that it reject the holding of the Court of Appeals as inconsistent with these values and Illinois public policy.

Dated: March 8, 2023

Respectfully Submitted,

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RULE 341(c) CERTIFICATE OF COMPLIANCE

I certify that this brief conforms to the requirements of Rules 341(a) and (b). The length of this brief, excluding the pages or words contained in the Rule 341(d) cover, the Rule 341(h)(1) table of contents and 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 4,685 words.

Dated: March 8, 2023 By: /s/ Bryan D. Pasciak
Bryan D. Pasciak

CERTIFICATE OF FILING AND SERVICE

The undersigned certifies under penalty of law as provided in 735 ILCS 5/1-109 that the statements set forth in this instrument are true and correct and that the foregoing Brief Amicus Curiae of the Product Liability Advisory Council, Inc. in Support of Petitioners-Appellants was electronically filed with the Clerk's Office using the Court's Odyssey eFileIL system, and was served on all counsel of record via the Odyssey eFile system on March 8, 2023.

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