

**SUPREME COURT
STATE OF ARIZONA**

DAVID FRANCISCO and KIMBERLY
FRANCISCO, husband and wife,

Plaintiffs/Appellants,

v.

AFFILIATED UROLOGISTS, LTD., an
Arizona corporation; KEVIN ART, M.D.
and JAND DOE ART, husband and wife,

Defendants/Appellees.

Case No. CV-23-0152-PR

**Arizona Court of Appeals
Case No. 1 CA-CV 21-0701**

Maricopa County Superior Court
No. CV 2020-010470
Hon. James D. Smith

**AMICUS CURIAE BRIEF
OF THE ARIZONA
ASSOCIATION FOR
JUSTICE/ARIZONA TRIAL
LAWYERS ASSOCIATION**

**(FILED WITH WRITTEN
CONSENT OF ALL PARTIES)**

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Legal Argument

1. Questions on patient education and patient consent that this Court may profitably address if it grants the petition for review.

The Court of Appeals wrote a narrow, six-step decision.

Step one: The FDA directed in the drug's package insert that the prescribing doctor should give a warning about all risks associated with the prescribed drug and gave a specific "black box" warning. *Mem. Dec.* ¶¶ 11-12.

Step two: The prescribing doctor did not do that. *Mem. Dec.* ¶ 12.

Step three: No specialized knowledge is needed to evaluate whether the FDA instructed the prescribing doctor to give certain warnings to patients. *Mem. Dec.* ¶ 12. The FDA did or the FDA did not.

Step four: The Franciscos should be allowed to present evidence that the FDA warnings for Cipro directed prescribing doctors to inform their patients about potential adverse reactions and give them instructions for further follow up. *Mem. Dec.* ¶ 12.

Step five(a): The prescribing doctor can offer responsive expert testimony that prescribing doctors "are free to ignore" the FDA directive. *Mem. Dec.* ¶ 12. It is hard to see how prescribing doctors, as the mandatory learned intermediaries between the drug manufacturer and the drug consumer, can ever ignore FDA directives and refuse to transmit to the patient for whom the drug is prescribed the "black box warnings" that the FDA created and mandated because of their extreme

importance for patient choice, health, and safety. There is, after all, a difference between negligent ignorance of the law and willfully ignoring it. Thus the Court of Appeals' unexpected suggestion that a prescribing doctor can offer responsive expert testimony that prescribing doctors "are free to ignore" the FDA directive is something this Court may want to address if it grants the petition for review. *Mem. Dec.* ¶ 12.

Step five(b): Left unspoken is whether that responsive expert testimony needs to be rebutted by testimony from the patient's expert. One would think that what the FDA says controls, and no expert opinion that a mandatory legal directive can be ignored would be needed.

That is, if the FDA says to do something and the prescribing doctor says: "No thanks, I don't want to," is there a question concerning standard of care? Or is there just a question of failure to do what the law requires the prescribing doctor to do, leaving the patient uninformed about how to decide whether to agree to take Cipro?

Step six: In any event, the Court of Appeals held "a layperson is well able to determine whether, in the context of all evidence from both sides, the failure to warn constitutes negligence." *Mem. Dec.* ¶ 12. On that note, the memorandum decision ends.

The Court of Appeals analysis leaves several important points that this Court

may want to explore. First, it seems an unexceptional proposition that expert testimony is not needed to prove that a patient would have declined treatment if there had been adequate disclosure. *Gorney v. Meaney*, 214 Ariz. 226, 231 ¶ 15 (App. 2007). That is a simple question of fact. Well, it is a question of fact simple to pose, although there will need to be testimony from the percipient witnesses and evidence from relevant medical records concerning what was disclosed and what the patient says the patient would have done if the patient had received what the patient regarded as a timely, adequate disclosure.

Second, in cases like the present one, where a patient has testified that, if he had been reasonably informed about the risks, he would not have agreed to take a drug highly dangerous for someone of his age and medical condition, the patient's testimony should be "sufficient to present a question of fact requiring the jury to assess the risks and benefits" of the proposed treatment, and then to decide if a reasonably provident person would have agreed to the treatment. *Osorio v. Brauner*, 662 N.Y.S.2d 488, 489 (App. Div. 1997).

That is, no "expert testimony would be required with respect to whether a particular disclosure did or did not occur, nor as to whether the plaintiff herself would have chosen different treatment if she had known of the risk involved with the performed treatment." *Perez v. Hu*, 87 N.E.2d 1130, 1137 (Ind. App. 2017). The patient can testify directly on both points. Indeed, on the second point, only

the patient would be competent to testify.

That sort of patient-oriented “standard focuses on what the reasonable patient would want to know” and “avoids the necessity of using expert testimony to prove that the disclosure standard has not been met.” Evelyn M. Tenebaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon Objective Causation*, 64 Okla. L. Rev. 697, 738-39 (2012).

The sufficiency of disclosure under a patient-oriented standard “requires that the disclosure be viewed through the mind of the patient, not the physician. Implicit in this shift of emphasis is the recognition that expert testimony is no longer required in order to establish the medical community’s standard for disclosure and whether a physician failed to meet that standard.” *Febus v. Barot*, 616 A.2d 933, 935 (N.J. App. Div. 1992).

Those are simple, important concepts the Court of Appeals did not fully address and that this Court should address if it grants the petition for review.

2. The learned-intermediary doctrine imposes a duty of care on the doctor who prescribes the medication.

The memorandum decision never mentioned the learned-intermediary doctrine. Under that doctrine, “a manufacturer satisfies its duty to warn end users by giving appropriate warnings to the specialized class of persons who may prescribe or administer the product.” *Watts v. Medicis Pharmaceutical Corp.*, 239 Ariz. 19, 22 ¶ 1 (2016).

The drug manufacturer provides product warnings to a learned intermediary (the prescribing doctor) who then has the duty to transmit the warnings to the patient. Indeed, the Court of Appeals concluded in another case that “a drug manufacturer cannot be required legally to foresee that a licensed physician will disregard express warnings regarding a drug’s use.” *Dyer v. Best Pharmaceutical*, 118 Ariz. 465, 469 (App. 1978).

The rationale is that medical ethics and the realities of medical practice require the prescribing doctor to act as an informed intervening party who will use independent judgment to translate technical drug information on possible adverse drug effects into a format the patient can understand because, as a practical matter, the manufacturer cannot do that. *Id.* (citing *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 400-401 (App. 1971)).

As the Third Restatement’s commentary explains, the effect of the learned-intermediary doctrine is that the duty to warn patients about medical risks associated with drugs “devolves on the health-care provider” who must “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.” *Restatement (Third) of Torts: Product Liability* § 6 cmt. b (1998).

That is, the drug “manufacturer’s duty to provide warnings to patients transfers to the doctor, who is in a better position to communicate them to the

patient.”” *Dearinger v. Eli Lilly and Co.*, 510 P.3d 326, 329 ¶ 8 (Wash. 2022) (quoting *Taylor v. Intuitive Surgical, Inc.*, 389 P.3d 517, 524 ¶ 27 (Wash. 2017)). The duty to give “black box warnings” and other warnings thus passes from the drug manufacturer to the doctor—an important point to recognize and apply in this case and in all similar ones.

Because the learned-intermediary doctrine imposes a strong, clear duty on doctors to provide adequate warnings to patients before prescribing manufactured drugs to them, this is not a case where there can be quibbles about the existence of a duty to warn. It exists. That is a point this Court should address and further explore in the event it grants the petition for review.

3. Conclusion for the legal argument.

True consent to what happens to one’s self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each.

Canterbury v. Spence, 464 F.3d 772, 780 (D.C. Cir. 1972).

In informed-consent cases such as the present one, no expert guidance or testimony is needed for an Arizona jury: (1) to determine if a healthcare provider provided material information to a patient to allow informed consent for a proposed medical treatment or for a proposed prescription and (2) to determine what the patient would have done if the material information had been provided. Those are questions of fact.

The memorandum decision treated duty to warn as if there might be some doubt about its existence. The decision spoke of a “possible duty to warn,” a “duty of disclosure,” and a duty to warn of a specific risk that would depend on the facts and circumstances of a particular case. *Mem. Dec.* ¶¶ 9-10.

But when a doctor is prescribing manufactured drugs, there is no question about duty. Under the learned-intermediary doctrine, the drug-prescribing doctor has a strong, clear, mandatory duty to warn the patient about possible adverse drug effects. That is a point the Court of Appeals elided, but that should be addressed and explored if this Court grants the petition for review. Arizona courts are often reluctant to find a duty. Here, under the learned-intermediary doctrine, there can be no reluctance. There is a duty to warn.

4. Basis for filing the amicus curiae brief.

Introduction. Under Arizona Rule of Civil Appellate Procedure 16, Amicus Arizona Association for Justice—also known as the Arizona Trial Lawyers Association—is filing this amicus curiae brief after obtaining consent from the parties.

Amicus’s lawyers have, for over a half-century, represented Arizona tort victims and their loved ones. Amicus’s members have fostered and protected the rights of their clients and the public by: (1) continuing legal training, (2) general public education, (3) legislative presentations, and (4) appellate and trial advocacy.

Amicus is the sole Arizona legal association dedicated to fighting for the rights of tort victims and their families.

The fight for justice for Arizona tort victims and their families includes vigorous advocacy in Arizona state and federal trial and appellate courts. The Arizona Court of Appeals, the Arizona Supreme Court, the United States Court of Appeals for the Ninth Circuit, and the United States Supreme Court have all accepted and considered amicus curiae briefs from the Arizona Association for Justice-Arizona Trial Lawyers Association in important cases, including:

- *Franklin v. CSAA General Ins. Co.*, 532 P.3d 1145 (Ariz. 2023).
- *Laurence v. Salt River Project Agri. Improv. & Power Dist.*, 255 Ariz. 95 (2023).
- *United States v. June*, 575 U.S. 402 (2015).
- *Parra v. PacifiCare of Arizona, Inc.*, 715 F.3d 1146 (9th Cir. 2013).

Interest of Amicus Curiae. Amicus's members often represent clients in cases involving informed consent to medical therapies and drug prescriptions. Issues of informed consent and the effect of the learned-intermediary doctrine on the duty of a prescribing physician are issues that have statewide importance and that repeatedly arise. Amicus and its members thus have a strong interest in the proper development of the law in this unique and important area.

Preparation for the brief. Amicus's counsel has read the briefs filed in this

matter and has carefully and diligently researched the relevant principles that apply to matters of informed consent, duty to provide sufficient information to patients concerning possible adverse drug effects and hazards, and the effect of the learned-intermediary doctrine on a prescribing doctor's duty of care.

Desirability of accepting the brief. Amicus submits that this Court should accept and consider this amicus curiae brief because Amicus can provide case law, information, perspective, and argument that can help the Court beyond the help the parties' lawyers have provided and will provide in this case. *See* Ariz. R. Civ. App. Proc 16(b)(1)(C)(iii). Amicus's brief offers a unique, well-researched, and, we hope, useful perspective on the informed-consent, duty, and learned-intermediary doctrine issues that are crucial to a proper resolution of this matter.

DATED this 24th day of August, 2023.

AHWATUKEE LEGAL OFFICE, P.C.

/s/ David L. Abney, Esq.
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Certificate of Compliance

This document: (1) uses Times New Roman 14-point proportionately spaced typeface for text *and* footnotes; (2) contains 1,989 words (by computer count); and (3) averages less than 280 words per page, including footnotes and quotations.

Certificate of Service

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