IN THE SUPREME COURT
STATE OF ARIZONA

DAVID FRANCISCO, et al., Plaintiffs/Appellants/Respondents, vs. AFFILIATED UROLOGISTS LTD., et al., Defendants/Appellees/Petitioners.	No. CV-23-0152 PR Court of Appeals, Division One 1 CA-CV 21-0701 Maricopa County Superior Court No. CV2020-010470

DEFENDANTS'/PETITIONERS' SUPPLEMENTAL BRIEF

Eileen Dennis GilBride, Bar #009220
Cristina M. Chait, Bar #015094
JONES, SKELTON & HOCHULI P.L.C.
40 N. Central Avenue, Suite 2700
Phoenix, Arizona 85004
(602) 263-1700
egilbride@jshfirm.com
cchait@jshfirm.com

Attorneys for
Defendants/Appellees/Petitioners
Affiliated Urologists, Ltd. and
Kevin Art, M.D.

I. A DRUG INSERT CANNOT SUPPLANT EXPERT TESTIMONY TO PROVE THE STANDARD OF CARE

Plaintiffs have argued that not only can a jury "read and understand the [black box] warnings without the need for medical testimony," but also that from this information alone, the jury can "decide whether Dr. Art should have given this information to David Francisco." [PR Rsp., p. 3.] Not so.

A. Arizona law requires expert testimony to establish a *prima facie* case that a physician failed to act as a reasonable, prudent health care provider in the same or similar circumstances.

1. Expert testimony is required to prove the standard of care.

In order to present a *prima facie* claim, a medical malpractice claimant must come forward with a medical expert to testify that a physician failed to exercise that degree of care, skill and learning expected of a reasonable, prudent health care provider acting in the same or similar circumstances. *Riedisser v. Nelson*, 111 Ariz. 542, 544 (1975); *Seisinger v. Siebel*, 220 Ariz. 85, 94 (2009) ("Arizona courts have long held that the standard of care normally must be established by expert medical testimony."). As the *Seisinger* Court noted,

> [T]he requirement of expert testimony in a medical malpractice action is a substantive component of the common law governing

> this tort action. The common law requirement reflected a policy decision by the courts that the plaintiff's substantive burden of production could only be met by a particular kind of evidence. The common law requirement thus effectively established an element of the cause of action, by specifying the kind of proof necessary to meet the plaintiff's burden of production.

Id. at 95.

To be eligible to testify, the medical expert must meet the specific qualification requirements set forth in A.R.S. § 12-2604.[1]

2. <u>The only exception to the expert testimony requirement--where negligence is "grossly apparent to a layman"—does not apply here.</u>

Below, Plaintiffs recognized that the only exception to the expert testimony requirement is "where the negligence is apparent to a lay person." [OB, p. 28.] Actually, the exception is this: "the standard of care need not be established by expert medical testimony if the negligence is 'so grossly apparent that a layman would have no difficulty in recognizing it.'" *Riedisser v. Nelson*, *supra*.

---

[1] And given that Section 12-2604 sets forth those specific qualification requirements for a testifying expert, it is irrelevant what purported scientists and non-U.S. urologists "would have wanted" (at least according to Plaintiff). [PR Resp., p. 8.]

This is not a "grossly apparent" case, and Plaintiffs do not cite one authority supporting their argument that it is. Grossly apparent cases do not involve medical judgment. For example, in *Revels v. Pohle*, 101 Ariz. 208, 211 (1966), expert testimony was not necessary to determine a physician's negligence where he left steel sutures in a patient after an operation and then failed to even examine her after she complained for months about abdominal pain. In *Tiller v. Von Pohle*, 72 Ariz. 11 (1951), expert testimony was not necessary where a physician left a large cloth sack in a woman's abdomen after an operation. In *Landgraff v. Wagner*, 26 Ariz. App. 49, 57 (1976), a surgical instrument was left in the patient's body after an operation. Expert testimony was not required because "[t]he error is so self-evident that a jury can determine the question of negligence without reliance upon the opinion of an expert." In none of these cases would a jury need to read a drug insert to try to comprehend the medical implications involved.

In contrast, whether Cipro was or was not an appropriate antibiotic to prescribe for David Francisco, and whether Cipro posed risks to him that should have been disclosed, are matters of medical judgment. Our cases recognize that such a claim requires expert testimony to establish a *prima*

facie case. As such, it is not a claim that falls under the "grossly apparent" exception to the expert testimony requirement. *See, e.g.*,

> *Duncan v. Scottsdale Med. Imaging Ltd.*, 205 Ariz. 306, 309–10 (2003) ("the precise parameters of the required disclosure for any particular informed consent case [are] to be established by expert testimony in accordance with the applicable standard of care.");
>
> *Riedisser v. Nelson*, 111 Ariz. 542, 544–45 (1975) ("Whether or not a surgeon is under a duty to warn a patient of the possibility of a specific adverse result of a proposed treatment depends upon the circumstances of the particular case and upon the general practice followed by the medical profession in the locality; and the custom of the medical profession to warn must be established by expert medical testimony.");
>
> *Rice v. Brakel*, 233 Ariz. 140, 144 (Ct. App. 2013) ("the duty to disclose relevant risks already exists under the informed consent theory of medical malpractice.");
>
> *McGrady v. Wright*, 151 Ariz. 534, 537 (Ct. App. 1986) ("The duty of a physician in a malpractice case is the duty to disclose the risks as measured by the usual practices of the medical profession.");
>
> *Gurr v. Willcutt*, 146 Ariz. 575 (Ct. App. 1985) (affirming summary judgment for physician where plaintiff failed to come forward with expert testimony to support lack of informed consent claim).

B. Expert testimony is also necessary to explain the insert's import in relation to the particular patient.

Not only is expert testimony necessary to establish the standard of care, but it is also necessary to explain the insert itself to the jury, and how

and why the information in that insert might—or might not—pertain to a particular patient. This is because drug manufacturers draft inserts for physicians, not laypersons.

In this case, for example, the black box warning was not as simplistic as Plaintiffs make it out to be. [*See* Plaintiffs' Supplemental Brief, "SB," p. 3.] It did not prohibit the use of Cipro for Plaintiff. It identified three scenarios in which the FDA recommended against using Cipro if there are viable alternatives—bronchitis, sinusitis, and uncomplicated UTI—none of which Plaintiff had. [R. 52-54, Ex. 7, p. 1.] It then referred the reader to the guts of the insert, which indicated that the risk of developing 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.

[R. 52-54, Ex. 7, p. 57 at PLF0000039.] The insert also stated that the "most frequently reported adverse reactions, from clinical trials of all formulations,

all dosages, all drug-therapy durations, and for all indications of ciprofloxacin therapy were:

> nausea (2.5%), diarrhea (1.6%), liver function tests abnormal (1.3%), vomiting (1 %), and rash (1 %).

[*Id*., p. 62, at PLS 0000044.] There were two pages of "medically important adverse reactions that occurred in less than 1% of Cipro patients" [*id*., pp. 63-64, at PLF 00000045-46], another page of "postmarketing reports of adverse drug reactions," [*id*., pp. 66-67], and another three pages of "drugs that are affected by and affecting Cipro." [*Id*., pp. 67-69.] While the insert stated that "geriatric" patients are at increased risk, it is unclear whether reasonable medical professionals would even have considered David geriatric, given that he was a self-proclaimed active hiker who enjoyed keeping physically fit. [*See* OB, p. 7.] And further complicating the medical judgment involved here was the fact that David had a reported allergy to doxycycline and a history of hypothyroidism, which meant other antibiotics were contraindicated. [*See* R. 50-51, p. 6.]

This nuanced situation is exactly why the jury would need a urology expert to guide them in understanding the import of the insert's warnings

as applied to this particular patient. It is also understandable why jurisdictions around the country recognize so. *See, e.g.*,

> *Morlino v. Medical Ctr. of Ocean Cnty.*, 706 A.2d 721, 729–30 (N.J. 1998) ("expert testimony often is needed to explain the information contained in package inserts or the PDR. Drug manufacturers write explanations and warnings for doctors, not the general public. Comprehension of the terms and their significance may depend on medical expertise.");
>
> *Richardson v. Miller*, 44 S.W.3d 1, 16 (Tenn. Ct. App. 2000) (expert testimony is required because "the FDA-required labeling and parallel PDR reference may not be easily understood by the jury without expert assistance because these materials are written for the medical profession, not the general public.");
>
> *Spensieri v. Lasky*, 701 N.Y.S.2d 689, 693 (1999) ("The testimony of an expert is necessary to interpret whether the drug in question presented an unacceptable risk for the patient in either its administration or the monitoring of its use.").

C. Allowing a drug insert to supplant standard of care expert testimony makes bad policy.

Defendants have shown above that not only does Arizona law require expert testimony to establish a *prima facie* claim of medical malpractice, but also a lay jury needs expert guidance in interpreting and understanding the application of a complex drug insert to a particular patient's circumstance. In addition to the foregoing, however, allowing a claimant to supplant that

expert testimony with a written drug insert makes bad policy, for several reasons.

First, drug manufacturers do not design package inserts to establish a provider's standard of care. They design drug inserts to serve their own purposes: to comply with FDA requirements, to limit their own liability, to sell their products, and to provide useful information to the physician. The manufacturers leave it to the physician, who has the expertise and relationship with the patient, to take that information (which in this case was contained in a 52-page insert) and decide in his or her best medical judgment which of that information might pertain to and is appropriate to provide to the patient based on the patient's unique situation. This reasoning is cited in the many cases around the country holding that a drug insert alone cannot set the standard of care for a physician. [*See* Pet., pp. 4-5, 7-8, 12-13 (citing 17 such cases).]

Indeed, this is precisely the justification underlying the Learned Intermediary Doctrine: The manufacturer providing full information to the physician/learned intermediary is absolved of liability to the patient because it is the physician who is in the best position to take that information and, using his or her best medical judgment, decide what to do with it based

on the patient's specific circumstances. *See* RESTATEMENT (THIRD) OF TORTS: Prod. Liab. § 6 cmt. b ("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.") (emphasis added); *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 24 (2016) ("The premise for the LID is that certain types of goods (such as prescription drugs) are complex and vary in effect, depending on the end user's unique circumstances, and therefore can be obtained only through a qualified intermediary like a prescribing physician, who can evaluate the patient's condition and weigh the risks and benefits."). This is the second reason it makes bad policy to allow a drug insert to set the physician's standard of care without the requisite expert testimony: it undermines—indeed eliminates—the physician's expertise and medical judgment which is central to the Learned Intermediary Doctrine.

Third, if a drug insert were admitted as substantive evidence of the standard of care, in lieu of expert testimony, it would be inadmissible

hearsay—admitted for the truth of the matter asserted. Opposing counsel would be unable to cross-examine or impeach it. *See, e.g.*, *Spensieri v. Lasky*, 94 N.Y.2d 231, 237-39 (1999) (package insert information for prescription drugs included in PDR is hearsay; plaintiff barred from offering contents of the PDR as standalone proof of the standard of care); *In re Richardson–Merrell, Inc. Bendectin Prods. Liab. Litig.*, 624 F. Supp. 1212, 1232 (S.D. Ohio 1985) (drug manufacturer's warnings are out-of-court statements offered to prove the truth of the matter asserted, therefore inadmissible hearsay); *Saccone v. Gross*, 923 N.Y.S.2d 878 (N.Y. App. Div. 2011) (court properly precluded package insert as republished in Physicians' Desk Reference as inadmissible hearsay); *Drs. Co. v. Plummer*, 210 So. 3d 711, 718–19 (Fla. Dist. Ct. App. 2017) (trial court erred in admitting insert into evidence; opposing party is precluded from cross-examining or impeaching the source of the statement of fact or opinion). Allowing a claimant to use a drug insert alone as the standard of care would thus thwart, not serve, the search for truth.

Fourth, physicians often use drugs for off-label purposes based on their experience and medical judgment. Allowing the insert to set the standard of care would impede these therapeutic uses—to the public's detriment. Indeed, according to the American Society of Hospital

Pharmacists, off-label use of a drug is "not indicative of inappropriate usage," because a product's labeling sometimes fails to represent the most current therapeutic information for a drug.[2]

Finally, and perhaps most importantly, neither the medical profession nor the FDA itself regards package inserts as establishing the medical standard of care. The FDA states, "With respect to its role in medical practice, the package insert is informational only."[3] And the AMA states that a medication package insert "should not be regarded as the sole standard of acceptable or accepted medical practice nor as a substitute for clinical judgment or experience nor as a limitation on usage of the drug in medical practice. The official labeling statements approved by the FDA establish the parameters governing advertising or promotion of the drug product."[4]

---

[2] https://www.ashp.org/-/media/assets/policy-guidelines/docs/statements/use-of-medications-for-unlabeled-uses.pdf.

[3] FDA Drug Bulletin 1982 (April);12(1):4–5, available at https://www.circare.org/fda/fdadrugbulletin_041982.pdf

[4] American Medical Association, House of Delegates Policy H-115.994, available at https://policysearch.ama-assn.org/policyfinder/detail/H-115.994?uri=%2FAMADoc%2FHOD.xml-0-141.xml

In short, Arizona law requires expert testimony to establish the standard of care in a case alleging medical negligence. Allowing a manufacturer's package insert to entirely supplant that expert testimony would not only contravene Arizona law, but also make bad policy.

II. PLAINTIFFS' ALTERNATIVE ARGUMENTS DO NOT HELP THEM

In their response to Defendants' petition for review, Plaintiffs suggested that if review were granted, the Court should address two additional "alternative" arguments (but did not brief either one). The first alternative argument is that their lack of informed consent claim is not a medical malpractice claim at all, so it is not subject to the preliminary affidavit statute. The second argument is that if lack of informed consent *is* a medical malpractice claim subject to the preliminary affidavit statute, then the statute is unconstitutional because they cannot find an expert to testify for them and thus the statute abrogates their right of action. [PR Rsp., pp. 13-14.] Plaintiffs have not preserved the argument about the nature of an informed consent claim, and the constitutional argument lacks merit.

A. Plaintiffs have not preserved the argument that a lack of informed consent claim is not a medical malpractice claim.

In the court of appeals, Plaintiffs argued that an informed consent claim is not a medical malpractice claim but rather is one of "negligent disclosure." [OB, pp. 13-25.] They also devote a substantial portion of their Supplemental Brief to this argument. [*See* SB, pp. 1-2, 5-9.] But this is not "the underlying issue" here [*id*., p. 1], it was not the "question presented" in Defendants' petition for review [*id*., p. 5], and it was not the issue on which this Court granted review. The Court granted review on Defendants' issue of "how to prove" the standard, not on Plaintiffs' issue of "what is the standard." Because Plaintiffs failed to seek review on the latter issue, they have not preserved it here.

Below, Defendants cited several Arizona cases establishing not only that lack of informed consent cases fall within the definition of a medical malpractice case, but also that the preliminary affidavit statute applies to lack of informed consent cases. [AB, pp. 6-15.] Citing these cases, the court of appeals squarely rejected Plaintiffs' contrary argument. Slip op. ¶¶ 6-7. The court ruled that Plaintiffs' lack of informed consent claim is a medical malpractice claim and that the preliminary affidavit statute applies to lack

of informed consent cases. *Id.* The court also noted that "the medical profession's custom to warn must usually be established by expert medical testimony," *id.*, ¶ 8, and that the "duty to warn of a specific risk depends . . . 'upon the general practice followed by the medical profession.'" *Id.*, ¶ 10.[5]

Plaintiffs did not file a cross-petition for review on that ruling, and thus forfeited the argument in this Court. *See State v. Ikirt*, 160 Ariz. 113, 117 (1987) ("We see no distinction between not raising an issue on appeal and not filing a petition or cross-petition for review—if an issue is not presented for review, it is waived."); *Cramer v. Starr*, 240 Ariz. 4, 8 n.1 (2016) (refusing to consider issue resolved against plaintiff at the trial court where plaintiff waived the issue on appeal and attempted to argue it in her Supreme Court supplemental brief).[6] More importantly, Plaintiffs' failure to raise the issue

---

[5] Plaintiffs have thus erred in asserting that the court of appeals "did not address" these issues. [PR Rsp., p. 2.]

[6] Though the court of appeals' decision was in their favor, Plaintiffs could have and should have filed a conditional cross-petition for review arguing that the court of appeals erred in rejecting their alternative argument. *See, e.g., State v. Bradshaw*, 152 P.3d 288, 290, n.3 (Utah 2006) ("On appeal below, the court of appeals rejected this argument. Mr. Bradshaw failed to raise this issue on a cross-petition for certiorari, and we did not grant certiorari on this issue. It is, therefore, improperly before us, and we decline to consider it."); *State v. Keenan*, 377 P.3d 439, 444 (Kan. 2016)

in a cross-petition for review precluded the Court from deciding whether to grant review on that issue, and precluded the parties from briefing it in this Court. These are significant reasons the Court should not address the issue.

Finally, the Rules of Appellate Procedure do not authorize this Court to consider an issue not properly raised or briefed here. Rule 23(m), ARCAP, authorizes the Court to decide issues that were raised in, but *not* decided by, the court of appeals. Nothing in Rule 23 allows a party to have the Court consider an issue he lost in the court of appeals but on which he failed to seek review in this Court. The Court should not—arguably cannot—consider Plaintiffs' argument that their claim is not a medical malpractice claim.[7]

("Because the State did not cross-petition to challenge the Court of Appeals' preservation ruling in favor of Keenan, we will not consider whether the panel erred on this point.")

[7] This is not a case of fundamental error. *See In re Pima Cnty. Mental Health No. 20200860221*, 255 Ariz. 519, ¶ 20 (2023) ("Although we apply fundamental error review sparingly in civil cases, it is appropriate where the issue concerns a deprivation of a party's constitutional rights").

B. Plaintiffs' constitutional argument lacks merit.

The court of appeals did not address Plaintiffs' constitutional argument. Though Rule 23(m) authorizes this Court to address the argument, it lacks merit.

Below, Plaintiffs argued that applying the preliminary affidavit requirement here would abrogate their right of action because they could not find any expert who would support their claim. But the reason they could not find an expert had nothing to do with the statute; the reason is that Defendant Dr. Art followed the American Urology Association's recommendations[8] and thus Plaintiffs could not find a board-certified urologist who believed Dr. Art fell below the standard of care. [OB, pp. 29-37.] This is not unconstitutional abrogation. That is the statute doing its job to eliminate frivolous cases before significant time and money is wasted on lengthy litigation.

---

[8] Nothing in the record supports Plaintiffs' accusation that the U.S. board that certifies urologists—which is the American Board of Urology, *not* the AUA—"instructs its members to ignore" the FDA's warnings. [Pet. Resp., p. 10.]

Preliminarily, statutes are entitled to a strong presumption of constitutionality. The Court will not declare a statute unconstitutional unless it is satisfied beyond a reasonable doubt that it conflicts with the federal or state constitutions. *Jilly v. Rayes*, 221 Ariz. 40, 42 (Ct. App. 2009) (upholding constitutionality of preliminary affidavit statute against a claim of unconstitutional rulemaking). Thus, in challenging the constitutionality of A.R.S. § 12-2603, Plaintiffs bear the burden of overcoming that presumption. *Baker v. Univ. Physicians Healthcare*, 231 Ariz. 379, 387 (2013). Plaintiffs cannot meet that burden.

Arizona common law has long required a claimant to have expert testimony to establish a prima facie medical malpractice claim. *Seisinger v. Siebel*, 220 Ariz. 85, 94 (2009). If the claimant does not have the requisite evidence, he can still file the claim, but like all litigants who fail to prove their claim, he will be unsuccessful. The same is true under A.R.S. § 12-2603, the preliminary affidavit statute. The statute simply requires the claimant to present his *prima facie* evidence at the beginning of the case so as to forestall the waste of time and money on unsuccessful litigation and thus curb the skyrocketing cost of insurance and medical care. That is not abrogation.

Abrogation might occur if a statute were to so strictly limit the qualifications of testifying experts that no experts would qualify. *See, e.g., Lo v. Lee*, 231 Ariz. 531, 534 (Ct. App. 2012). Abrogation occurs when a statute entirely precludes a claimant from even filing a claim that was recognized at statehood. *Duncan v. Scottsdale Med. Imaging, Ltd.*, 205 Ariz. 306, 314 (2003). But requiring a claimant to present his common law *prima facie* evidence at the beginning of the case rather than later is not abrogation. *Cf. Governale v. Lieberman*, 226 Ariz. 443, 447 (Ct. App. 2011) (statute does not effectively prevent the plaintiff from finding a qualified expert witness or create "'insurmountable hurdles to recovery for large and foreseeable classes' of plaintiffs"). Urologists with the necessary statutory qualifications to testify are plentiful; it's just that the two people whom Plaintiffs' counsel claims to have contacted (an expert witness and an Associate Dean or Urology at a medical school), disagreed with Plaintiffs' position. It is not the statute that is preventing Plaintiffs from finding a qualified urologist to testify. It is the invalidity of their claim. That does not make the statute unconstitutional.

CONCLUSION

For the foregoing reasons, Defendants Affiliated Urologists, Ltd. and Kevin Art, M.D again respectfully request the Court to grant review, vacate the court of appeals' decision, and reinstate the trial court's dismissal of Plaintiffs' complaint.

RESPECTFULLY SUBMITTED this 2nd day of February 2024.

JONES, SKELTON & HOCHULI P.L.C.

By /s/ Eileen Dennis GilBride
Eileen Dennis GilBride
Cristina M. Chait
40 N. Central Avenue, Suite 2700
Phoenix, Arizona 85004

Attorneys for
Defendants/Appellees/Petitioners
Affiliated Urologists, Ltd. and
Kevin Art, M.D.