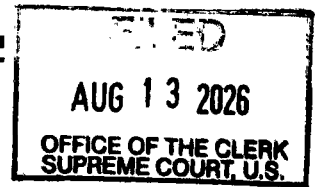


26-5677

ORIGINAL

No.

In the
Supreme Court of the United States



DAVID J. DEARINGER, and
GANNA P. DEARINGER,
Petitioners,

vs.

ELI LILLY AND COMPANY,
Respondent.

On Petition for Writ of Certiorari to the
United States Court of Appeals for the Ninth Circuit

PETITION FOR WRIT OF CERTIORARI

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August 13, 2026

QUESTIONS PRESENTED

(I) Does the Learned Intermediary Doctrine, Which the Supreme Court Has Not Yet Examined, Violate Due Process?

(II) Should the Supreme Court Reexamine Its Decision in *Mallard v. United States Dist. Court for Southern Dist. of Iowa*, 490 U.S. 296 (1989) Because of the Lower Courts' Misapplication of 28 U.S.C. § 1915(e)(1)?

PARTIES TO THE PROCEEDING

All parties to the proceeding are listed in the caption:

The petitioners, David J. Dearing and Ganna P. Dearing are a marital community. They were plaintiffs in the district court and appellants in the court of appeals.

Respondent Eli Lilly and Company (NYSE: LLY) is a publicly traded Indiana corporation with no parent corporation and no publicly held company owning 10% or more of its stock. Eli Lilly and Company was the defendant in the district court and the appellee in the court of appeals.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Supreme Court Rule 29.6, the petitioners have no parent corporation or publicly held company that owns 10% or more of its stock.

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OPINIONS AND ORDERS ENTERED

The opinion of the court of appeals, (App. A), is unpublished. The opinions and orders of the district court (App. B, C, D & E) are also unpublished. The district court denied two motions to request counsel. The first denial on May 5, 2001 (App. B) and the second on December 11, 2023 (App. C).

BASIS FOR JURISDICTION

The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1). The judgment of the court of appeals was entered on March 20, 2026. (App. A). A motion for panel rehearing or rehearing en banc was timely filed on April 3, 2026 but went unheard by the court of appeals. The formal mandate was entered on April 13, 2026 pursuant to Rule 41(a) of the Federal Rules of Appellate Procedure.

This Petition for Writ of Certiorari is filed with this Court on August 17, 2026 pursuant to Supreme Court Rule 13.1; 28 U. S. C. § 2101(c).

CONSTITUTIONAL AND STATUTARY PROVISIONS INVOLVED IN THE CASE

Article IV, Section 2, Clause 1 of the United States Constitution provides:

The Citizens of each State shall be entitled to all Privileges and Immunities of Citizens in the several States.

Amendment I, Petitions Clause of the United States Constitution provides, in pertinent part:

Congress shall make no law ... abridging ... the right of the people ... to petition the government for a redress of grievances.

Amendment V, Due Process Clause of the United States Constitution provides:

No person shall be . . . deprived of life, liberty, or property, without due process of law.

Amendment XIV, Section 1, Due Process and Equal Protection Clauses of the United States Constitution provide, in pertinent part:

No State . . . shall . . . deprive any person of life, liberty, or property, without due process of law; nor deny to any person within its jurisdiction the equal protection of the laws.

28 U.S.C. § 1915(e)(1) provides:

The court may request an attorney to represent any person unable to afford counsel.

STATEMENT OF THE CASE

A. Introduction:

Congress intended for “state tort suits” to be at the very foundation of drug safety in the United States. See *Wyeth v. Levine*, 555 U.S. 555, 579 (2009) (“State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly”).

Yet, despite the importance of state tort suits to the overall public safety in the United States, the Learned Intermediary Doctrine (LID) works to obstruct state tort suits from doing their intended function to protect the public from dangerous drugs.

This case involves the Learned Intermediary Doctrine (LID), ¹ a legal concept that has existed

¹ The Learned Intermediary Doctrine (LID) is an exception to the general rule that manufacturers must warn end users directly about the risks of their products. Under the LID a manufacturer of prescription drugs or medical devices satisfies its duty to warn consumers by directing risk information to the prescribing physician rather

at common law in the United States for over sixty (60) years. Yet, despite this lengthy duration, the Supreme Court has never once agreed to hear a single case to determine whether the LID is even constitutional or to determine whether the LID conflicts with the stated purposes and goals of Congress to establish safeguards that advance drug safety in the United States.

This certiorari petition places before the Court a case that shows how the LID not only violates several provisions of the United States Constitution, but also how the LID obstructs the goals of Congress to promote drug safety.

This petition shows how the LID removes from the law the critical incentive, designed by Congress, to induce drug manufacturers to self-report any newly discovered adverse side-effects of their products. See *Wyeth v. Levine, supra*.

Moreover, this petition shows that the LID also removes from the law the "compensatory function," that was also designed by Congress, "to motivate injured persons to come forward with information" concerning their drug injuries, to provide "an additional, and important, layer of consumer protection that complements FDA regulation." *Id.*

than directly to the consumer. The LID was adopted in the State of Washington in *Terhune v. AH Robins Co.*, 90 Wn.2d 9, 577 P. 2d 975 (1978).

Congress established a regulatory scheme of drug safety in the United States that can function only if drug manufacturers willingly police themselves and self-report the dangerous side-effects of their products to the FDA that are discovered after a drug is approved for marketing. This regulatory scheme also needs injured persons to come forward with "state tort suits," which they cannot do without the assistance of an attorney.

Mr. Justice Stevens, writing for a 6-3 majority, rejecting the drug manufacturer's argument that Congress intended to preempt Vermont tort law, explained that "state tort suits" function to "provide incentives" for "drug manufacturers to disclose safety risks promptly."

The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge.

Wyeth v. Levine, supra.

As explained below, the LID obstructs the stated goals ² of Congress to promote drug safety. The

² The statutory purpose and policy goal of Congress with the enactment of the FDCA is implied throughout Title 21 of the United States Code "to protect public health," see 21 U.S.C. §331(a)(authorizing the FDA to take action

proof of the LID's obstruction is the fact that Respondent Eli Lilly and Company (Lilly) has concealed from the FDA (also from doctors and consumers) the side-effect of their product Cialis® which causes Intracerebral Hemorrhage (ICH). Lilly knows that the LID will protect it from ever facing a jury, which is contrary to the intent of Congress to defend the public from unsafe drugs through "state tort suits." *Wyeth, supra*.

This case is also about this Court's earlier interpretation of 28 U.S.C. § 1915 in the case of *Mallard v. U.S. Dist. Ct. for S. Dist. of Iowa*, 490 U.S. 296 (1989) where the Court decided 5-4 that trial courts cannot "coerce" attorneys (under the former statute § 1915(d)(1979)) to represent indigent clients in civil cases. The Supreme Court should revisit its thirty-seven (37) year-old decision in that case, to at least determine when, and under which circumstances, a trial court may refuse to follow § 1915(e)(1)(1996) to "request an attorney to represent any person unable to afford counsel" and when failure to do so is "harmless."

B. Facts

prohibiting "adulterated" and "misbranded" food, drugs, and cosmetics *to protect public health*); §333 (authorizing the FDA to prohibit importation of the same *to protect public health*); §337 (authorizing the FDA to prohibit interstate commerce of the same *to protect public health*); §340 (requiring drugs to be "safe" and "effective" *to protect public health*); §341 (requiring drugs be "properly labeled" *to protect public health*), etc.

Petitioner David J. Dearing (Mr. Dearing) became permanently paralyzed two hours after he ingested a popular prescription drug called Cialis that caused him to suffer an intracerebral hemorrhage (ICH).

(1) Lilly's Concealment of the ICH Side-Effect of Cialis

Respondent Eli Lilly and Company (Lilly), the manufacturer of Cialis, knew ³ as early as 1998 that Cialis has a dangerous side-effect that causes ICH. Yet, Lilly concealed the ICH side effect, despite its legal obligation to report to the Food and Drug Administration (FDA) any "adverse drug experience" of Cialis under Dept. of Health and Human Services (HHS) regulation 21 C.F.R. § 310.305.

³ Petitioners attach hereto (Appendix F through R) twelve (12) peer-reviewed studies, that are admissible evidence, see *Daubert v. Merrell Dow Pharmaceuticals, Inc.* 509 U.S. 579, 593-594 (1993), dated between 1998 and 2020, that demonstrate the nexus between Cialis and ICH. The studies originate from several medical universities and teaching hospitals from virtually every continent. The Petitioners had presented these published studies to every court below that has reviewed this case, yet currently with few exceptions, most courts in the United States consider enforcement of the LID to supersede drug safety for the consumer.

(2) Mr. Dearinger's prior efforts to avoid having an ICH

Mr. Dearinger never should have asked ⁴ his physician to prescribe Cialis because he was in a high-risk category to suffer an ICH due to his family's history ⁵ of ICH.

As a precaution, years before he suffered the ICH, Mr. Dearinger arranged an appointment at Swedish Edmonds Neurology to see neurologist Dr. Helen Modell to ask specifically how he can avoid suffering the ICH that had plagued his family for at least two generations. Dr. Modell recommended that Mr. Dearinger continue taking his blood pressure medication, which he did, but because Lilly concealed the ICH side-effect of Cialis, Dr. Modell could not warn Mr. Dearinger not to take Cialis.

(3) Mr. Dearinger's Decision to take Cialis

⁴ Cialis is a drug of choice. No one *needs* to take Cialis. Cialis does not extend life like insulin or alleviate pain like opioids. It is a recreational drug that is mass-marketed to the general public as a "recreational" drug to possibly delay the onset of sexual impotence. Impotence in the human male is not a disease, and is certainly not fatal or debilitating, but is a natural and inevitable part of aging, not unlike graying of the hair or balding.

⁵ Four (4) of Mr. Dearinger's paternal relatives, his father, grandmother, and two uncles, all suffered an ICH, each after they turned 62 years of age.

Mr. Dearinger made the decision to take Cialis after he watched Lilly's multiple television commercials.⁶ that contained no warning about a possible ICH.⁷

On the morning of January 17, 2018 Mr. Dearinger ingested a 20 mg tablet of Cialis (given him as a free sample by urologist Dr. Earl Bardin) and a 5 mg daily dose tablet (prescribed by his primary physician Dr. Thomas Horst). Two hours later Mr. Dearinger suffered an ICH, as was predicted by some of the case studies attached hereto in the Appendix (F through R).

Mr. Dearinger was taken by ambulance to the emergency room of Providence Hospital in Everett, Washington. The hospital recorded his systolic blood pressure as 205 mmHg. Mr. Dearinger's systolic blood pressure had never before been recorded above 150 mmHg until he took Cialis.

(4) Mr. Dearinger's Discovery That Cialis Caused His ICH

Mr. Dearinger spent a month at a rehabilitation

⁶ United States and New Zealand are the only two countries in the world, that permit direct-to-consumer marketing of prescription drugs.

⁷ Lilly did, however, offer a warning about a possible four (4) hour erection, but we would argue that was not a warning at all, but was rather intended to be an *inducement* to take Cialis.

hospital learning how to live as a cripple. When he was discharged he made another appointment at Swedish Edmonds Neurology and saw Dr. Dadong Zhou (who had replaced Dr. Modell when she retired).

Dr. Zhou told Mr. Dearinger that ingesting the Cialis tablet was probably the cause of his ICH.

Upon hearing this for the first time that Cialis causes ICH, Mr. Dearinger began searching the internet for information concerning a connection between ICH and Cialis. Mr. Dearinger discovered that medical universities and hospitals from all over the world had conducted research to study a new category of drugs called the "Phosphodiesterase Enzyme No.5 Inhibitor" (PDE-5 Inhibitor) ⁸ of which category includes Cialis.

Among the published studies discovered by Mr. Dearinger was a case from the University of Missouri School of Medicine where a neurology professor Dr. Scott Lucchese stated:

This case bolsters existing evidence that PDE-5 inhibitors as a class should be viewed with caution. As of publication, FDA warns against possible cardiovascular adverse reactions, hearing loss, hypotension, and priapism, however *does not warn that ICH may be possible side effect.*

⁸ Included in the PDE-5 Inhibitor category are the popular drugs Cialis® Viagra® and Levitra®.

Lucchese, Dhaliwal, Kaur, Qi; *A Case of Recurrent Lobar Intracerebral Hemorrhage in the Setting of Phosphodiesterase-5 Inhibitor Use*, Missouri Medicine, 2019 116:5 (emphasis added)(App. Q).

In the opinion of neurology Professor Lucchese the manufacturers of the PDE-5 Inhibitors, including Lilly, failed to notify the FDA of the ICH side-effect of Cialis and Viagra, *et al.*

(5) The Reason That Cialis Causes Brain Hemorrhage

(a) Why the PDE-5 Inhibitor Creates An Erection In Males

Within the body of every human adult male, a naturally produced regulatory cyclic nucleotide called cyclic guanosine monophosphate ("cGMP"), which relaxes the smooth muscle tissue of the corpus cavernosum in the penis, permits "increased flow of blood into the trabecular spaces of the corpora cavernosa" thus to "facilitate penile erectile responses."⁹

When the male becomes sexually aroused an erection is produced by the introduction of the cGMP, thus making the act of sexual intercourse

⁹ Ballard, et al., (1998) *Effect of Sildenafil on the Relaxation of Human Corpus Cavernosum Tissue In Vitro and on the Activities of Cyclic Nucleotide Phosphodiesterase Isoenzymes*. J Urol 159:2164-2171 (Appendix F).

possible. Once sexual intercourse is concluded, the effect of the cGMP to produce the penile erection is counteracted by the male body's manufacture and introduction of the Phosphodiesterase Enzyme No. 5 ("PDE-5") which cancels the effect of the cGMP to produce a penile erection.

The product at issue in this case, Cialis, is a PDE-5 "Inhibitor" which prevents the counteracting effect of PDE-5 to prevent the cGMP from creating and maintaining a penile erection.

(b) Cialis Also Inhibits PDE-1 and PDE-2

Cialis, and the other PDE-5 Inhibitors like Viagra® and Levitra®, work by inhibiting PDE-5.

But Cialis also inhibits PDE-1 and PDE-2. PDE-1 and PDE-2 are what regulate blood pressure:

Ensuing sympathetic hyperactivity through PDE-1 and PDE-2 might lead to rupture of vessels We suggest that these inciting and propagating factors for ICH even in a young adult male patient without known risk factors *should be warned before prescribing sildenafil* [Viagra, a PDE-5 Inhibitor].

Byoun, et al., (2010) *Subarachnoid Hemorrhage and Intracerebral Hematoma Due to Sildenafil Ingestion in a Young Adult*, Jour. of Korean Neurosurg Soc, 47:210-212, at 212 (emphasis added)(App. L).

**(c) Lilly's Misinformation Campaign that
Cialis Lowers Blood Pressure**

Cialis inhibits PDE-1 and PDE-2, which can cause blood pressure go EITHER up or down. Lilly misinforms the public that Cialis only lowers blood pressure. At least one judge on the Ninth Circuit panel stated that he believed the misinformation, thus discounting the scientific evidence:

The following colloquy took place at oral argument on April 13, 2026 at minute 16:15:

JUDGE BUMATAY: The lynchpin in all that everyone agrees that Cialis lowers blood pressure versus increases blood pressure.

LILLY ATTORNEY: Correct . . .

Judge Bumatay ignored the scientific evidence (attached hereto) and the briefing that Cialis inhibits PDE-1 and PDE-2, the regulation of blood pressure, causing blood pressure to go EITHER up or down. In Mr. Dearing's case, blood pressure went up.

It is Lilly's misinformation campaign that Cialis causes blood pressure to only go down.

Mr. Dearing's systolic blood pressure rose to 205 mmHg after he took Cialis, which caused his ICH.

After Mr. Dearing read the peer-reviewed medical-scientific evidence (attached hereto as

Appendix F - R) that PDE-5 Inhibitors cause ICH, and that Lilly refused to warn that Cialis has an ICH side-effect, he wanted to sue Lilly in a "failure-to-warn" action (see *Wyeth v. Levin, supra*).

(6) The LID Deters Attorneys From Suing Drug Manufacturers

But no lawyer would even listen to Mr. Dearinger even talk about his case after he mentioned that a drug manufacturer would be the defendant. Every lawyer told him that drug manufacturers cannot be sued because of the LID.

Because no lawyer would take their case, Mr. Dearinger and his wife, Petitioner Ganna P. Dearinger, ¹⁰ were forced to file a *pro se* civil complaint in U.S. District Court against Lilly, without the assistance of an attorney, on the final day allowed by the statute of limitations.

(7) Congress Never Intended That "State Tort Suits" Under *Wyeth v. Levine* Be Litigated By *Pro Se* Victims of Malfeasant Drug Manufacturers

The trial court recognized that:

¹⁰ Petitioner Ganna P. Dearinger joined the suit against Lilly for loss of consortium. She is a naturalized immigrant whose primary language is Russian.

Pharmaceutical product liability claims are among the most complex claims that the Court sees . . .

Order of the trial court, dated May 20, 2021 (App. B).

Mr. Dearinger is not qualified to litigate any civil case whatsoever, much less a "complex" case such as one that involves "pharmaceutical product liability claims" like the case at hand. Beside lacking the necessary legal training, Mr. Dearinger suffers from cognitive and memory deficits, due to his ICH, that hinder his ability to represent his interests through discovery.

Mr. Dearinger is now disabled because of the ICH he suffered and now lacks the ability to work to provide the financial means to retain the services of a product liability attorney. Ordinarily attorneys are asked to represent injured clients on a contingency basis to recover their fees when and if the suit is won.

But, because of the LID, attorneys know the chances of recovering the costs of litigation against a drug manufacturer are nearly zero, Attorneys therefore avoid taking cases involving drug manufacturers, contrary to the intent of Congress to use lawsuits as a means to coerce "drug manufacturers to disclose safety risks promptly." *Wyeth v. Levine, supra*. The LID, therefore, puts consumers in the United States at grave risk of exposure to dangerous drugs because of lack of safety regulation enforcement.

Drug manufacturers are aware that attorneys will not take cases involving them. This explains why Lilly ignored 21 C.F.R. § 310.305 and refused to notify the FDA of the ICH side-effect of Cialis. Lilly knows that it will be protected from liability by the LID and could benefit from higher sales by concealing the ICH side-effect.

(8) The Trial Court's Refusal to Request Counsel

Mr. Dearinger, who is proceeding *in forma pauperis* under 28 U.S.C. § 1915, twice moved the trial court, pursuant to § 1915(e)(1), to request counsel to represent him and his wife.

Mr. Dearinger argued that he needed the court to request counsel because:

(A) The ICH suffered by Mr. Dearinger left him with cognitive and memory deficits that hinder his ability to prosecute this case. He has difficulty studying product liability law and understanding civil procedure;

(B) Mr. Dearinger struggles with understanding the esoteric language of the legal briefing filed by his opponent Lilly. Moreover, his mental deficits from the ICH make it difficult to respond;

(C) Mr. Dearinger has no knowledge or experience with the discovery phase of lawsuits and was therefore unable to properly respond to Lilly's interrogatories or to represent himself at Lilly's deposition. Moreover, Mr. Dearinger's cognitive

and mental deficits were a disadvantage to him protecting his own legal interests;

(D) Mr. Dearinger's wife Ganna Dearinger is unable to help because she is a naturalized citizen from the Ukraine, whose primary language is Russian, and lacks sufficient understanding of the English language to assist her husband with prosecuting this case;

(E) An expert witness is essential to establish causality in a product liability case, especially when the case involves a drug or medical device. Yet, because Mr. Dearinger is acting *pro se*¹¹ he cannot retain an expert witness because expert witnesses speak only to attorneys but not to unrepresented parties. Mr. Dearinger's case was doomed from the outset without an expert witness;

(F) Mr. Dearinger's paralysis limits his ability to type with only two fingers and thumb of his right hand. This fact hinders his ability to prosecute this case;

(G) Because of Mr. Dearinger's indigency he cannot afford to subscribe to Westlaw® (his temporary trial subscription had expired), thus

¹¹ Mr. Dearinger contacted several expert witnesses, and several agencies that represent expert witnesses, but every one of them refused to discuss the case with him unless he retains an attorney to represent him. Expert witnesses only talk to lawyers and refuse to even allow *pro se* litigants past their office receptionists.

limiting his ability to do legal research. Also, the COVID-19 pandemic limited his ability to use the University of Washington and Snohomish County law library resources. Moreover, walking with a quad cane is difficult, especially when carrying heavy law books to the table with a paralyzed left arm. Legal research in law libraries is extremely difficult, if not nearly impossible for Mr. Dearing.

The trial court denied Mr. Dearing's two (2) motions to request counsel stating:

Pharmaceutical product liability claims are among the most complex claims that the Court sees, and the Court has no doubt that Mr. Dearing's paralysis and his limited access to legal materials is impacting his ability to litigate this case.

Order of the trial court, dated May 20, 2021 (App. B).

While the trial court acknowledged that *Mallard v. U.S. Dist. Ct. for S. Dist. of Iowa*, 490 U.S. 296, 307 (1989)

. . . authorizes courts to ask but not compel lawyers to represent indigent litigants . . .

Appendix B (quotation marks omitted), the trial court refused to even ASK whether an attorney would be willing to consider taking the case:

. . . the Court is doubtful that an attorney will take Mr. Dearing's case.

* * *

. . . Mr. Dearing reports that he has contacted several attorneys with product liability experience over the past several months, but they have all declined to take his case . . . Given that several attorneys with relevant experience have declined to take his case despite the prospect of potentially recovering a contingency fee, the Court is doubtful that an attorney will volunteer to take the case for free.

Id.

When ruling upon the second motion to request counsel the trial court stated:

. . . Mr. Dearing argues that appointment of counsel is necessary for him to hire an expert witness . . . But this is not a basis, alone, for the Court to appoint counsel . . .

Order of the trial court, dated December 11, 2023 (Appendix C).

(9) Absence of Counsel Impaired Mr. Dearing's Case and Led To Adverse Summary Judgment

The trial court granted Lilly's motion for summary judgment because of Mr. Dearing's lack of training and experience with the discovery phase.

(a) Mr. Dearing was not qualified to answer interrogatories ¹²

Had an attorney agreed to represent the Dearings, the answer to the Interrogatory would have been framed appropriately.

Mr. Dearing (who has no legal or medical training) was presented with an interrogatory requiring him to suggest a warning that Lilly should have provided to warn about the ICH side effect of Cialis.

Mr. Dearing has no knowledge of medical terminology and was refused the help of an expert witness. Mr. Dearing, without knowledge of discovery, didn't know about his objection to the interrogatory. So, he answered the interrogatory with the small amount of legal and medical expertise that he possessed.

Mr. Dearing's suggested warning, which had no basis in medicine or medical terminology, suggested an inept warning that he thought would

¹² Mr. Dearing had no prior warning that his answers would be used to obtain summary judgment against him. Had he been so warned he would have borrowed money to pay for the advice of an expert in medicine or law before answering.

fulfill the spirit of the requirements of civil discovery.

At Lilly's deposition, for which Mr. Dearinger was totally unprepared due to his ignorance and incompetence, Lilly called the two physicians that prescribed Cialis to Mr. Dearinger.

(b) Mr. Dearinger Has No Legal Training or Experience With Conducting Depositions

Had an attorney been present at the deposition to represent Mr. and Mrs. Dearinger, the outcome would have been different.

(i) An attorney could have exposed Dr. Bardin's conflicts and biases

Mr. Dearinger complained to the Washington Medical Commission in 2021 about Dr. Biden's concealment of his medical file from Mr. Dearinger. (See App. R). The medical file that Dr. Bardin refused to release to Mr. Dearinger contained proof that Dr. Bardin was aware of Mr. Dearinger's family history of ICH. The concealed file was proof of Dr. Bardin's malpractice, by prescribing Cialis to Mr. Dearinger who has a family history of ICH.

An attorney could have exposed Dr. Bardin's bias on cross-examination after Dr. Bardin testified that a warning about ICH would not have changed his decision to prescribe Cialis to Mr. Dearinger.

Dr. Biden testified in Lilly's favor in exchange for Lilly's promise not to add him as a co-defendant through party joinder. (Mr. Dearinger is ignorant of the legal tactics used in civil litigation but recently did an internet search about "joinder").

Mr. Dearinger did not find out until years later that such challenges can be made during depositions and that he did not need to sit silently while Dr. Bardin testified.

Mr. Dearinger also discovered that lawyers can take classes and attend seminars to improve their deposition skills. Some law firms hire lawyers based upon those specialized skills to conduct depositions.

Mr. Dearinger was an easy prey for the tactics of the highly skilled lawyers hired by a major drug manufacturer like El Lilly and Company. In retrospect, Mr. Dearinger can now see how Lilly took full advantage of Mr. Dearinger's ignorance and inexperience with discovery, not to mention his cognitive and disabilities from the ICH.

What compounds this travesty of the lop-sided discovery in this case, was the trial court's sanctioning of this travesty. It was as if the trial court wanted Lilly to find a way to end the case.

Moreover, the Ninth Circuit panel ruled that the trial court refusal to request an attorney for Petitioners was harmless error because of his memory and cognitive deficits during discovery.

(ii) An attorney could have exposed Dr. Bardin's medical incompetence

Dr. Bardin testified that a warning about ICH would not have changed his decision to prescribe Cialis, even with Mr. Dearing's family history of ICH.

Yet, at this point Mr. Dearing, acting as his own lawyer, assumed the statute of limitations had expired, and it was too late to sue Dr. Bardin for malpractice.

The Ninth Circuit panel stated:

The district court did not err by failing to advise the Dearings, as pro se litigants, to seek leave to amend their complaint to assert claims against Dearing's physicians. The physicians were not "obvious[ly]" omitted defendants because the Dearings never made allegations of wrongdoing against them in their complaint, even construing it liberally. See *Wilborn v. Escalderon*, 789 F.2d 1328, 1332 (9th Cir. 1986).

Appendix A.

Had the trial court requested counsel for Mr. Dearing, he could have included Dr. Bardin as a defendant. But because of the trial court's error not to ask for counsel, Mr. Dearing had no idea

he could have included Dr. Bardin as a defendant or even make the allegation at this late stage.¹³

Dr. Bardin is of the opinion that ischemic stroke is equivalent to hemorrhagic stroke. Even with Mr. Dearing's limited medical knowledge he knows that Dr. Bardin's medical opinion is open to challenge.

Mr. Dearing has often quoted U.S. District Judge Rothstein:

Hemorrhagic stroke results from the rupturing of a blood vessel in the brain. The hemorrhage may be either intracerebral (within the brain itself) or subarachnoid (within the fluid-filled space surrounding the brain) (hereinafter "ICH" and "SAH" respectively). Approximately fifteen to twenty percent of strokes fall into the hemorrhagic category.

¹³ The Ninth Circuit panel said that "The physicians were not 'obvious[ly]' omitted defendants because the Dearings never made allegations of wrongdoing against them in their complaint, even construing it liberally." (App. A, at page 6). Yet, Mr. Dearing, with his lack of knowledge about civil procedure, had no idea of Dr. Bardin's wrongdoing until his deposition testimony demonstrating his incompetence in not knowing the dynamics of ischemic vs. hemorrhagic strokes.

* * *

Ischemic stroke results from the blocking of blood flow in a cerebral vessel, depriving brain tissue beyond the blockage of oxygen. The vast majority of strokes are ischemic.

In re Phenylpropanolamine (PPA) Prods. Liab. Litig.,
289 F.Supp.2d 1230, 1238 (W.D. Wash. 2003).

The previously cited study from the University of Missouri demonstrates that Dr. Bardin's opinion is at least open to challenge:

This case bolsters existing evidence that PDE-5 inhibitors as a class should be viewed with caution. As of publication, FDA warns against possible cardiovascular adverse reactions, hearing loss, hypotension, and priapism, however *does not warn that ICH may be possible side effect*.

Lucchese, *supra* (emphasis added). This study shows that the failure to warn about ICH is distinguishable from the existing warnings given.

Even the trial court took judicial notice of the anemic warning by Lilly:

In this case, there is sufficient ambiguity in Cialis's label and about whether a more specific stroke warning was needed to prevent the Court from

deciding the issue at the pleadings stage.

Order of the Trial Court, June 30, 2022, Page 3, Lines 17-19.

Yet, despite this comment made by the trial court on June 30, 2022, the trial court considered Mr. Dearing's challenge to Dr. Bardin's possible biases and conflicts to be unjustified "aspersions."

... they cast aspersions on Dr. Bardin's judgment and professional competence. (See *id.* at 9-11.) This is irrelevant to the case at hand, which is against Eli Lilly, not Dr. Bardin ...

Order of the Trial Court, December 18, 2023, page 6, LL 17-18.

Dr. Bardin had definite biases against Mr. Dearing, and a self-interest to give testimony favoring Lilly, yet the trial court called this legitimate challenge to be casting "aspersions" when Mr. Dearing's challenge is clearly justified.

(11) Contradictory answers of the two (2) prescribing doctors

Lilly questioned both Drs. Bardin and Horst whether Mr. Dearing's suggested warning would have changed their decisions to prescribe Cialis.

Dr. Bardin (Mr. Dearing's urologist), who gave Mr. Dearing the free samples of the 20mg Cialis

tablets, testified that Mr. Dearing's suggested warning would *not* have changed his mind about prescribing Cialis to Mr. Dearing.

However, Dr. Horst (Mr. Dearing's primary physician), who prescribed daily doses of 5mg Cialis tablets, testified that Mr. Dearing's suggested warning *would* have changed his mind about prescribing Cialis to Mr. Dearing. Dr. Horst testified that had he received the warning about ICH he would *not* have prescribed Cialis to Mr. Dearing.

The trial court granted summary judgment for the defendant Lilly because Dr. Bardin prescribed Mr. Dearing a higher dose of Cialis. Nothing could be as arbitrary.

ARGUMENT

(I) Does the Learned Intermediary Doctrine, Which the Supreme Court Has Not Yet Examined, Violate Due Process?

A. Supreme Court Should Grant Certiorari in this Case to Review the LID for the First Time

This is the type of case that was envisioned by Rule 10(c), which provides that the Supreme Court may grant a petition for a writ of certiorari when:

... a United States court of appeals has decided an important question of federal law that has not been, but should be, settled by this Court ...

Supreme Court Rule 10(c).

The LID certainly qualifies as an "important question of federal law" because the LID obstructs "state tort suits" from their Congressional purpose to enhance drug safety, which have been declared by the Supreme Court to be "an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth v. Levine*, 555 U.S. 555, 579 (2009). This is discussed in greater detail below.

Without the guidance of the Supreme Court, the lower courts have allowed LID jurisprudence to evolve into nothing more than an apparatus that shields drug manufacturers from the intent of Congress "to provide incentives for drug manufacturers to disclose safety risks promptly." *Wyeth v. Levine*, at 579.

LID removes the consequences from drug manufacturers for concealing side-effects of their products from the FDA. This obviously degrades and obstructs drug safety in the United States.

The LID guarantees that a drug manufacturer will never go to trial for injuring consumers and rewards them with higher sales when they conceal dangerous side-effects from the FDA.

B. The LID Violates the Constitution

(1) The LID Violates Due Process by Denying Access to the Courts

While not expressly mentioned in the Bill of Rights, the Supreme Court has in various ways articulated that access to the courts ¹⁴ is a

¹⁴ The Supreme Court has grounded the right of access to the courts in many different constitutional contexts, as noted by Mr. Justice Souter a quarter century ago:

Decisions of this Court have grounded the right of access to courts in the Article IV Privileges and Immunities Clause, *Chambers v. Baltimore & Ohio R. Co.*, 207 U. S. 142, 148 (1907); *Blake v. McClung*, 172 U. S. 239, 249 (1898); *Slaughter-House Cases*, 16 Wall. 36, 79 (1873), the First Amendment Petition Clause, *Bill Johnson's Restaurants, Inc. v. NLRB*, 461 U. S. 731, 741 (1983); *California Motor Transport Co. v. Trucking Unlimited*, 404 U. S. 508, 513 (1972), the Fifth Amendment Due Process Clause, *Murray v. Giarratano*, 492 U. S. 1, 11, n. 6 (1989) (plurality opinion); *Walters v. National Assn. of Radiation Survivors*, 473 U. S. 305, 335 (1985), and the Fourteenth Amendment Equal Protection, *Pennsylvania v. Finley*, 481 U. S. 551, 557 (1987), and Due Process Clauses,

necessary component, in certain instances, of the Due Process Clause of the Fifth and Fourteenth Amendments. See e.g. *Boddie v. Connecticut*, 401 U.S. 371 (1971)(Due process requires that states allow indigents access to divorce court); *Bounds v. Smith*, 430 U.S. 817 (1977)(Due process requires that states provide prison inmates with adequate law libraries to facilitate meaningful access to the courts).

(2) Meaningful Access to the Courts

The Constitutional requirement of access to the courts means more than just being able to file a civil complaint with the clerk of the court. Access to the courts must be a "meaningful" access. See *Bounds v. Smith*, *supra* (access to the courts involves more than mere physical access to the entryway into the courthouse; "[M]eaningful access to the courts is the touchstone").

Taken in the context of the case at hand, merely "accessing" the clerk's window to file the civil complaint is meaningless if the case is already predetermined by the LID to rule for the defendant on summary judgment.

Wolff v. McDonnell, 418 U. S. 539, 576 (1974); *Boddie v. Connecticut*, 401 U. S. 371, 380-381 (1971).

Christopher v. Harbury, 536 U.S. 403, 415 n. 12 (2002).

Under the LID drug manufacturers know they will never go to trial for their “failure to warn,” see *Wyeth v. Levin*, 555 U.S. 555, 575 (2009), as intended by Congress to establish drug safety.

(a) Attorneys Shun Cases That Involve the LID

Attorneys know that they will go broke if they sue a drug manufacturer. This is why Mr. Dearinger could not find an attorney to take this case. The LID shields drug manufacturers from lawsuits and attorneys know that they will never recover their cost for of their involvement with a “state tort suit” against a drug manufacturer.

Moreover, every lawyer knows that drug manufacturers pay lawyers more for defending them in litigation than a lawyer could earn while suing them.

This being the case, a drug injured person must file his case *pro se*. The average *pro se* litigant is at a colossal disadvantage while trying to navigate his way through a product liability case involving a drug manufacturer without the assistance of an attorney.

(b) The Advent of the Learned Intermediary Doctrine

Sixty (60) years ago three (3) judges of the Eighth Circuit panel created from the ether the “Learned Intermediary Doctrine” (LID) that eventually

would be adopted in some form in nearly every state. ¹⁵ *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir.1966) (“... the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer”).

The three judges were Circuit Judge Charles Joseph Vogel (born in 1898), ¹⁶ Circuit Judge Pat

¹⁵ The West Virginia Supreme Court of Appeals was the only high court in the United States to reject the LID outright. See *State ex rel. Johnson & Johnson Corp. v. Karl*, 220 W. Va. 463, 647 S.E.2d 899 (2007) (“Under West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. We decline to adopt the learned intermediary exception to this general rule.”). Yet, after *Karl* was decided, the drug industry parachuted its lobbyists onto the City of Charlson to shower the West Virginia state capital with campaign contributions to persuade the West Virginia Legislature to adopt the LID by statute. See West Virginia Code § 55-7-30 (2016).

It is no secret that drug manufacturers are among the largest contributors in U.S. politics. See:

<https://www.opensecrets.org/industries/indus?ind=H04> (last visited July 28, 2026).

¹⁶ The years that the judges were born is important when considering which inventions of mass communications were available during, and at

Mehaffy (born in 1904), and District Judge Edward Joseph McManus of the Northern District of Iowa sitting by designation (born in 1920).

Judge Vogel was in his mid-twenties when commercial radio was introduced in Fargo, N.D. Commercial television came along thirty years after that. It is safe to assume that Judge Vogel wasn't yet familiar with the drug manufacturers' practice of marketing prescription drugs directly to consumers, thus bypassing the prescribing physicians.

what point of, their lifetimes. For example, the radio became available to the public in around the year 1922, television around 1953 and the world-wide-web around 1991. It was a considerable time later that those inventions would be used to mass-market prescription drugs directly to consumers outside of the influence of their family doctors (which is allowed in only two countries: the United States and New Zealand -- discussed below).

The three judges of the *Sterling* panel were not aware of the approaching rapid and exponential growth of mass media communications to appear in the United States. Just a quarter century after *Sterling* was decided the mass media would begin to disseminate prescription drug information directly to consumers and would thereby bypass the influence of the prescribing physicians. The premises that existed in the year 1966, upon which the LID is based, are therefore now obsolete.

The same can be said of the early experiences of Circuit Judge Mehaffy growing up in Little Rock, Arkansas, or District Judge McManus in Keokuk, Iowa. The three judges were born to a time where the decision to ingest a prescription drug was "exclusively a matter for medical judgment."¹⁷ But the world has greatly changed over the 60 years when the LID was first born from the ether.

(i) The Premises Upon Which the LID is based are no longer valid

When patients arrive at their doctor's appointments, the patient had already made the decision to ingest Cialis. The prescribing physician had no part in the patient's decision to take Cialis. This was not what was anticipated by the Eighth Circuit panel of *Sterling Drug, Inc. v. Cornish* when it invented the LID in 1966, the year before President Lyndon B. Johnson appointed Justice Thurgood Marshall to replace Justice Tom C. Clark on the Supreme Court.

(ii) New Jersey Reject the LID For Drug Manufacturers That Mass Market Their Product

The New Jersey Supreme Court found that the foundational premises upon which the LID were based are no longer valid, particularly the "doctor

¹⁷ Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 40 Food Drug Cosm. L.J. 135, 136 (1985).

knows best" premise that no longer applies because the doctor-patient relationship has been modified, indeed diminished, by the aggressive "direct to consumer" marketing campaigns advanced by drug manufacturers:

. . . physicians may relent to patient pressure, even if it is not in the best interest of the patient. In fact, physicians state that they are increasingly asked and pressured by their patients to prescribe drugs that the patient has seen advertised.

Perez v. Wyeth Laboratories Inc., 734 A.2d 1245, 1260, 161 N.J. 1 (1999), quoting Terzian, *Direct-to-Consumer Prescription Drug Advertising*, 25 Am. J.L. & Med. 149, 157 (1999). This was one of the reasons that the New Jersey Supreme Court refused to allow the LID to rescue drug manufacturers from liability for drug injuries if the drug in question was mass-marketed:

We believe that when mass marketing of prescription drugs seeks to influence a patient's choice of a drug, a pharmaceutical manufacturer that makes direct claims to consumers for the efficacy of its product should not be unqualifiedly relieved of a duty to provide proper warnings of the dangers or side effects of the product.

Perez v. Wyeth Laboratories Inc., 734 A.2d at 1247.

In New Mexico the United States District Judge James O. Browning of the District of New Mexico rejected three opinions of the New Mexico Court of Appeals (dating from 1974 to 1984) that adopted the LID to proclaim that the LID was outdated, predicting that the New Mexico Supreme Court would reject the LID:

With the advent of DTC [direct to consumer] advertising and the trend of people self-diagnosing and, based on that diagnosis, requesting particular prescription drugs, the reliance on physicians is not the same as it was in the 1970s and 1980s. While the Court does not in any way minimize the importance of doctors in the prescription-drug claim, neither the drug manufacturers nor the patient totally relies on the intermediary. The manufacturer and the patient are communicating directly and the consumer is relying on that direct communication.

Rimbert v. Eli Lilly and Co., 177 F.Supp.2d 1174, 1226 (D.N.M. 2008). Judge Browning predicted that the New Mexico Supreme Court would refuse to adopt the LID. To date Judge Browning's prediction remains valid insofar as eighteen (18) years later the New Mexico Supreme Court has not yet adopted and appears unlikely to adopt the LID in the future, and neither has the New Mexico Legislature adopted the LID by statute.

We see that in the United States, judges and legal scholars are far from unanimous in the acceptance of the Learned Intermediary Doctrine providing refuge to miscreant drug manufacturers when they kill ¹⁸ or cripple trusting and unaware consumers of Cialis.

Perhaps the world is waiting for the United States Supreme Court will finally weigh-in on this highly polarizing issue of the Learned Intermediary Doctrine (LID).

(II) Should the Supreme Court Reexamine Its Decision in Mallard v. United States Dist. Court for Southern Dist. of Iowa, 490 U.S. 296 (1989) Because of the Lower Courts' Misapplication of 28 U.S.C. § 1915(e)(1)?

Congress intended for "state tort suits" to function as an important component of its layer of consumer protection in the United States. *Wyeth v. Levine, supra*.

Under this congressional plan, "injured persons" are "motivated" to "come forward with information" when they are injured by a prescription drug. This act of injured persons to "come forward" is what Congress intended to

¹⁸ ICH is 60% fatal to those so inflicted. Immediate treatment during the "golden hour" is critical to an ICH patient surviving an ICH event. Mr. Dearing was fortunate that his wife called 911 immediately on the morning of January 17, 2018.

“provide incentives for drug manufacturers to disclose safety risks promptly.” *Id.*

Yet, state tort suits cannot perform this function unless the “injured person” has the representation of an attorney that is skilled in the highly specialized area of “product liability” law, especially where the product is a “prescription drug” that invokes the “learned intermediary doctrine (LID).” See *Sterling Drug, Inc. v. Cornish*, *supra*.

A *pro se* party lacks the knowledge and experience to navigate his way through what the trial court considers to be

the most complex claims that the Court sees . . .

Order of the trial court, dated May 20, 2021 (App. B).

In 1942 this Court wrongly decided 6-3 that a Maryland state criminal defendant was not entitled to the appointment of counsel. See *Betts v. Brady*, 316 U.S. 455 (1942).

Twenty-one (21) years later this Court corrected that wrong decision with the case of a Florida state criminal defendant. See *Gideon v. Wainwright*, 372 U.S. 335 (1963).

This petition illustrates how drug safety in the United States depends upon lawsuits against drug manufacturers.

State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly.

Wyeth v. Levine, supra, at 579.

Congress established a system whereby the threat of lawsuits incentivizes “drug manufacturers to disclose safety risks promptly.”

. . . injured persons to come forward with information [concerning their drug injury].

Wyeth v. Levine, supra, at 579.

This is the safety regimen instituted by Congress which depends upon the willingness of drug-injured persons like Mr. Dearing to come forward with information about how a recreational drug crippled him. Thus, without state torts against drug manufacturers the entire system of drug safety collapses. Yet, without the participation of lawyers there can be no state torts. Drug safety therefore collapses in the United States without the participation of lawyers. The LID discourages attorney participation in drug lawsuits. Therefore, drug safety in the United States is defunct because of this Court’s interpretation of the word “request” to mean.

The court may request an attorney to represent any person unable to afford counsel.

28 U.S.C. § 1915(e)(1)(1996).¹⁹

CONCLUSION

The Petitioners have done their best without the assistance of counsel, due to the LID, which discourages attorney participation in cases that involve drug manufacturers.

Mr. Dearing's physical and mental disabilities have been a disadvantage throughout the history of this case. Petitioners ask that this case be remanded back to the Ninth Circuit to consider whether the LID is constitutional and whether the trial court's refusal to ask for counsel was harmless.

DATED: August 12, 2026


David J. Dearing


Ganna P. Dearing

¹⁹ The Court in *Mallard v. U.S. Dist. Ct. for S. Dist. of Iowa*, 490 U.S. 296 (1989) dealt with the former codification 28 U.S.C. § 1915(d)(1979).