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.

Respectfully Submitted,

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