Supreme Court of Arizona

MEDICIS PHARMACEUTICAL CORPORATION, an Arizona corporation, Defendant/Petitioner, v. AMANDA WATTS, an adult individual, Plaintiff/Respondent.	No. CV-15-0065-PR No. 1 CA-CV 13-0358 Maricopa County Superior Court No. CV2012-008081

BRIEF OF *AMICI CURIAE* THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, THE U.S. CHAMBER OF COMMERCE, THE U.S. CHAMBER LITIGATION CENTER, THE ARIZONA CHAMBER OF COMMERCE & INDUSTRY, AND THE ARIZONA MANUFACTURERS COUNCIL IN SUPPORT OF PETITIONER

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I. INTEREST OF *AMICI CURIAE*

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association comprised of the leading pharmaceutical research and technology companies. In 2014 alone, PhRMA members invested roughly $51.2 billion in discovering and developing new medicines.[1] The U.S. Chamber of Commerce (the "U.S. Chamber") is the world's largest business federation. It represents 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations, and through the U.S. Chamber Litigation Center, regularly files amicus curiae briefs in cases raising issues of vital concern to the Nation's business community. The Arizona Chamber of Commerce and Industry is a nonpartisan, nonprofit organization that is the leading statewide advocate for the Arizona business community. The Arizona Manufacturers Council is a coalition of manufacturers that work together to promote and enhance a positive business climate for manufacturing and related industries that operate within Arizona.

Amici have a critical interest in uniform and fair liability standards. Loss of uniformity in liability standards for prescription medicines will subject pharmaceutical manufacturers to fundamentally different standards of liability in

[1] *See* PhRMA, *2015 Biopharmaceutical Research Industry Profile*, at 35 (2015), *available at* http://www.phrma.org/sites/default/files/pdf/2014_PhRMA_PROFILE.pdf.

each state. The new liability standard announced below has no basis in law or logic and runs contrary to both the FDA's carefully-constructed regulatory scheme, and the unfounded liability-expanding reasoning of the decision below, if allowed to stand, has broad negative implications for larger business community.

II. INTRODUCTION AND SUMMARY OF ARGUMENT

The learned intermediary doctrine provides that a pharmaceutical manufacturer fulfills its legal duty to a patient taking a prescription medicine by providing an adequate warning to the prescribing medical professional. This doctrine flows directly from the longstanding federal regulatory scheme, which categorizes prescription medicines as those that can only be safely administered under the care of a licensed medical professional. Since adopting this doctrine nearly forty years ago, Arizona courts have consistently applied it, as have courts in nearly every other jurisdiction in the country.

The decision below is an extraordinary break from this well-established precedent. The Court of Appeals' error follows from a fundamental misunderstanding of the learned intermediary doctrine, and from a distortion of Arizona's liability-limiting version of UCATA to *expand* liability in a way at odds with federal law and the law of nearly every other state. Because the ruling is contrary to public health and an exception is not justified by direct-to-consumer ("DTC") advertising, review should be granted and the decision reversed.

III. THE LEARNED INTERMEDIARY DOCTRINE DOES NOT CONFLICT WITH ARIZONA'S VERSION OF UCATA.

The Court of Appeals' ruling rests on the fundamental premise that Arizona's version of the Uniform Contribution Among Tortfeasors Act ("UCATA"), A.R.S. § 12-2506, which abolishes joint and several liability, is at odds with the learned intermediary doctrine. That premise is simply incorrect.

A. The Learned Intermediary Doctrine Works in Harmony with the Federal Regulatory Scheme.

Federal law defines a prescription medicine as one that "is not safe for use *except under the supervision of a practitioner licensed by law to administer such drug*." 21 U.S.C. § 353(b)(1)(A) (emphasis added). The U.S. Food & Drug Administration ("FDA") strictly regulates the content of the physician prescribing information ("PI" or "label") that accompanies each prescription medicine and provides the essential scientific information necessary for healthcare professionals to determine whether a medicine is appropriate for a particular patient. The FDA carefully specifies the format and content of the PI for each medicine, including dosing, efficacy, and safety information. *See* 21 C.F.R. § 201.57(c).

The FDA has long recognized the unique need for the medical professional in the prescribing process, acknowledging that the technically-written PI is of "questionable" value when provided directly to patients because it is "relatively inaccessible to consumers." 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995). Thus,

while the FDA requires PIs for every medication, the FDA only employs patient-directed warnings on a medication-by-medication basis. Where it does employ such patient-specific warnings, it does so as an express complement to physician warnings, not as a replacement for them. *See* Final Rule, Medication Guide Requirements, 63 Fed. Reg. 66,378, 66,386 (Dec. 1, 1998) ("FDA agrees that health care providers should be the primary source of information about medications for their patients. The purpose of written information is to reinforce and supplement, not to interfere with, the doctor-patient relationship.").

The learned intermediary doctrine developed in tandem with the modern federal regulatory scheme[2] and harmonizes perfectly with it. Instead of requiring direct-patient warnings that may be at odds with federal regulation, the doctrine hinges liability on the whether the company properly met its duty to warn prescribers. The doctrine thus recognizes that the risk-benefit weighing necessary to make a decision to prescribe hinges on specialized medical knowledge. As Judge Wisdom aptly put it forty years ago:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its

[2] *See generally* Michelle Meadows, *Promoting Safe and Effective Drugs for 100 Years*, FDA Consumer Magazine (Jan-Feb. 2006), *available at* http://www.fda.gov/AboutFDA/WhatWeDo/History/ProductRegulation/PromotingSafeandEffectiveDrugsfor100Years/.

> potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.

Reyes v. Wyeth Labs, 498 F.2d 1264, 1276 (5th Cir. 1974). When Arizona adopted the doctrine four years later, it echoed this reasoning: "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." *Dyer v. Best Pharmacal*, 118 Ariz. 465, 469, 577 P.2d 1084, 1088 (Ct. App. 1978) (quotation marks omitted).

Since this groundbreaking decision, the doctrine has become the overwhelming common law of the nation. It has been adopted on a nationwide basis with only one state -- West Virginia -- rejecting it, in an opinion that has subsequently been construed narrowly by another court in that state.[3]

These courts repeatedly recognize the twin rationales for the learned intermediary doctrine. First, the patient's physician, not a manufacturer, is best able to evaluate the needs of the patient: "[t]he physician is in the best position . . . to balance the needs of patients against the risks and benefits of a particular drug or therapy, and then supervise its use." *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164 (Ohio 2002) (quotations omitted); *see also McCombs v.*

[3] Appendix A lists the 51 jurisdictions -- state courts in 44 states, federal courts applying the law of an additional five states, and courts in the District of Columbia and Puerto Rico -- that have endorsed the learned intermediary doctrine.

Synthes (U.S.A.), 587 S.E.2d 594, 595 (Ga. 2003) (same); *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928-29 (Utah 2003) (same). As the Eighth Circuit stated, "medical ethics and practice dictate that the doctor ***must*** be an intervening and independent party between patient and drug manufacturer." *Hill v. Searle Labs.*, 884 F.2d 1064, 1070 (8th Cir. 1989) (emphasis added); *see also North v. W. Va. Bd. of Regents*, 332 S.E.2d 141, 147 (W. Va. 1985) (same); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989) (same).

Second, requiring manufacturers to circumvent prescribers by warning patients directly "would interfere with the relationship between the doctor and the patient." *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991). Taking the doctor out of the equation leads to patients missing or misunderstanding risk information relevant to them and potentially spurning otherwise vital medical treatment. *See Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 764 (Ky. 2004).

B. The Court of Appeals Misconstrued the Doctrine.

As the Court of Appeals recognized, although the learned intermediary doctrine is sometimes framed as a causation doctrine, it is better understood as defining the manufacturer's duty: "In its application, the learned intermediary doctrine appears to be less a rule of causation and more a standard for determining when a drug manufacturer has satisfied its duty to warn." *Watts v. Medicis Pharm. Corp.*, 236 Ariz. 511, 517 ¶ 31, 342 P.3d 847, 853 (Ct. App. 2015); *see also Kirk v.*

Michael Reese Hospital & Med. Ctr., 513 N.E.2d 387, 393 (Ill. 1987) ("[T]here is no duty on the part of manufacturers of prescription drugs to directly warn patients."); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012) ("[B]y providing adequate warnings to the intermediaries who prescribe the drug … [the manufacturer] has no further duty to warn the end users directly."). Stated differently, the doctrine does not alleviate a manufacturer's obligations, it instead defines how they are met: by appropriately warning prescribers through the PI.

This proper understanding of the learned intermediary doctrine shows the error in the Court of Appeals' reasoning. The learned intermediary doctrine does not, as the Court of Appeals misconceived, "preclude[] a complete assessment of comparative fault among tortfeasors." *Watts*, 236 Ariz. at 518 ¶ 36, 342 P.3d at 854. Instead, it defines when fault may exist by specifying where the duty lies. If the duty is met through appropriate physician warnings, no apportionment need be made: one cannot apportion fault where there is no fault to apportion. On the other hand, if the duty to warn the physician is not met, then fault may be apportioned as appropriate, consistent with UCATA.

This error by the Court of Appeals explains why no other court has reached that same outcome. This includes four Arizona Court of Appeals decisions that have recognized the learned intermediary doctrine even after Arizona's

establishment of several-only liability in 1987,[4] along with decisions from sixteen other jurisdictions that continue to apply the doctrine after the adoption of several-only liability schemes.[5] As one court facing this question recognized, there simply is no conflict between a several-only system and the learned intermediary doctrine:

> Wyoming's comparative fault scheme . . . presents evidence of another's negligence in order to reduce damages; it in no way defines or affects the scope of the

[4] *See Myers v. Hoffman-La Roche, Inc.*, 217 Ariz. 5, 170 P.3d 254, 263 (Ct. App. 2008), *review denied and ordered depublished*, 218 Ariz. 293, 183 P.3d 544 (2008)); *Piper v. Bear Med. Sys., Inc.*, 180 Ariz. 170, 178, 883 P.2d 407, 415 (Ct. App. 1993), *review denied* (Ariz. Nov. 1, 1994); *Dole Food Co. v. N.C. Foam Indus.*, 188 Ariz. 298, 302, 935 P.2d 876, 880 (Ct. App. 1996), *review dismissed* (Ariz. June 25, 1997) (non-medical product); *Davis v. Cessna Aircraft Corp.*, 182 Ariz. 26, 38, 893 P.2d 26, 38 (Ct. App. 1994), *review denied* (Ariz. April 25, 1995) (non-medical product).

[5] In eleven of these states, the highest court in the state has continued to recognize the learned intermediary doctrine. *See* Alaska Stat. § 09.17.080 (1989); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200, n.17 (Alaska 1992); Ark. Code § 16-55-201 (2003); *Kowalski v. Rose Drugs of Dardanelle, Inc.*, 378 S.W.3d 109, 120 (Ark. 2011); Conn. Gen. Stat. § 52-572h (1999); *Hurley v. Heart Physicians, P.C.*, 898 A.2d 777, 783-84 (Conn. 2006); Fla. Stat. § 768.81 (1987) (amended in 1988); *E.R. Squibb & Sons, Inc. v. Farnes*, 697 So.2d 825, 827 (Fla. 1997); Ga. Code § 51-12-33(b) (1987); *McCombs v. Synthes*, 587 S.E.2d 594, 595 (Ga. 2003); Kan. Stat. § 60-258a(d) (1974); *Savina v. Sterling Drug, Inc.*, 795 P.2d 915, 928 (Kan. 1990); Ky. Stat. § 411.182 (1988); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 761 (Ky. 2004); 23 Okl. Stat. § 15 (2009); *Edwards v. Basel Pharms.*, 933 P.2d 298, 300-01 (Okla. 1997); *Tortorelli v. Mercy Health Ctr., Inc.*, 242 P.3d 549, 558 (Okla. Ct. App. 2010); Tex. Civ. Prac. & Rem. Code § 33.013 (2007); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 154-59 (Tex. 2012); Ut. Code § 78B-5-818 (1986); *Schaerrer v Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928-29 (Utah 2003); Wyo. Stat. § 1-1-109 (1986); *Rohde v. Smiths Med.*, 165 P.3d 433, 438, n.5 (Wyo. 2007). In another five states, a lower state court or federal court has continued to recognize the learned intermediary doctrine. *See* Colo. Stat. § 13-21-111.5 (1986); *O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1281-82 (Colo. App. 2010); Ind. Code § 34-51-2-8 (1985); *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 548-59 (Ind. App. 1979); La. C.C. Art. 2323 (1979); *Kampmann v. Mason*, 921 So.2d 1093, 1094 (La. App. 2006); Mich. Comp. L. § 600.6304 (1961); *Mowery v. Crittenton Hospital*, 400 N.W.2d 633, 637 (Mich. App. 1986); N.D. Code § 32-03.2-02 (1987); *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1017 (8th Cir. 2004) (applying North Dakota law).

> defendant's initial duty. The adoption of comparative negligence does not abrogate the necessity of an initial finding that the defendant owed a duty to the plaintiff.

Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 853 (10th Cir. 2003) (citations and quotation marks omitted).

C. Invoking UCATA To Eliminate the Learned Intermediary Doctrine Is Both Contrary to the Purpose of UCATA and Results in a Fundamental Unfairness on These Facts.

UCATA was adopted and amended to provide fairness to defendants by limiting their liability, such that liability extends only to their "own contribution to the plaintiff's injury." *Watts*, 236 Ariz. at 518 ¶ 34, 342 P.3d at 853. There is something fundamentally wrong in transforming a statute intended to limit liability into a vehicle for creating a new category of liability previously nonexistent in Arizona. Reinterpreting UCATA to have this effect runs afoul of a basic principle of Arizona jurisprudence that courts should not "find that a statute changes common law unless the legislature . . . clearly and plainly manifests an intent to have the statute do so." *Young v. Beck*, 227 Ariz. 1, 4 ¶ 13, 251 P.3d 380, 383 (2011) (citations and quotation marks omitted); *see also Pleak v. Entrada Prop. Owners' Ass'n*, 207 Ariz. 418, 422, 87 P.3d 831, 835 (2004) (same); *Hayes v. Cont'l Ins. Co.*, 178 Ariz. 264, 274, 872 P.2d 668, 678 (1994) (same). This presumption has compelling force here, given that the purpose of UCATA was to

limit liability, not dramatically expand it in a way at odds with the federal regulatory regime and the common law of every state but one.

The facts of this case illustrate why the Court of Appeals' misapplication of UCATA is inimical to its original goals of promoting fairness and limiting liability. There is no dispute here that the manufacturer warned the plaintiff's prescribing physician of the specific risk at issue and thus met its duty as it has been defined for decades in Arizona. It is thus especially nonsensical to use a statute intended to materially limit liability as a vehicle for expanding a company's duty.

IV. Arizona Should Reject a DTC Exception to the Learned Intermediary Doctrine.

In rejecting the learned intermediary doctrine, the court below reasoned that, because of the "realities of modern-day pharmaceutical marketing," in which "consumers are regularly presented with advertisements for medications," a physician "no longer is necessarily the consumer's sole source of information." *Watts*, 236 Ariz. at 519 ¶ 37, 342 P.3d at 855. Accordingly, a "manufacturer should not be shielded from liability simply because it provided adequate warnings to a third party." *Id* at ¶ 38.

As a threshold factual matter, the record is undisputed that none of the Medicis-originating materials provided to Ms. Watts by her doctor and pharmacist implicate the concerns about DTC advertising voiced by the Court of Appeals.

Ms. Watts received a discount savings card ***from her physician*** "at the time of her appointment" and thus after the medical decision to prescribe Solodyn had been made. While these materials must contain a summary of risk information, courts have refused to re-characterize these types of important doctor-distributed patient materials as "DTC advertising" sufficient to warrant an exception to the learned intermediary doctrine, even in the one state to have formally adopted such an exception. *See Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 162-63 (Tex. 2012) (affirming that "patient materials" are "supplement[s] to the physician-patient relationship" that must be reviewed by the learned intermediary who distributes them to the patient) (citation omitted); *Banner v. Hoffmann-La Roche Inc.*, 891 A.2d 1229, 1236-37 (N.J. App. Div. 2006) ("[T]he material developed by Roche as part of its Pregnancy Prevention Program does not, in our judgment, constitute direct-to-consumer advertising [and such information] . . . is intended to memorialize the information supplied to the patient by the prescribing physician."). As for the product monograph Ms. Watts received from the pharmacy, there is nothing in the record to demonstrate that this came from Medicis, and it is well understood that pharmacies generate these patient summaries from independent publishers. *See, e.g., Rivera v. First Databank, Inc.*, 187 Cal. App. 4th 709, 713 (2010).

Even if these materials could be construed as DTC advertising, they would not justify gutting the learned intermediary doctrine.

First, the emergence of DTC advertising has not prevented physicians from exercising their "independent judgment, unaffected by the manufacturer's control." *Dyer*, 118 Ariz. at 469 (quotation marks omitted). On the contrary, the lower court's suggestion that consumers will "pressure" their medical providers to prescribe specific medications -- and the implication that providers will succumb to this pressure -- both lacks empirical support and ignores the professional obligations of Arizona physicians. It is illogical to assume that, simply because a prescription medication has been advertised, physicians will abdicate their professional responsibility to "independently weigh relevant risks and benefits in prescribing [the] advertised drug." Richard B. Goetz & Karen R. Growdon, *A Defense of the Learned Intermediary Doctrine*, 63 Food & Drug Law Journal 421, 432 (2008). Indeed, physicians who blindly prescribe medications are subject to discipline by the Arizona Medical Board. A.R.S. § 32-1401(27)(ss); *see also Golob v. Ariz. Med. Bd.*, 217 Ariz. 505, 509-10, 176 P.3d 703, 707-08 (Ct. App. 2008) (enforcing discipline against physician who prescribed drugs without examining patients or establishing doctor-patient relationship).

Second, notwithstanding DTC advertising, physicians remain uniquely positioned to provide individualized warnings to patients. While manufacturers

can and do convey additional information in brief advertisements directly to patients, it does not follow that manufacturers can effectively communicate complex and personally-tailored warnings about prescription medications to individual patients in the same way a physician can. Only the physician has information about both the risks of a certain medicine *and* the medical history or condition of a particular patient. Applying this information to make an individualized risk assessment properly remains the physician's central role, for "[t]he doctor is intended to be an intervening party in the full sense of the word." *Dyer*, 118 Ariz. at 469, 577 P.2d at 1088 (quotation marks omitted).

Third, empirical evidence shows that DTC advertising of prescription medications has had an overall salutary effect on the physician-patient relationship. A 2004 joint report by the Federal Trade Commission and the U.S. Department of Justice found that DTC advertising "provides consumers with useful information, stimulates productive discussions between doctors and patients, and encourages consumers to learn more about previously undiagnosed conditions." FTC & DOJ, *Improving Health Care: A Dose of Competition*, at Chapter 7, Part V, *available at* http://usdoj.gov/atr/public/health_care/204694/chapter7.htm. The FDA itself has pointed to data showing that many physicians credit DTC advertising with prompting more thoughtful patient questions. Kathryn Aiken, *The Impact of Direct-to-Consumer Prescription Drug Advertising on the Physician-Patient*

Relationship, Presentation at FDA-Sponsored Public Meeting on Direct to Consumer Advertising (Sept. 23, 2003), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandT obacco/CDER/UCM213625.pdf.

It is for these reasons that only a single jurisdiction, New Jersey, recognizes a DTC advertising exception. *See Perez v. Wyeth Labs. Inc.*, 734 A.2d 1245 (N.J. 1999). In the more than fifteen years since this decision, no other court has followed this view and several have expressly rejected it. *See, e.g., Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 162 (Tex. 2012) (declining to "follow the New Jersey Supreme Court's sweeping departure from the learned intermediary doctrine."); *DiBartolo v. Abbott Labs*., 914 F. Supp. 2d 601, 616 (S.D.N.Y. 2012); *Mendez Montez De Oca v. Aventis Pharma*, 579 F. Supp. 2d 222, 229 (D. Puerto Rico 2008); *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376-77 (S.D. Fla. 2007); *In re Meridia Prods. Liab. Litig*., 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004), *aff'd*, 447 F.3d 861 (6th Cir.); *Albertson v. Wyeth Inc.*, 63 Pa. D. & C. 4th 514, 2003 WL 21544488, at *12 (Pa. Comm. Pl. July 8, 2003). The court below simply ignored this line of cases, placing Arizona at odds with virtually every other jurisdiction in the country that has rejected the DTC advertising exception.

V. CONCLUSION AND PRAYER

For the reasons stated above, undersigned *amici* join Medicis in urging this Court to grant the petition and reverse the lower court.

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APPENDIX A TO BRIEF OF AMICI CURIAE THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, THE U.S. CHAMBER OF COMMERCE, THE U.S. CHAMBER LITIGATION CENTER, THE ARIZONA CHAMBER OF COMMERCE & INDUSTRY, AND THE ARIZONA MANUFACTURERS COUNCIL IN SUPPORT OF PETITIONER

United States Jurisdictions Endorsing the Learned Intermediary Doctrine

State/Territory	State or Federal Authority	Key Opinion(s) and Relevant Language
Alabama	State courts	• *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 674 (Ala. 2014) ("This Court has adopted the learned-intermediary doctrine, which provides that a prescription-drug manufacturer fulfills its duty to warn users of the risk associated with its product by providing adequate warnings to the learned intermediaries who prescribe the drug and that, once that duty is fulfilled, the manufacturer owes no further duty to the ultimate consumer.").

		• *Nail v. Publix Super Markets, Inc.*, 72 So. 3d 608, 614 (Ala. 2011) ("In *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301 (Ala. 1984), this Court adopted the learned-intermediary doctrine in a case addressing whether a manufacturer's duty to warn extends beyond the prescribing physician to the physician's patient who would ultimately use the drugs."). • *Walls v. Alpharma USPD, Inc.*, 887 So. 2d 881, 884-86 (Ala. 2004) ("'[W]here prescription drugs are concerned, the manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use.'") (quoting *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1304-05 (Ala. 1984)). • *Morguson v. 3M Corp.*, 857 So.2d 796. 801-2 & n.1 (Ala. 2003) (finding that "[p]ursuant to the learned-intermediary doctrine," manufacturer had duty only to warn physician, and observing that "[c]ourts rely on the expertise of physicians to 'bridge the gap' in cases where the medical product and its related warning are too complex to be fully appreciated by the patient.").
Alaska	State courts	• *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1194-95 & n.6 (Alaska 1992) ("A prescription drug's performance safety depends on many variables, including the nature of the drug itself, the patient's medical history, dosage, and combination with other medications, whose complex interplay is beyond the comprehension of the ordinary consumer. . . . In a sense, prescribing doctors are the

		consumers of prescription drugs. It is the doctor's evaluation of the patient's condition and consideration of the available treatment alternatives which leads to the choice of a specific prescription drug product.").
Arizona	State courts	• *Myers v. Hoffman-La Roche, Inc.*, 217 Ariz. 5 ¶ 36, 170 P.3d 254, 263 (Ariz. Ct. App. 2008), *review denied and ordered depublished*, 218 Ariz. 293, 183 P.3d 544 (2008) ("The learned-intermediary doctrine provides that the manufacturer or supplier of a prescription drug has no legal duty to warn a consumer of the dangerous propensities of its drug, as long as adequate warnings are provided to the prescribing physician.") (internal quotation marks omitted). • *Dole Food Co. v. N.C. Foam Indus.*, 935 P.2d 876, 880 (Ariz. Ct. App. 1996) ("[U]nder the learned intermediary doctrine, the manufacturer's duty to warn is ordinarily satisfied if a proper warning is given to the specialized class of people that may prescribe or administer the product.") (internal quotation marks omitted). • *Piper v. Bear Med. Sys., Inc.*, 180 Ariz. 170, 178 & n.3, 883 P.2d 407, 415 (Ariz. Ct. App. 1993) (explaining that the learned intermediary doctrine, which applied to medical device at issue, "means the manufacturer's duty to warn is ordinarily satisfied if a proper warning is given to the specialized class of people that may prescribe or administer the product."). • *Dyer v. Best Pharmacal*, 118 Ariz. 465, 468, 577 P.2d 1084, 1087 (Ariz. Ct. App. 1978) ("A

		drug manufacturer has discharged his duty to the public if he has properly warned the administering physician of the contraindications and possible side effects of the drug."). • *Gaston v. Hunter*, 121 Ariz. 33, 47, 588 P.2d 326, 340 (Ariz. Ct. App. 1978) ("In the case of prescription drugs . . . the manufacturer's duty to warn is ordinarily satisfied if a proper warning is given to the prescribing physician.").
Arkansas	State courts	• *Kowalski v. Rose Drugs of Dardanelle, Inc.*, 378 S.W.3d 109, 120 (Ark. 2011) ("Arkansas adopted the learned-intermediary doctrine in *West v. Searle & Co.* That doctrine provides an exception to the general rule that a manufacturer has a duty to warn the ultimate user of the risks of its products.") (internal citation omitted). • *West v. Searle & Co.*, 806 S.W.2d 608, 613 (Ark. 1991) (stating that the learned intermediary doctrine applies for three reasons: "First, a physician must prescribe the drug, the patient relies upon the physician's judgment in selecting the drug, and the patient relies upon the physician's advice in using the drug. That is to say that there is an independent medical decision by the learned intermediary that the drug is appropriate. Second, it is virtually impossible in many cases for a manufacturer to directly warn each patient. Third, imposition of a duty to warn the user directly would interfere with the relationship between the doctor and the patient.").

California	State courts	• *Brown v. Superior Court*, 751 P.2d 470, 477 n.9 (Cal. 1988) ("It is well established that a manufacturer fulfills its duty to warn if it provides adequate warning to the physician."). • *Carlin v. Superior Court*, 920 P.2d 1347, 1354 (Cal. 1996) ("Moreover, in the case of prescription drugs, the duty to warn runs *to the physician*, not to the patient."). • *Stevens v. Parke, Davis & Co.*, 507 P.2d 653, 661 (Cal. 1973) ("In the case of medical prescriptions, if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.") (internal quotation marks omitted).
Colorado	Federal and State courts	• *Caveny v. Ciba-Geigy Corp.*, 818 F. Supp. 1404, 1406 (D. Colo. 1992) ("A warning is adequate when it explains to the physician the risk which the plaintiff is asserting to be associated with the drug and which caused the death. It is the responsibility of the physician as a learned intermediary to assess the risks and benefits of a particular course of treatment."). • *O'Connell v. Biomet, Inc.*, 250 P.3d 1278, 1281-82 (Colo. App. 2010) ("Based on the above authorities, we are persuaded that the learned intermediary doctrine should apply to failure to warn claims in the context of a medical device installed operatively when it is available only to physicians and obtained by prescription, and the doctor is in a position to reduce the risks of harm in accordance with the instructions or warnings.").

		• *Peterson v. Parke Davis & Co.*, 705 P.2d 1001, 1003 (Colo. Ct. App. 1985) ("Where, as here, an attending physician, in prescribing and in supervising the use of the drug, disregards the manufacturer's warnings and instructions, it is that conduct which renders the product unreasonably dangerous, and thus defective, and the adequacy of the warnings and instructions are not relevant.").
Connecticut	State courts	• *Hurley v. Heart Physicians, P.C.*, 898 A.2d 777, 783-84 (Conn. 2006) ("The learned intermediary doctrine provides that adequate warnings to prescribing physicians obviate the need for manufacturers of prescription products to warn ultimate consumers directly. The doctrine is based on the principle that prescribing physicians act as learned intermediaries between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess [the] risks and benefits of a particular course of treatment. …") (internal quotation marks omitted) (alteration in original). • *Vitanza v. Upjohn Co.*, 778 A.2d 829, 836-38 (Conn. 2001) ("[P]rescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess [the] risks and benefits of a particular course of treatment.") (internal quotation mark omitted) (alteration in original). • *Id.* at 841 ("The learned intermediary doctrine stands for the proposition that, as a matter of law, the prescribing physician of a prescription drug is the person best able to

		take or recommend precautions against the harm.").
Delaware	State courts	• *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989) ("In the final analysis it is the physician who ultimately prescribes the drug or device. Thus, if the manufacturer of prescription products provides the physician with the legally appropriate information, it has satisfied its duty to warn.").
District of Columbia	N/A	• *Mampe v. Ayerst Labs.*, 548 A.2d 798, 801-02 n.6 (D.C. 1988) (the prescribing physician is "the user" of a prescription medication; "[w]hen the purchase of the product is recommended or prescribed 'by an intermediary who is a professional, the adequacy of the instructions must be judged in relationship to that professional.'") (quoting *Payne v. Soft Sheen Prods., Inc.*, 486 A.2d 712, 722 n.10 (D.C. 1985)).
Florida	State courts	• *E.R. Squibb & Sons, Inc. v. Farnes*, 697 So.2d 825, 827 (Fla. 1997) (approving lower court's statement that "Florida law requires that the manufacturer provide an adequate warning only the physician, or 'learned intermediary.' … Pharmaceutical manufacturers discharge their duty to warn the learned intermediary by way of a package insert which accompanies each vial of vaccine."). • *Upjohn Co. v. MacMurdo*, 562 So.2d 680, 683 (Fla. 1990) ("The manufacturer's duty to warn of the drug's dangerous side effects is directed to the physician rather than the patient."). • *Felix v. Hoffmann-La Roche Inc.*, 540 So. 2d 102, 104 (Fla. 1989) ("[I]t is clear that the

		manufacturer's duty to warn of [the drug's] dangerous side effects was directed to the physician rather than the patient" because "the prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs.").
Georgia	State courts	• *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003) ("Under the learned intermediary doctrine, the manufacturer of a prescription drug or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer. The rationale for the doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities.") (footnotes and quotation marks omitted) (alteration in original).
Hawaii	State courts	• *Craft v. Peebles*, 893 P.2d 138, 155 (Haw. 1995) (applying the learned intermediary doctrine and stating that it applies to prescription pharmaceutical products because "physicians are in a better position [than manufacturers] to assess risks and determine when a particular patient reasonably should be informed about a risk.") (internal quotation marks omitted).

Idaho	State courts	• *Sliman v. Aluminum Co. of Am.*, 731 P.2d 1267, 1270-71 (Idaho 1986) (holding that "a supplier positioned on the commercial chain remote from the ultimate consumer may fulfill its duty to warn by adequately warning an intermediary" such as "when a drug manufacturer properly warns a prescribing physician of the dangerous propensities of its product") (internal quotation mark omitted).
Illinois	State courts	• *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002) ("Generally, the manufacturer of a prescription medical device has a duty to warn prescribing physicians or other health professionals who may prescribe the device of the product's known dangerous propensities. … The duty to warn the health-care professional, rather than the ultimate consumer or patient, is an expression of the "learned intermediary" doctrine.") (internal citations omitted). • *Kirk v. Michael Reese Hosp. & Med. Ctr.*, 513 N.E.2d 387, 393 (Ill. 1987) ("The doctor, functioning as a learned intermediary between the prescription drug manufacturer and the patient, decides which available drug best fits the patient's needs and chooses which facts from the various warnings should be conveyed to the patient, and the extent of disclosure is a matter of medical judgment. As such, we believe the learned intermediary doctrine is applicable here and that there is no duty on the part of manufacturers of prescription drugs to directly warn patients.") (internal citations omitted). • *Martin by Martin v. Ortho Pharm. Corp.*, 661 N.E.2d 352, 354 (Ill. 1996) ("[M]anufacturers

		of prescription drugs have a duty to warn prescribing physicians of a drug's known dangerous propensities and that physicians, in turn, using their medical judgment, have a duty to convey any relevant warnings to their patients."). • *Happel v. Wal-Mart Stores, Inc.*, 766 N.E.2d 1118, 1125 (Ill. 2002) (noting that in *Kirk* "this court adopted the learned intermediary doctrine.").
Indiana	Federal and State courts	• *Ziliak v. AstraZeneca LP*, 324 F.3d 518, 521 (7th Cir. 2003) ("The duty to provide adequate warning arises only when the manufacturer knows or should know of a risk posed by the product, and, in cases involving drugs available only by prescription, extends only to the medical profession, not the consumer.") • *Ortho Pharm. Corp. v. Chapman*, 388 N.E.2d 541, 553 (Ind. Ct. App. 1979) ("In the case of ethical drugs, the manufacturer's duty is discharged if adequate warning is given to doctors, who act as 'learned intermediaries' between the manufacturer and the ultimate user.").
Iowa	Federal and State courts	• *McCormick v. Nikkel & Assocs., Inc.*, 819 N.W. 2d 368, 375 (Iowa 2012) (observing that "we recognize various 'no duty' rules in the warning area" and citing the "learned intermediary rule" as one such "no duty" rule the court recognizes). • *Madsen v. Am. Home Prods. Corp.*, 477 F. Supp. 2d 1025, 1033 (E.D. Mo. 2007) ("Iowa would adopt the [learned intermediary] doctrine. . . . ").

		• *Petty v. United States*, 740 F.2d 1428, 1440 (8th Cir. 1984) (learned intermediary doctrine did not apply in case involving swine flu vaccine because "in a mass immunization context, *where there is no learned intermediary*, the duty extends to the ultimate recipient of the vaccine") (emphasis added). • *Brazzell v. United States*, 788 F.2d 1352, 1358 (8th Cir. 1986) ("We hold that the doctor's intervention is not enough to dispel the manufacturer's duty to warn the ultimate consumer in view of the swine flu program's exigent circumstances. . . . We have little trouble in viewing doctors in the program, rather than learned intermediaries, as distributors of a defective product. As stated above, the emergency nature of the program forced this role on them.").
Kansas	State courts	• *Humes v. Clinton*, 792 P.2d 1032, 1039-41 (Kan. 1990) ("Since prescription drugs are available only to a physician, it is the physician's duty to inform himself or herself of the characteristics of the drugs prescribed and to exercise his or her judgment of which drug to administer in light of the drug's propensities and the patient's susceptibilities. . . . [W]e have adopted the learned intermediary rule, which relieves the manufacturers of the duty to warn consumers directly, in IUD cases.") (internal citations omitted). • *Wooderson v. Ortho Pharm. Corp.*, 681 P.2d 1038, 1052 (Kan. 1984) ("A second important limitation on liability ... applies to manufacturers of ethical [prescription] drugs. Since such drugs are available only by prescription, a manufacturer's duty to warn

		extends only to the medical profession, and not the ultimate users.") (internal quotation marks omitted) (alterations in original).
Kentucky	State courts	• *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 109 (Ky. 2008) ("Approximately three months after the trial in the case at bar, this Court rendered its decision in *Larkin*, wherein we adopted the learned intermediary doctrine from the *Restatement (Third) of Torts*. This doctrine, which is an exception to the general rule that a manufacturer's duty to warn of any risks or dangers inherent in the product runs to the ultimate consumer, relieves the prescription drug manufacturer from liability to the ultimate consumer if it provides an adequate warning about the drug to the prescribing physician.") (internal citations omitted). • *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 765, 770 (Ky. 2004) ("[P]roviding an adequate warning to the prescribing physician relieves the manufacturer of its duty to warn the patient regardless of how or if the physician warns the patient."); *id.* ("[W]e now adopt *Restatement (Third) of Torts: Products Liability* § 6(d) (duty to warn of possible side effects satisfied if adequate warning given to patient's health care provider . . .).")
Louisiana	Federal and State courts	• *Stahl v. Novartis Pharms. Corp.*, 283 F.3d 254, 265 (5th Cir. 2002) ("Louisiana applies the 'learned intermediary doctrine' to products liability claims involving prescription drugs."). • *Kampmann v. Mason*, 921 *So.* 2d 1093, 1094 (La. Ct. App. 2006) ("In an inadequate warning claim against a drug manufacturer, a

		plaintiff must show that the manufacturer failed to warn the physician of a potential risk of taking the drug and, second that this failure to warn the doctor was the proximate cause of his injury."). • *Calhoun v. Hoffmann-La Roche, Inc.*, 768 So. 2d 57, 61 (La. Ct. App. 2000) ("'The manufacturer has no duty to warn the consumer directly of any risks or contraindications associated with the drug. The manufacturer of the drug has fulfilled its obligation when it has informed the prescribing and treating physicians of the risks of harm from the drug so that they may intelligently decide on its use and advise the patient.'") (quoting *Cobb v. Syntex Labs., Inc.*, 444 So. 2d 203, 205 (La. Ct. App. 1983)).
Maine	Federal and State courts	• *Doe v. Solvay Pharms., Inc.*, 153 F. App'x 1, 2 (1st Cir. 2005) ("We also reject Doe's contention that the court should not have applied the learned intermediary rule to her defective warning claim. This court already has decided that Maine courts would adopt that rule."). • *Tardy v. Eli Lilly & Co.*, No. CV-03-538, 2004 WL 1925536, at *2 (Me. Super. Ct. Aug. 3, 2004) (holding that the learned intermediary doctrine shields pharmacists from liability for failure to warn and noting that "[i]f the doctor is properly warned [by the manufacturer] of the possibility of a side effect in some patients, and is advised [by the manufacturer] of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can

		be avoided.") (quotation omitted). • *Violette v. Smith & Nephew Dyonics, Inc.*, 62 F.3d 8, 13 (1st Cir. 1995) (applying Maine law) ("[T]he general rule regarding medical devices (and, more frequently and by analogy, prescription drugs) is that the manufacturer must warn the physician—the so-called 'learned intermediary'—and not the patient directly.").
Maryland	State courts	• *Rite Aid Corp. v. Levy-Gray*, 894 A.2d 563, 631 (Md. 2006) ("'The obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider's prescription traditionally has required warnings directed to health-care providers and not to patients. The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.'") (quoting *Restatement (Third) of Torts: Products Liability* § 6 cmt. b). • *Nolan v. Dillon*, 276 A.2d 36, 40 (Md. 1971) (holding, without specifically addressing whether the learned intermediary doctrine applied, that "[manufacturer's] package insert and the label on the 50 milligram concentration fully discharged its duty to

		warn").
Massachusetts	State courts	• *Cottam v. CVS Pharmacy*, 764 N.E.2d 814, 821 (Mass. 2002) ("This court has already recognized the learned intermediary doctrine in the context of prescription drug manufacturers. Because the physician is the appropriate person to perform the duty of warning a patient of the possible side effects of prescription drugs, we now extend [the learned intermediary doctrine] to pharmacies.") (internal citation omitted).
Michigan	State courts	• *Smith v. E.R. Squibb & Sons, Inc.*, 273 N.W. 2d 476, 479 (Mich. 1979) ("A manufacturer of a prescription drug has a legal duty to warn the medical profession, not the patient, of any risks inherent in the use of the drug which the manufacturer knows or should know to exist.").
Minnesota	State courts	• *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 n.1 (Minn. 1970) ("The manufacturer has no duty to warn the lay public regarding prescription drugs.") (citations omitted).
Mississippi	State statute and courts	• Miss. Code Ann. § 11-1-63(c)(ii) ("An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be

		used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product."). • *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So. 2d 31, 58 (Miss. 2004) ("When the product in question is a prescription drug, Mississippi follows the learned intermediary doctrine. Under this doctrine, the manufacturer's failure to warn the patient of the product's risks does not render the product defective or unreasonably dangerous so long as the manufacturer adequately warns the learned intermediary."). • *Moore v. Memorial Hosp. of Gulfport*, 825 So.2d 658, 664 (Miss. 2002) ("We affirm the circuit court's findings and extend the learned intermediary doctrine to pharmacists. As one court has stated, the cornerstone of the learned intermediary doctrine is the ability of the physician to intervene between the drug and the patient, and to make an informed decision as to the course of treatment based on the physician's knowledge of the drug as well as the propensities of the patient. The physician is best situated to know the propensities of a drug and to know the needs and characteristics of his patient.") (internal citations and quotation marks omitted). • *Bennett v. Madakasira*, 821 So.2d 794, 804 (Miss. 2002) ("Under Mississippi law, *as in virtually every jurisdiction in a prescription drug case*, a manufacturer of a prescription drug has no duty to warn the patient, consumer, or general public of adverse

		effects. Under the learned intermediary doctrine, manufacturers do have a duty, however, to adequately warn the treating physician.") (emphasis added) (citing *Wyeth Labs., Inc. v. Fortenberry*, 530 So.2d 688, 691 (Miss. 1988)).
Missouri	State courts	• *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 151-52 (Mo. 1967) ("[I]n this case we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided.") (internal quotation marks omitted) • *Doe v. Alpha Therapeutic Corp.*, 3 S.W.3d 404, 419 (Mo. Ct. App. 1999) ("Missouri courts adhere to the learned intermediary doctrine.").
Montana	State courts	• *Hill v. Squibb & Sons, E.R.*, 592 P.2d 1383, 1387-88 (Mont. 1979) ("As a general rule, the duty of a drug manufacturer to warn of the dangers inherent in a prescription drug is satisfied if adequate warning is given to the physician who prescribes it.").
Nebraska	Federal and State courts	• *Tyler v. Bristol-Meyer Squibb*, 8:10CV107, 2010 U.S. Dist. LEXIS 40268, at *3 (D. Neb. Apr. 23, 2010) ("To determine whether a manufacturer may be liable for a warning or a defect in a prescription drug case, Nebraska uses the learned intermediary doctrine . . . .").

		• *Freeman v. Hoffmann-La Roche Inc.*, 618 N.W.2d 827, 841-42 (Neb. 2000) ("Pharmaceutical products have historically been treated differently in regard to a duty to warn. . . . [I]n cases involving prescription drugs, it is widely held that the duty to warn extends only to members of the medical profession and not to the consumer. This concept, known as the learned intermediary doctrine, is based upon the premise that, as a medical expert, a patient's prescribing or treating physician is in the best position to evaluate the often complex information provided by the manufacturer concerning the risks and benefits of its drug or product and to make an individualized medical judgment, based on the patient's particular needs and susceptibilities, as to whether the patient should use the product. . . . We adopt § 6(d) of the *Third Restatement*.") (internal quotation marks omitted).
Nevada	State courts	• *Kerns v. Hoppe*, No. 55615, 2012 Nev. Unpub. LEXIS 425, at *20 (Nev. Mar. 21, 2012) ("Moreover, in *Klasch v. Walgreen Co.*, this court adopted the learned-intermediary doctrine . . . . It is up to the doctor who has knowledge of the patient's particular situation to convey any relevant safety information to that patient.") (internal citation omitted). • *Klasch v. Walgreen Co.*, 264 P.3d 1155, 1159 (Nev. 2011) ("Because we believe that these public-policy considerations are sound, we adopt the learned-intermediary doctrine in the context of pharmacist/customer tort litigation.").

New Hampshire	Federal courts	• *Brochu v. Ortho Pharm. Corp.*, 642 F.2d 652, 656 (1st Cir. 1981) ("In cases involving ethical drugs, the manufacturer must warn the physician, not the patient."). • *Nelson v. Dalkon Shield Claimants Trust*, No. 84-276-SD, 1994 WL 255392, at *4 (D.N.H. June 8, 1994) ("'[I]t is generally accepted that in a case involving medical products prescribed or used by a physician or trained medical personnel, the warning runs to the physician not the patient.'" (quoting *Knowlton v. Deseret Med., Inc.*, 930 F.2d 116, 120 n.2 (1st Cir. 1991))).
New Jersey	State courts	• *Perez v. Wyeth Labs., Inc.*, 734 A.2d 1245, 1257 (N.J. 1999) ("In New Jersey, as elsewhere, we accept the proposition that a pharmaceutical manufacturer generally discharges its duty to warn the ultimate users of prescription drugs by supplying physicians with information about the drug's dangerous propensities.") (quoting *Niemiera v. Schneider*, 555 A.2d 1112, 1117 (N.J. 1989)).
New Mexico	State courts	• *Serna v. Roche Labs., Div. of Hoffmann-La Roche, Inc.*, 684 P.2d 1187, 1189 (N.M. Ct. App. 1984) ("Where the product is a prescription drug, the manufacturer's duty to warn is fulfilled if it warns the physician, not the patient.") • *Silva v. Smithkline Beecham Corp.*, No. 31,276, 2013 N.M. App. Unpub. LEXIS 46 (N.M. Ct. App. Feb. 7, 2013) (assuming applicability of learned intermediary doctrine in rejecting innovator liability).
New York	State	• *Martin v. Hacker*, 628 N.E.2d 1308, 1311

	courts	(N.Y. 1993) ("Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects. The physician acts as an 'informed intermediary' between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient.") (internal citations omitted). • *Spensieri v. Lasky*, 723 N.E.2d 544, 549 (N.Y. 1999) ("The learned intermediary doctrine focuses on the scope of a drug manufacturer's duty to warn of the dangers of using the drug in question. That duty is fulfilled by giving adequate warning to the prescribing physician The physician must then balance the risks and benefits of various drugs and treatments and act as an 'informed intermediary' between manufacturer and patient.") (internal citations omitted).
North Carolina	Federal courts, State statute and courts	• N.C. Gen. Stat. Ann. § 99B-5(c) ("[N]o manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product."). • *Foyle v. Lederle Labs.*, 674 F. Supp. 530, 536 (E.D.N.C. 1987) (holding that "when

		prescription drugs are used, the manufacturer's duty to warn does not extend to the patient" because "[t]he doctor is responsible for gathering the information, weighing the dangers and benefits, and making a decision in the best interest of the patient"). • *Holley v. Burroughs Welcome Co.*, 330 S.E.2d 228, 235 (N.C. Ct. App. 1985) (holding that "a pharmaceutical company [is] required to provide adequate warnings regarding its products to [those members of] the 'medical profession'" who are "responsible for the patient's care") (quoting *Whitley v. Cubberly*, 210 S.E.2d 289, 292 (N.C. Ct. App. 1974)).
North Dakota	Federal courts	• *Ehlis v. Shire Richwood, Inc.*, 367 F.3d 1013, 1016 (8th Cir. 2004) ("[P]rescribing physicians act as 'learned intermediaries' between a manufacturer and consumer and, therefore, stand in the best position to evaluate a patient's needs and assess risks and benefits of a particular course of treatment.") (quotation marks omitted).
Ohio	State statute and courts	• Ohio Rev. Code Ann. § 2307.76(C) ("An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it."). • *Howland v. Purdue Pharma, L.P.*, 821 N.E.2d

		141, 146 (Ohio 2004) ("The [] learned-intermediary doctrine has been adopted and applied by this court. . . . The doctrine is an exception to the rule that a manufacturer has a duty to warn the ultimate consumer. It precludes manufacturer liability for failure to warn the consumer when an adequate warning has been given to a 'learned intermediary,' e.g., the consumer's physician.") (citing *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 834, 836-37 (Ohio 1981)). • *Vaccariello v. Smith & Nephew Richards, Inc.*, 763 N.E.2d 160, 164 (Ohio 2002) ("'[T]he rationale behind [the learned intermediary doctrine] is that the physician stands between the manufacturer and the patient as a learned intermediary. The physician has the duty to know the patient's condition as well as the qualities and characteristics of the drugs or products to be prescribed for the patient's use. The physician is in the best position, therefore, to balance the needs of patients against the risks and benefits of a particular drug or therapy, and then supervise its use. . . . The learned intermediary doctrine achieves a proper allocation of responsibility, since not all patients are alike and it is the physician who best knows the patient.'") (quoting *Tracy v. Merrell Dow Pharm., Inc.*, 569 N.E.2d 875, 878 (Ohio 1991) (omission in original)).
Oklahoma	State courts	• *Edwards v. Basel Pharm.*, 933 P.2d 298, 300 (Okla. 1997) ("The [learned intermediary] doctrine operates as an exception to the manufacturer's duty to warn the ultimate consumer, and shields manufacturers of prescription drugs from liability if the manufacturer adequately warns the

		prescribing physicians of the dangers of the drug."). • *McKee v. Moore*, 648 P.2d 21, 24 (Okla. 1982) ("In the absence of FDA regulations to the contrary, the manufacturer has no obligation to warn a consumer if the prescribing physician has been adequately warned of any adverse side effects. The manufacturer's duty is to warn the physician, who acts as a learned intermediary between the manufacturer and the consumer, because he is in the best position to evaluate the patient's needs, assess the benefits and risks of a particular therapy, and to supervise its use."). • *Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Okla. 1982) (noting that "Oklahoma has adopted the learned intermediary doctrine," which "permits a manufacturer to warn the physician, rather than the ultimate consumer, of the problems associated with the product."). • *Cunningham v. Charles Pfizer & Co.*, 532 P.2d 1377, 1381 (Okla. 1974) ("As a general rule it has been held that in cases involving prescription drugs the drug manufacturer has only a duty to warn the prescribing physician.").
Oregon	State courts	• *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 528-29 (Or. 1974) (stating, in a case where the plaintiff's "sole theory of recovery" was "the alleged failure of defendants to adequately warn the medical profession" and where the plaintiff thus did not assert that the manufacturer had a duty to warn her directly,

		that "the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient"). • *Oksenholt v. Lederle Labs.*, 625 P.2d 1357, 1362 (Or. Ct. App. 1981) (stating, in a case where a physician sued a manufacturer for misrepresenting the risks of a drug that he prescribed, that "[a] drug manufacturer's duty, as described in *McEwen*, is a duty to adequately inform doctors of the harm associated with prescription drugs"). • *Griffith v. Blatt*, 51 P.3d 1256, 1261-62 (Or. 2002) (holding that Or. Rev. Stat. § 30.920 "does not create a defense to strict liability based on the learned intermediary doctrine," in a case where a pharmacist placed in a generically labeled bottle a lotion that could be used no more than twice and had to be washed off within 12 hours, and the plaintiff suffered severe injury as a result).
Pennsylvania	State courts	• *Coyle ex rel. Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385 (Pa. 1991) ("[W]hen a drug 'is available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor.' . . . We formulated this rule with reference to comment k and the policies expressed therein.") (quoting *Incollingo v. Ewing*, 282 A.2d 206, 220 (Pa. 1971)). • *Balding v. Castagna*, 478 A.2d 807, 812 (Pa. 1984) (citing *Incollingo*, and stating that "we held that where such drugs are available by prescription only, 'the warning required is not to the general public or to the patient, but to the prescribing doctor.'").

Puerto Rico	Federal courts	• *Guevara v. Dorsey Labs*., 845 F. 2d 364, 366 (1st Cir. 1988) ("It is generally accepted, and the parties do not contest, that a prescription drug manufacturer has a duty to adequately warn prescribing physicians of hazards posed by the use of its drugs. The warning is directed not to the ultimate user but to the doctor prescribing the drug, who must then take into account the propensities of the drug and the susceptibilities of the patient and make an informed decision regarding the advisability of its use.") (internal citations and quotation marks omitted).
Rhode Island	Federal courts	• *Greaves v. Eli Lilly & Co.*, 503 F. App'x 70, 71 (2d Cir. 2012) ("[T]he Rhode Island Supreme Court would likely adopt the learned intermediary doctrine. . . ").
South Carolina	Federal and State courts	• *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) ("Under [the learned intermediary doctrine], the manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device."). • *Madison v. Am. Home Prods. Corp.*, 595 S.E.2d 493, 496 (S.C. 2004) ("[S]trict liability is inconsistent with the learned intermediary doctrine, which places the duty to warn on the prescribing physicians . . .").
South Dakota	Federal courts	• *McElhaney v. Eli Lilly & Co.*, 575 F. Supp. 228, 231 (D.S.D. 1983) ("In cases involving prescription drugs 'the manufacturer must warn the physician, not the patient.' The prescribing physician acts as a learned intermediary between the patient and manufacturer.") (quoting *Brochu v. Ortho*

		Pharm. Corp., 642 F.2d 652, 656 (1st Cir. 1981)). • *Schilf v. Eli Lilly & Co.*, 687 F.3d 947, 952 (Gruender, J., concurring in part, dissenting in part) (8th Cir. 2012) ("South Dakota likely would adopt the learned intermediary doctrine and the heeding presumption . . . .").
Tennessee	State courts	• *Nye v. Bayer Cropscience, Inc.*, No. E2008-01596-COA-R3-CV, 2009 Tenn. App. LEXIS 697, at *33 (Tenn. App. Oct. 14, 2009) ("The learned intermediary doctrine is well established in Tennessee in relation to product liability claims against manufacturers and distributors of prescription drugs and medical devices."). • *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994) ("Under the 'learned intermediary doctrine,' makers of unavoidably unsafe products who have a duty to give warnings may reasonably rely on intermediaries to transmit their warnings and instructions. Physicians are such intermediaries because of the pivotal role they play in the unique system used to distribute prescription drugs. . . . [T]he manufacturer of an unavoidably unsafe prescription drug can discharge its duty to warn by providing the physician with adequate warnings of the risks associated with the use of its drug.") (internal citations omitted).
Texas	State courts	• *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140, 157 (Tex. 2012) ("We hold that a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has

		no further duty to warn the end users directly"). • *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 91 (Tex. App. - Texarkana 2000) ("In prescription drug cases, the courts have found that it is reasonable for the manufacturer to rely on the health care provider to pass on its warnings. This is reasonable because the learned intermediary understands the propensities and dangers involved in the use of a given drug, and as the prescriber, he stands between this drug and the ultimate consumer.").
Utah	State courts	• *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003) (holding that "[u]nder [the learned intermediary doctrine], manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient," and thus pharmacist had no duty to warn patient about prescription medication's risks). • *Barson v. E.R. Squibb & Sons, Inc.*, 682 P.2d 832, 835 (Utah 1984) ("The manufacturer of ethical drugs has the duty of making timely and adequate warnings to the medical profession of any dangerous side effects produced by its drugs of which it knows or has reason to know.").
Vermont	State courts	• *Estate of Baker v. Univ. of Vt.*, No. 233-10-03, 2005 Vt. Super. LEXIS 102, at *26 (Vt. Super. May 5, 2005) ("While apparently never explicitly treated by our Supreme Court, we consider the so-called 'learned intermediary doctrine' adopted in a majority of jurisdictions to be of significant dispositive

		effect in determining the present claims. The learned intermediary doctrine, first recognized in 1966, initially stood for the proposition that a prescription drug manufacturer had a duty to warn of possible side effects in some patients only to a purchasing doctor, the learned intermediary between the manufacturer and patient, and not directly to the patient.").
Virginia	State courts	• *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 44 (Va. 1980) ("[I]n the case of prescription drugs, it is the general rule that the duty of the drug manufacturer is to warn the physician who prescribes the drug in question.") (internal quotation marks omitted).
Washington	State courts	• *Wash. State Physicians Ins. Exch. & Ass'n v. Fisons Corp.*, 858 P.2d 1054, 1061 (Wash. 1993) ("Under the learned intermediary doctrine, a drug company fulfills its duty by giving warnings regarding prescription drugs to the physician rather than to the patient."). • *Rogers v. Miles Labs., Inc.*, 802 P.2d 1346, 1353 (Wash. 1991) ("In *Terhune v. A.H. Robins Co.*, 90 Wash.2d 9, 577 P.2d 975 (1978), we said that 'it has become a well-established rule that in [cases involving prescription drugs], the duty of the manufacturer to warn of dangers involved in use of a product is satisfied if he gives adequate warning to the physician who prescribes it.'") • *McKee v. Am. Home Prods. Corp.*, 782 P.2d 1045, 1149 (Wash. 1989) ("This court has addressed a closely related issue-the manufacturer's duty to warn. Adopting the 'learned intermediary' doctrine, we held in

		Terhune v. A.H. Robins Co., 90 Wash.2d 9, 577 P.2d 975 (1978) that a prescription drug manufacturer's duty to warn of dangers associated with its product runs only to the physician; it is the physician's duty to warn the ultimate consumer.") • *Terhune v. A.H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978) ("Where a product is available only on prescription or through the services of a physician, the physician acts as a 'learned intermediary' between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient.") (internal footnote omitted).
Wisconsin	Federal and State courts	• *Monson v. Acromed Corp.*, No. 96-C-1336, 1999 WL 1133273, at *20 (E.D. Wis. May 12, 1999) (manufacturer had no duty to warn plaintiff because "[t]he general rule regarding medical devices is that the manufacturer must warn the physician — the so-called 'learned

		intermediary' — and not the patient directly"). • *Stupak v. Hoffman-La Roche, Inc.*, No. 8:05-CV-926T30TBM, 2007 WL 2350561, at *2 (M.D. Fla. Aug. 17, 2007), *aff'd* 326 Fed. App'x. 553 (11th Cir. 2009) (applying Wisconsin law and holding that "in the case of prescription drugs, the provision of proper warnings to a physician will satisfy the manufacturer's duty to warn since the patient cannot obtain the drug but through the physician") (internal quotation marks omitted). • *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (stating, in a case governed by Wisconsin law, that "under the learned intermediary doctrine, manufacturers of prescription medical products have a duty only to warn physicians, rather than patients, of the risks associated with the use of the product"). • *Kurer v. Parke, Davis & Co.*, 679 N.W.2d 867, 879 (Wis. Ct. App. 2004) ("We reject Kurer's assertion . . . that 'Warner-Lambert asks the Court to immunize it from any liability . . . because it allegedly provided adequate warnings to [her] prescribing physician, Dr. Lalich.' That is not what Warner-Lamber has asked, and that is not what this court has done. If the patient insert in this case had said nothing about the very symptoms Kurer suffered, and instead simply placed all the warnings in her doctor's hands, this could have been a very different case."). • *But see Maynard v. Abbott Labs*, No. 12-C-0939, 2013 WL 695817, at *5 (E.D. Wis. Feb.

		26, 2013) (asserting, without citation or explanation, and without reference to prior precedent to the contrary, that "Wisconsin does not apply the learned intermediary doctrine").
Wyoming	Federal and State courts	• *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 851-52 (10th Cir. 2003) (following *Jacobs v. Dista Prods. Co.*, 693 F. Supp. 1029, 1030-31 (D. Wyo. 1988), and holding that the learned intermediary doctrine applies under Wyoming law because it "derives from § 402A of the *Restatement (Second) of Torts*, which the Wyoming Supreme Court has adopted in its entirety.") (internal citation omitted). • *Rohde v. Smiths Med.*, 165 P.3d 433, 436 n.5 (Wyo. 2007) ("The 'learned intermediary' principle generally states that a manufacturer has a duty to adequately warn medical professionals about risks associated with use of healthcare products. So long as it complies with that obligation, the manufacturer may rely on medical professionals, as learned intermediaries, to properly warn their patients of the risks.").