# IN THE SUPREME COURT STATE OF ARIZONA

David Francisco, DDS and Kimberley Francisco, husband and wife,

Plaintiffs/Appellants,

٧.

Affiliated Urologists, Ltd., an Arizona Corporation; Kevin Art, M.D. and Jane Doe Art, husband and wife; Doe Entities I-X; and Roes I-X;

Defendants/Appellees.

No. CV-23-0152-PR

Court of Appeals, Division One No. 1 CA-CV-21-0701

Maricopa County Superior Court No. CV2020-010470

#### **RESPONSE TO AMICUS PETITION**

Jason M. Kelly (SBN 020525) Richard D. Lyons (SBN 020558) KELLY & LYONS, PLLC 5020 E. Shea Blvd., Ste. 150 Scottsdale, Arizona 85254 Phone: (480) 867-3410

Fax: (480) 867-3411

jkelly@kellylyonslaw.com rlyons@kellylyonslaw.com

Attorneys for Plaintiffs/Appellants

Plaintiffs/Appellees/Respondents David and Kimberley Francisco, through their counsel and pursuant to ARCAP 15, submit this Response to the Amicus Curiae Brief filed by various healthcare corporations (hereinafter, "Amici") filed on August 24, 2023.

#### I. SUPREME COURT REVIEW IS NOT WARRANTED

The Amici petitioners pepper their brief with fallacious strawman arguments instead to distract from what the Court of Appeals actually, and narrowly, decided. The strawmen that the Amici set up are bottomed on a doomsday-styled slippery slope argument which suggests that allowing this unpublished decision to stand would subject medical practitioners to frivolous lawsuits for not "strictly adhering" to *all* drug warnings and advising their patients of *every*, *single* warning on a product insert. However, what the Court of Appeals really decided was that citizens of Arizona reading plain English could determine (for or against David and Kimberley, without the necessity of an expert witness) that the particular Black Box Warning at issue was material to David Francisco and that Dr. Art should have advised him of the same.

Amici ignore that this Court has positioned medical providers as "Learned Intermediaries" who are "in a superior position [than the pharmaceutical manufacturers] to impart the warning ..." *Watts v. Medicis Pharmaceutical Corp.*, 239 Ariz. 19, 25, ¶ 16 (2016) (citations omitted). Rather, the Amici view their

constituents' duty to their patients to provide adequate information regarding material risks that accompany prescription medications to be "too tedious and time-consuming to undertake." (*See* Amici Petition at p. 14).

David is merely asking is that his doctor – the "learned intermediary" upon whom he must rely for material information – advise him of the FDA Black Box Warning for Cipro that was peculiarly relevant to his medical history. FDA Black Box warnings only exist for material risks with a proven causal link. (*See* Opening Brief at pp. 26-27). After years of research and analysis, the FDA warned that persons over 60 who use corticosteroids were at an increased risk of tendon rupture if they took Cipro. As set forth more thoroughly in the Response to the Petition for Review (at pp. 5-7), the Opening Brief (at pp. 26-28), and Reply Brief (at pp. 14-16), a jury does not need the help of experts to assess whether Dr. Art's actions and/or inactions were reasonable. A "typical" juror, without any medical or pharmaceutical training, can decide whether he/she thinks that Dr. Art should have provided David Francisco with this particular Black Box Warning.

In its unpublished decision, the Court of Appeals simply applied longstanding Arizona case law about whether and when expert testimony is necessary in a medical negligence case and applied the law to the facts of this case. There is no request from the Amici or the Defendant to make a change to existing law or to resolve a split in the divisions of the Arizona Courts of Appeal. There is therefore no basis for Supreme Court review. *See* ARCAP 23(d)(3).

#### II. THE COURT OF APPEALS' DECISION IS SOUND

There is no Latin-based polysyllabic medical terminology to consider. The jury need only understand the words and phrases: "over 60", "steroids", "increased risk", "tendon rupture", and "Patients should be informed of this potential adverse reaction ..." This FDA warning was written for David Francisco, and the Learned Intermediary Doctrine<sup>1</sup> required Dr. Art to provide David with these warnings. The Court of Appeals' decision is in accord with well-settled Arizona law in medical negligence cases, because experts are not needed to explain this particular warning to the jury and this particular warning's importance to David.

One of the first Arizona cases discussing the need for expert testimony is *Boyce v. Brown*, 51 Ariz. 416, 421 (1938). While discussing when expert testimony is needed in medical negligence cases, *Boyce* cited to the California case of *Rising v. Veatch*, 3 P.2d 1023, 1024 (Ca.App.1931). *Rising* holds, "[I]n those instances where ... the matter is of such a nature as may be ascertained by the ordinary senses of a nonexpert ... expert testimony become[s] unnecessary." (citations omitted). *See also*, *e.g.*, *Kleinman v. Armour*, 12 Ariz.App. 383, 384 (1970) ("expert testimony is

\_

<sup>&</sup>lt;sup>1</sup> Watts v. Medicis Pharmaceutical Corp., 239 Ariz. 19 (2016).

not required where the resolution of the question to be determined does not require special and technical knowledge ..." (citations omitted)); and see, Bradshaw v. Iowa Methodist Hosp., 101 N.W.2d 375, 384 (Iowa 1960) (exceptions to the expert requirement include "where a physician's lack of care is so obvious as to be within the comprehension of laymen, and to require only common knowledge and experience to understand, expert testimony is not necessary." (citations omitted)).<sup>2</sup> See also, Opening Brief at pp. 28-29; and Reply Brief at pp. 14-16; and Amicus Brief of the Arizona Association for Justice/Arizona Trial Lawyers Association at 11-13.

The requirement of expert testimony in medical negligence cases is the exception to the general rule that experts are not necessary to prove negligence. *See Rodriguez v. Jackson*, 118 Ariz. 13 (App.1977) ("Unless the conduct complained of is readily ascertainable by laymen, the standard of care must be established by medical testimony." (citations omitted) (emphasis added)). Expert testimony is generally *inadmissible* where it "would add nothing to the jury's own common knowledge and experience." *State v. Dickey*, 125 Ariz. 163, 169 (1980) (citations omitted). *See also*, *e.g.*, *In re Apollo Group*, *Inc.*, *v. Securities Litigation*, 527 F.Supp.2d 957, 961-962 (D.Ariz.2007) ("expert testimony is inadmissible if it concerns factual issues within the knowledge and experience of ordinary lay people,

<sup>&</sup>lt;sup>2</sup> Cited approvingly in Kalar v. MacCollum, 17 Ariz.App. 176, 178 (1972).

because it would not assist the trier of fact in analyzing the evidence." (citations omitted)); and, Wal-Mart v. Indus. Comm'n of Arizona, 183 Ariz. 145, 147 (App.1995) ("Expert testimony is not 'a mechanism for having someone of elevated education or station engage in a laying on of the hands, placing an imprimatur upon the justice of one's cause," but rather 'is a device allowing the trier to receive information, beyond its competence, useful to a resolution of the dispute before it." (citing Udall, et al., Arizona Practice: Law of Evidence § 22 at 28 (3rd Ed. 1991)); and, Rudolph v. Arizona B.A.S.S. Federation, 182 Ariz. 622, 626 (App.1995) ("Expert testimony is unnecessary when the disputed subject is something that persons unskilled in the relevant area are capable of understanding ..." (citations omitted)).

In a case discussing product warnings, *Shell Oil Co. v. Gutierrez*, 119 Ariz. 426 (App.1978), held as follows:

Expert opinions will be rejected where the facts can be intelligently described to and understood by the jurors so that they can form reasonable opinions for themselves. *Hinson v. Phoenix Pie Company*, 3 Ariz.App. 523, 416 P.2d 202 (1966). As stated in *Walton v. Sherwin-Williams Co.*, 191 F.2d 277 at 285-86 (8th Cir. 1951): ". . . the adequacy of a set of warnings or directions is not a scientific matter. Whether or not a given warning is adequate depends upon the language used and the impression that it is calculated to make upon the mind of an average user of the product."

Shell Oil held that the jury was as competent as any expert to determine whether a warning label was adequate. Id. Similarly, here, the warning at issue is

understandable to any juror, and medical experts are therefore not required for a jury to make a decision for or against David's claim that Dr. Art failed to fully disclose the material risks of taking Cipro as prescribed.

## III. REVERSING THE COURT OF APPEALS WOULD REQUIRE THIS COURT TO ADDRESS NUMEROUS OTHER POINTS OF ALLEGED ERROR

If this Court were to reverse the narrow ruling from the Court of Appeals, this Court would need to address several issues that David raised but were not decided.<sup>3</sup> These issues are: (a) whether a claim for lack of informed consent is one of negligent disclosure or medical negligence; (b) whether the information to be divulged by a medical practitioner should be viewed from the patient's perspective or the provider's perspective; and (c) whether, as applied to the facts in this lawsuit, A.R.S. §§ 12-2603 and 12-2604 combine to unconstitutionally abrogate David's right to seek compensation for his injuries.

The bases of "informed consent" are: (1) the belief that an adult of sound mind should be able to have some modicum of personal autonomy as to what enters his body, and (2) the only manner in which this autonomy can be realistically exercised is for the medical provider to give patients all of the material information needed to make an informed decision as to whether or not to take the medication (or undergo the procedure, etc.). (*See* Opening Brief at pp. 13-23; *and* Reply Brief at pp. 6-13).

\_

<sup>&</sup>lt;sup>3</sup> Because they were mooted with the narrow ruling.

The pages just referenced in David's Opening and Reply appellate briefs painstakingly examine the foreign case law upon which Arizona formed its "informed consent" jurisprudence. The cases and the treatises all treat "informed consent" as a question of negligent disclosure - not negligence in practicing medicine. However, through imprecise analysis and writing, over the decades Arizona grafted an expert witness requirement into the cases from California, Washington, New York, Wisconsin, and D.C. where none previously existed. The materiality test for information that a patient would want provided was never intended to include any sort of medical standard and expert testimony was never envisioned as a required element. (See also, Amicus Brief of the Arizona Association for Justice/Arizona Trial Lawyers Association at p. 8 (citing, among others, Professor Dan Dobbs)). As such, a jury of patients are able to decide what they would want to know about putting Cipro into their bodies - regardless of whether the American Medical Association bemoans the purported tedium in which doctors would become mired in by disclosing the material risks (e.g., tendon rupture) and benefits of medical treatment(s) to their patients.

What the medical corporations filing the Amicus Brief would like to see is a situation in which juries never have a say. The American urologists thumb their

\_

<sup>&</sup>lt;sup>4</sup> The duty to provide "informed consent" is more properly described as the "duty to warn."

collective nose at the FDA Black Box Warnings<sup>5</sup> applicable to David's medical condition. By operation of A.R.S. §§ 12-2603 and 12-2604 and the American urologists' collective refusal to comply with the FDA's warnings, neither David nor any other man over 60 going to a urologist would have any recourse for tendon rupture caused by a prescription of Cipro. (See, Opening Brief at pp. 29-37; and Reply Brief at pp. 1-3, 4-5, 17-19; and Amicus Brief of the Arizona Association for Justice/Arizona Trial Lawyers Association at pp. 11-15). Left without the experts required by the Arizona Legislature, the urologists' collective conspiracy of silence would unconstitutionally abrogate David's right to seek redress for his injuries. Baker v. University Physicians Healthcare, 231 Ariz. 379, 388, ¶ 35 (2013); Lo v. Lee, 231 Ariz. 531, 534, ¶ 11 (App.2012); Governale v. Lieberman, 226 Ariz. 443, 447-448, ¶ 11 (App.2011); see also, Baker v. University Physicians, 228 Ariz. 587, 593, ¶ 21 (Div.One 2012), vacated in part on other grounds, Baker v. University Physicians, 231 Ariz. 379 (2013).

#### IV. CONCLUSION

Review is not warranted because there is nothing novel or contentious about the law applied by the Court of Appeals. Further, it is an unpublished decision based on a narrow set of facts. If, however, this Court were to examine the narrow, fact-

<sup>5</sup> Urologists in Canada and the EU heed the Black Box Warnings, and alarm has been raised by the biochemists and pharmacists in the United States. *See* Opening Brief at p. 1, 7-10; *and see* Appendix to Opening Brief at Exhibits 1-7.

specific decision, then David's other, larger arguments regarding the nature of an "informed consent" claim and the constitutionality of A.R.S. §§ 12-2603 and 12-2604 would also need to be addressed.

RESPECTFULLY SUBMITTED this 13th day of September, 2023.

### **KELLY & LYONS, PLLC**

By: /s/ Jason M. Kelly

Jason M. Kelly Richard D. Lyons

Attorneys for Plaintiffs/Appellants