

IN THE SUPREME COURT

STATE OF ARIZONA

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

Plaintiffs/Appellants,

v.

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 PETITION FOR REVIEW

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I. INTRODUCTION

The Petition for Review asks this Court to review an un-published Memorandum Decision that is only applicable to its narrow set of facts.¹ The Court of Appeals' decision is in accord with long-standing precedent, and the Petitioner/Appellee/Defendant does not present an no issue of statewide importance. Further, the Petition misstates the law when it suggests that “*every* lack of informed consent case [requires] ... expert testimony.” (*See* Petition at p. 1) (emphasis added). While expert testimony is normally required in such lawsuits, this case is simply the exception that proves the rule.

For nearly sixty (60) years, Arizona courts have held that not all medical negligence cases need expert testimony. *Carranza v. Tucson Medical Center*, 135 Ariz. 490, 492 (App.1983); *Revels v. Pohle*, 101 Ariz. 208, 210 (1966); *Hardy v. Southern Pacific Employers Ass'n*, 10 Ariz.App. 464, 468-469 (1969). This lawsuit is simply one of those rare cases.

The Memorandum Decision only addressed the narrow, fact-specific, threshold question as to whether an “affidavit of merit” was required, in this lawsuit with these facts, by A.R.S. §§ 12-2603 and 12-2604. The Petition does not present reasons supporting Supreme Court Review. *See* ARCAP 23(d)(3). There is

¹ The narrow holding, inapplicable in a general manner to most, if not all, other fact patterns that may arise, is most likely why the case was not published.

controlling Arizona law on point; the Petition does not request that any previous law be overruled or qualified; there is no conflict in the divisions of the Court of Appeals; and, finally, the dispute is about the application of facts to the law – not whether an important issue of law was incorrectly decided.

In contrast, if this Court were to review the Court of Appeals' Memorandum Decision, it would have to decide several purely legal issues that fall squarely within the parameters of ARCAP 23(d)(3), but which the Court of Appeals did not address. These are: (1) whether a "lack of informed consent" lawsuit is one of negligent disclosure (the Plaintiffs' position) or one of medical negligence (the Defendants' position), (2) whether A.R.S. §§ 12-2603 and 12-2604, by their plain language, apply to "informed consent" lawsuits, (3) whether the physician's standard of disclosure is measured from that of a similarly-situated patient or that of a similarly-situated medical provider, and (4) whether, as applied to this particular lawsuit, A.R.S. §§ 12-2603 and 12-2604, unconstitutionally abridge the Plaintiffs' rights to recover damages in violation of Ariz. Const. Art. 18 § 6.

II. ISSUE DECIDED BY THE COURT OF APPEALS

The Court of Appeals simply decided that, given the facts of this particular case, the jury could consider the FDA's Black Box warnings and decide, without the need for expert testimony, whether the Defendant, Dr. Art, should have provided those warnings to David Francisco. The FDA warnings are admissible evidence that

a jury may consider when determining the standard of care, but the ultimate decision remains with the jury. *Rodriguez v. Jackson*, 118 Ariz. 13, 18 (App.1977) (citing *Salgo v. Leland-Stanford Jr. University Board of Trustees*, 317 P.2d 170 (App.1957)). The Court of Appeals simply held that, with admissible evidence of the FDA's Black Box warning, the jury did not need an expert to come to a decision on the merits. The Defendant remains free to hire experts to explain why the warnings need not have been given in this case. The ultimate question breach of the standard of care will go to the jury, and the jury may still return a defense verdict.

III. ADDITIONAL FACTS TO CONSIDER

At its core, this case is about whether David Francisco should have received better information from Dr. Art. David would like to retain autonomous authority as to what he ingests – and to make an informed decision, he needs to be given good information from the doctor prescribing the medications. The FDA put clear warnings in large black boxes on the product insert (*i.e.*, the “Black Box Warnings”) to inform medical practitioners like Dr. Art about serious complications for persons with David’s medical history. Dr. Art chose not to inform David of those warnings. A jury can read and understand the warnings without the need for medical testimony to explain things to them. The jury can then decide whether Dr. Art should have given this information to David Francisco. Dr. Art is free to hire experts to explain to the jury why these warnings need not be given to patients with David’s medical

history. The jury is able to make the ultimate decision without education from any retained expert witnesses.²

A. David Francisco and his Right to Adequate Information

David Francisco retired from his dental practice in 2016 and moved to Sedona, Arizona with his wife Kimberley; they were active hikers, enjoyed keeping physically fit together, and they were looking to spend their retirement years enjoying the area. (*See* R. at 52-54, Exhibit 2, ¶¶ 1-3).

On August 30, 2018, Dr. Art performed a UroLift procedure on David. (*Id.* at ¶ 4). At the time, David was 66 years old, and he had been on corticosteroids for Addison's Disease; Dr. Art was aware of David's medical history. (*Id.* at ¶¶ 5, 9-10; *and see, id.* at Exhibit 3, Bates Page Nos. 011-12; *and see, id.* at Exhibit 4, Bate Page Nos. 015-18). After surgery, Dr. Art prescribed Cipro as a prophylactic antibiotic. (R. at 52-54, Exh. 1 at ¶ 6; *and see, id.*, at Exhibit 5, Bates Page Nos. 020-23). After taking five of the six prescribed tablets, David began experiencing symptoms of Cipro toxicity. (*Id.* at Exhibits 3 and 5).

David now experiences most, if not all, of the symptoms of Cipro toxicity. Dr. Hu, David's treating rheumatologist, has diagnosed David with Cipro toxicity. (*Id.* at ¶ 12; *and see, id.*, at Exhibit 8, Bates Page No. 086). Pharmacologist John Budny,

² David did hire an expert on causation, but his treating doctors have also diagnosed him with Cipro toxicity warned of in the Black Box.

Ph.D., has also opined that David suffers from Cipro toxicity. (*Id.* at Exhibit 9). As a result of the Cipro toxicity, David has severe pain in his joints, cartilage, and tendons; he has nerve damage in his legs and right arm; he has pain standing or walking; he has consistent pain, even while resting; all day he wears knee and ankle braces; he often wears back and elbow braces; he cannot move without increased pain. (*Id.* at Exhibit 2, at ¶¶ 13 to 18).

If Dr. Art had informed David of his increased risk of tendon rupture, David would have opted for a different antibiotic. (*Id.* at Exhibit 2, at ¶ 11).

B. The FDA’s Publication of Information to Medical Practitioners

The FDA has put multiple Black Box Warnings on Cipro, the most recent in 2016 – two years before David’s surgery and four years after the most recent statement on the use of Cipro from the American Urological Academy (*see* Appendix to Opening Brief at Exhibit 7). A Black Box Warning is the most serious warning the FDA can issue and “is designed to call attention to serious or life-threatening risks.” (R. at 52-54, at Exhibit 6, Bates Page Nos. 025-27).

The 2016 Black Box Warning advises that Cipro can cause “disabling and potentially irreversible serious adverse reactions ... includ[ing] ... Tendinitis and tendon rupture ... Peripheral neuropathy ... [and] Central nervous system effects ...” (*Id.* at Exhibit 7 at § 5.1, Bates Page No. 039). The short warning, in a clearly delineated black box at the beginning of the product insert, refers prescribers to § 5,

entitled “Warnings and Precautions,” for further information. (*Id.* at Bates Page No. 029). The warning in § 5.2 reads:

The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is **increased in patients over 60 years of age, in patients taking corticosteroid drugs ...**

(*Id.* Bates Page No. 039) (emphasis added). David fits in both categories – over 60 and on corticosteroids.

In the section entitled “Use in Specific Populations,” the FDA instructs:

8.5 Geriatric Use

Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolone such as CIPRO. This risk is *further increased in patients receiving concomitant corticosteroid therapy....* Caution should be used when prescribing CIPRO to elderly patients especially those on corticosteroids. **Patients should be informed of this potential adverse reaction** and advised to discontinue CIPRO and contact their healthcare provider if any symptoms of tendinitis or tendon rupture occur.

(*Id.* at Bates Page No. 053) (emphasis added).

In front of a jury, David’s lawyers could simply present the two slides on the next page and let the jury decide if Dr. Art should have advised David of these warnings:

5 WARNINGS AND PRECAUTIONS

5.1 Disabling and Potentially Irreversible Serious Adverse Reactions Including Tendinitis and Tendon Rupture, Peripheral Neuropathy, and Central Nervous System Effects

Fluoroquinolones, including CIPRO, have been associated with disabling and potentially irreversible serious adverse reactions from different body systems that can occur together in the same patient.

Commonly seen adverse reactions include tendinitis, tendon rupture, arthralgia, myalgia, peripheral neuropathy, and central nervous system effects (hallucinations, anxiety, depression, insomnia, severe headaches, and confusion). These reactions can occur within hours to weeks after starting CIPRO.

Patients of any age or without pre-existing risk factors have experienced these adverse reactions [see *Warnings and Precautions* (5.2, 5.3, 5.4)].

Discontinue CIPRO immediately at the first signs or symptoms of any serious adverse reaction. In addition, avoid the use of fluoroquinolones, including CIPRO, in patients who have experienced any of these serious adverse reactions associated with fluoroquinolones.

5.2 Tendinitis and Tendon Rupture

Fluoroquinolones, including CIPRO, have been associated with an increased risk of tendinitis and tendon rupture in all ages [see *Warnings and Precautions* (5.1) and *Adverse Reactions* (6.2)]. This adverse reaction most frequently involves the Achilles tendon, and has also been reported with the rotator cuff (the shoulder), the hand, the biceps, the thumb, and other tendons. Tendinitis or tendon rupture can occur, within hours or days of starting CIPRO, or as long as several months after completion of fluoroquinolone therapy. Tendinitis and tendon rupture can occur bilaterally.

The risk of developing fluoroquinolone-associated tendinitis and tendon rupture is increased in patients over 60 years of age, in patients taking corticosteroid drugs, and in patients with kidney, heart or lung transplants. Other factors that may independently increase the risk of tendon rupture include strenuous physical activity, renal failure, and previous tendon disorders such as rheumatoid arthritis. Tendinitis and tendon rupture have also occurred in patients taking fluoroquinolones who do not have the above risk factors. Discontinue CIPRO immediately if the patient experiences pain, swelling, inflammation or rupture of a tendon. Avoid fluoroquinolones, including CIPRO, in patients who have a history of tendon disorders or have experienced tendinitis or tendon rupture [see *Adverse Reactions* (6.2)].

8.5 Geriatric Use

Geriatric patients are at increased risk for developing severe tendon disorders including tendon rupture when being treated with a fluoroquinolone such as CIPRO. This risk is further increased in patients receiving concomitant corticosteroid therapy. Tendinitis or tendon rupture can involve the Achilles, hand, shoulder, or other tendon sites and can occur during or after completion of therapy; cases occurring up to several months after fluoroquinolone treatment have been reported. Caution should be used when prescribing CIPRO to elderly patients especially those on corticosteroids. Patients should be informed of this potential adverse reaction and advised to discontinue CIPRO and contact their healthcare provider if any symptoms of tendinitis or tendon rupture occur. [see *Boxed Warning*, *Warnings and Precautions* (5.2), and *Adverse Reactions* (6.2)].

In a retrospective analysis of 23 multiple-dose controlled clinical trials of CIPRO encompassing over 3500 ciprofloxacin-treated patients, 25% of patients were greater than or equal to 65 years of age and 10% were greater than or equal to 75 years of age. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals on any drug therapy cannot be ruled out. Ciprofloxacin is known to be substantially excreted by the kidney, and the risk of adverse reactions may be greater in patients with impaired renal function. No alteration of dosage is necessary for patients greater than 65 years of age with normal renal function. However, since some older individuals experience reduced renal function by virtue of their advanced age, care should be taken in dose selection for elderly patients, and renal function monitoring may be useful in these patients [see *Dosage and Administration* (2.3) and *Clinical Pharmacology* (12.3)].

In general, elderly patients may be more susceptible to drug-associated effects on the QT interval. Therefore, precaution should be taken when using CIPRO with concomitant drugs that can result in prolongation of the QT interval (for example, class IA or class III antiarrhythmics) or in patients with risk factors for torsade de pointes (for example, known QT prolongation, uncorrected hypokalemia) [see *Warnings and Precautions* (5.11)].

C. U.S. Scientists and Urologists from Around the Wester World would have wanted Dr. Art to Provide this FDA Black Box Warning to David Francisco

Urologists outside of the United States take the FDA warnings seriously. The European Association of Urology (EAU) advises its members as follows: “urologists should ... participate in **a shared-decision making process** with each patient, clearly outlining the associated complication risks for them.” (*See* Appendix to Opening Brief at Exhibit 1; *and see* R. at 52-54 at Exh. 1 (Bonkat, G. and Wagenlehner, F., “In the Line of Fire: Should Urologists Stop Prescribing Fluoroquinolones as Default?” *Eur Urol* (2018) at p. 2) (emphasis added). The Canadian Urological Association (“CUA”) also says that urologists “must now determine the benefit/harm ratio **each and every time**” they prescribe Cipro. (*See* Appendix to Opening Brief at Exhibit 2, Nickel and Doiron, “Dangerous Fluoroquinolones: The Urologist’s Dilemma” (2020)) (emphasis added). The Canadian authors continue, “Better yet, **the patient should be involved in the decision process** after being informed of the potential risks and complications.” (*Id.*) (emphasis added).

U.S. scientists also agree with the FDA warnings. The National Center for Biotechnology Information warns of the elevated risk for tendon problems in geriatric patients on corticosteroids. (*See* Appendix to Opening Brief at Exhibit 3; *and see* R. at 52-54, at p. 17, Exh. 10 (Corrao, G., *et al.*, “Evidence of Tendinitis

Provoked by Fluoroquinolone Treatment: A Case-Control Study” (2006)). Other U.S. studies provide similar warnings (*see* Appendix to Opening Brief at Exhibits 4, 5, and 6; *and see* R. at 52-54, Exhibits 11-13).

In stark contrast, the American Urological Association (“AUA”), which is the educational arm of the American Board of Urology, simply recommends blasting all surgical urology patients with Cipro, except in limited circumstances involving a few laparoscopic procedures. (*Id.* at Exhibit 7 (Wolf, *et al.*, Urologic Surgery Antimicrobial Prophylaxis (2012))). Thus, Dr. Art’s board does not follow the recommendations of the FDA, the National Center for Biotechnology Information, the European Urologists, the Canadian Urologists, or the other scientific groups who have warned against giving Cipro to persons over 60 on corticosteroids. While Cipro apparently has valid uses in urological surgeries, there are also very real dangers to a subset of the patient population. All that David is arguing is that, given his medical conditions, he should have been given the warnings and other options.

A.R.S. § 12-2604, which sets for the standard-of-care qualifications to testify at trial, requires David to find a board-certified urologist. The practical effect is that David could not find a board-certified urologist willing to testify against the urology board’s recommendations. The strictures of A.R.S. §§ 12-2603 and 12-2604 therefore create an untenable and unconstitutional “conspiracy of silence” whereby board-certified urologists in America are free to disregard important FDA warnings

heeded by the rest of the Western World's scientific and medical communities. Moreover, these warnings provide safe harbor for the drug manufacturers under the "Learned Intermediary" Doctrine ("LID"). Dr. Art's position would result in patients like David (over 60 and on corticosteroids) who are experiencing life-altering Cipro toxicity without a remedy.

IV. REVIEW IS NOT WARRANTED

The U.S. board that certifies urologists appears to be alone in the Western World in not following the particular FDA warning at issue in this lawsuit. A large percentage of male urology patients are likely over 60; therefore, this warning is of particular importance to a large portion of urology patients. Despite this, the board that certifies urologists in the United States instructs its members to ignore one of the FDA's direst warnings regarding the use of Cipro.

The Petition argues that the Court of Appeals came to the conclusory decision that non-experts could decide this case without the need for expert witness testimony. The only reason the decision is short in analysis is because lengthy consideration is not needed – if lengthy consideration was needed, then a typical jury would need assistance from expert witnesses. Ultimately, the standard of care is determined by the jurors, and, in the usual case, it need not be informed by expert witness testimony. Medical cases usually – but not always – require expert testimony to help the jury determine the standard of care; but, without or without expert

testimony, the ultimate issues of standard and breach are left to the jury to decide. There is nothing novel or extraordinary about the Court of Appeals' reasoning in this regard – the Defendants simply do not like the outcome in this case. That is not a reason for this Court to review the Memorandum Decision.

The Petition also presents a straw-man argument that the Defendants are somehow being held liable “as a matter of law” based on the FDA Black Box Warnings. (*See, e.g.*, Petition at p. 9). Nothing of the sort has occurred. The Plaintiffs did not argue, and the Court of Appeals did not hold, that the FDA inserts somehow established the standard of care. If the Court of Appeals had ruled that the Defendants are liable to the Plaintiffs as a matter of law,³ then that would be something the Supreme Court would want to look at. That is not the case here, and the jury can receive the evidence and could still return a defense verdict.

The jury is free to consider this particular FDA warning and any other evidence the Plaintiffs and Defendants may properly admit. Ultimately, the jury may still return a defense verdict – the memorandum decision merely holds that: (1) a jury should be able to make the determination in this particular case, and (2) the Plaintiffs need not produce expert witness testimony from a board-certified urologist to make their case.

³ Presumably, pursuant to a hypothetical plaintiff's Rule 56 Motion.

Most of the petition consists of arguments as to why this warning need not have been given to David Francisco. The Defendants are still free to make these arguments to the jury, as noted by the Court of Appeals. (*See* Memorandum Decision at ¶ 12 (“Should the Practice wish to offer responsive expert testimony that physicians are free to ignore such a directive, it may do so.”)).

It is difficult to follow the Defendants’ arguments regarding the Learned Intermediary Doctrine (“LID”). The LID protects drug manufacturers from liability; under the LID:

[A] learned intermediary (the prescribing physician) who received an adequate warning regarding a drug's side effects or proper use but unforeseeably disregarded the warning constituted an intervening, superseding event that broke the chain of causation between the manufacturer and the patient.

Watts v. Medicis Pharm. Corp., 239 Ariz. 19, 213, ¶ 11 (2016).

If the prescribing physician disregards the Black Box warning, what is the patient to do? He cannot sue the manufacturer. If the board that certifies urologists in this country does not heed the warnings, then, pursuant to the Defendants’ logic, he cannot pursue the learned intermediary, either. Certainly, the man living his life in braces over all his joints without recourse cannot be the preferred option.

The Defendant continues to argue that they simply “did what everyone else does” (*see* Petition at p. 11)⁴ and that this absolves them of liability. This, however, is the segue into the other arguments that this Court may need to decide if it grants review of the Petition. *See* ARCAP23(f)(2). The EU and Canadian urologists follow the FDA warnings that the U.S. urologists disregard. Evidence of custom is admissible but is not determinative. (*See* Memorandum Decision at ¶ 11). Where, as here, there is evidence that a community is: (i) lagging behind in the science and/or (ii) disregarding important information, the law of torts is one effective means of brining the community into compliance with socially-acceptable norms for a reasonably standard of care. (*See* Opening Brief at pp. 32-37; *and* Reply Brief at pp. 17-20).

V. OTHER ISSUES THAT MAY NEED TO BE DECIDED IF THIS COURT GRANTS REVIEW

As set forth more thoroughly in the Appellants’ Opening and Reply Briefs and the *Amicus* Brief, Mr. and Mrs. Francisco assert that “informed consent” cases have been wrongly framed in recent Arizona decisions as medical negligence cases. Rather, the early Arizona case law and the foreign cases upon which the early Arizona cases relied framed the issue as one of negligent disclosure. The scholarly materials – both legal and medical – cited in the briefing also support the theory of

⁴ “The fact that Plaintiff could not find one urologist who agreed with his claim of negligence is telling.”

negligent disclosure (as opposed to medical negligence). Given this context, if this Court were to accept review and overturn the narrow, fact-specific holding in the Memorandum Decision, this Court would need to address the Franciscos' alternative arguments that: (1) a "lack of informed" consent lawsuit is one of negligent disclosure (the Plaintiffs' position) and not one of medical negligence (the Defendants' position), (2) A.R.S. §§ 12-2603 and 12-2604, by their plain language, do not apply to "informed consent" lawsuits, and (3) whether the physician's standard of disclosure is measured from that of a similarly-situated patient or that of a similarly-situated medical provider,

Arizona case law indicates that, in certain as-applied fact patterns, the requirements set forth in A.R.S. §§ 12-2603 and 12-2604 may unconstitutionally abrogate a plaintiff's right of action. *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). If an expert is required for the Plaintiffs to present their case to the jury, then the Plaintiffs submit that this case would present the fact pattern which makes the statutes unconstitutional as applied to these facts.

VI. REQUEST FOR COSTS

Pursuant to ARCAP 22, the Plaintiffs request recovery of their taxable costs on appeal.

RESPECTFULLY SUBMITTED this 3rd day of August, 2023.

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