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-_____ PR Court of Appeals, Division One 1 CA-CV 21-0701 Maricopa County Superior Court No. CV2020-010470

PETITION FOR REVIEW

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Kevin Art, M.D.

Plaintiffs filed this medical malpractice action against Defendant Dr. Art and his urology practice. They alleged that Dr. Art prescribed Cipro, an antibiotic, for Plaintiff David Francisco after a prostate procedure, and failed to tell David about the potential risks to him of taking the antibiotic. Plaintiffs alleged that David had an adverse reaction to the antibiotic and was harmed thereby.

To date, every lack of informed consent case in Arizona has required plaintiffs to establish the standard of care, and any breach thereof, with expert testimony. Yet the court of appeals held that Plaintiffs did not need any expert testimony in this case because the 52-page FDA insert for Cipro included a "black box" warning that alerted prescribing physicians to potential serious adverse reactions in patients who are taking fluoroquinolones (as Plaintiff was). The black box warning did not prohibit the use of Cipro for Plaintiff. It identified three scenarios when the FDA recommended against using Cipro if there are viable alternatives—bronchitis, sinusitis, and uncomplicated UTI, none of which Plaintiff had:

WARNING: SERIOUS ADVERSE REACTIONS INCLUDING TENDINITIS, TENDON RUPTURE, PERIPHERAL NEUROPATHY, CENTRAL NERVOUS SYSTEM EFFECTS AND EXACERBATION OF MYASTHENIA GRAVIS

See full prescribing information for complete boxed warning.

- Fluoroquinolones, including CIPRO®, have been associated with disabling and potentially irreversible serious adverse reactions that have occurred together (5.1), including:
  - Tendinitis and tendon rupture (5.2)
  - Peripheral neuropathy (5.3)
  - Central nervous system effects (5.4)

  Discontinue CIPRO immediately and avoid the use of fluoroquinolones, including CIPRO, in patients who experience any of these serious adverse reactions (5.1)

- Fluoroquinolones, including CIPRO, may exacerbate muscle weakness in patients with myasthenia gravis. Avoid CIPRO in patients with known history of myasthenia gravis. (5.5)
- Because fluoroquinolones, including CIPRO, have been associated with serious adverse reactions (5.1 5.15), reserve CIPRO for use in patients who have no alternative treatment options for the following indications:
  - Acute exacerbation of chronic bronchitis (1.10)
  - Acute uncomplicated cystitis (1.11)
  - Acute sinusitis (1.12)

[R. 52-54, Ex. 7, p. 1.][1] The court of appeals concluded that in a case with a black box warning like this, "a layperson is well able to determine whether . . . the failure to warn constituted negligence." Mem. Dec. ¶ 12.

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[1] The insert 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. [R. 52-54, Ex. 7, p. 11.] It also said: other factors may independently increase the risk of tendon rupture, including strenuous physical activity, renal failure, and previous tendon disorders such as rheumatoid arthritis [*id.*]; and that tendinitis and tendon rupture have also occurred in patients taking fluoroquinolones who do not have the above risk factors. [*Id.*] The warnings also stated that the "most frequently reported adverse reactions, from clinical trials of all formulations, all dosages, all drug-therapy durations, and

The court of appeals cited no case to support its ruling. Nor did the court provide any reasoning or analysis. Instead, it (a) noted that FDA package inserts are admissible (though not conclusive evidence) on standard of care, Mem. Dec., ¶ 11; and then (b) conclusorily stated that "specialized knowledge is not needed to evaluate *whether the FDA instructed the doctor* to give certain warnings to patients." Mem. Dec., ¶ 12 (emphasis added).

This ruling is legally erroneous. The issue in a medical malpractice case is not whether "the FDA instructed" the doctor to do anything. The medical standard of care in Arizona is neither set by the FDA nor breached when a medical professional acts reasonably in determining the best course of action for his patient, regardless of the suggestions in an FDA insert. *See,*

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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. 16.] The insert included two pages of "medically important adverse reactions that occurred in less than 1% of Cipro patients" [*id*., pp. 17-18], another page of "postmarketing reports of adverse drug reactions," [*id*., pp. 20-21], and another three pages of "drugs that are affected by and affecting Cipro." [*Id*., pp. 21-23.] While the warnings also stated that "geriatric" patients are at increased risk [*Id*., p. 25], it is unclear whether reasonable medical professionals would have considered Plaintiff geriatric, given that he was a self-proclaimed active hiker who enjoyed keeping physically fit. [Opening Brief, p. 7.]

e.g., *Ramon v. Farr*, 770 P.2d 131 (Utah 1989) (drug insert does not set the standard of care of a physician, even as prima facie evidence), *abrogated on other grounds*, *Miller v. Utah Dep't of Transp.*, 285 P.3d 1208, 1212, n.1 (Utah 2012); *Grayson v. State*, 838 P.2d 546, 548-49 (Okla. App. 1992) ("We decline to hold that departure from the drug manufacturer's recommendations found on the package insert is prima facie evidence of negligence"; plaintiff must prove "through expert testimony, the standard of medical care required of physicians").

As importantly, the court of appeals' decision is analytically flawed. It fails to recognize the differing purposes and standards for a package insert as opposed to accepted medical practice. FDA materials are designed to comply with the FDA's regulations, to provide advertising and promotional material, and to limit the manufacturer's liability—not to set the medical standard of care. *Richardson v. Miller*, 44 S.W.3d 1 (Tenn. App. 2000). "[D]ifferences between the package insert and accepted medical practice represent the difference between the rigorous proof a regulatory agency must demand and the clinical judgment of a physician based on his training, experience, and skill as related to the needs of his individual patient. One cannot be taken as a standard for the other." *Ramon, supra,* at 136 (quoting

Peter H. Rheinstein, Drug Labeling as a Standard for Medical Care, 4 J. Legal Med. 22, 24 (1976)). *See also Ramon* at 135-36 ("The American Medical Association, while recognizing inserts as one useful source of information, has repeatedly alleged that inserts are an inadequate standard for medical practice, pointing to the inconsistent purposes served by the document[s]—advertising for the manufacturer, regulation by the government, and information for the doctor—and to the poor quality of past inserts."). Indeed, it is for this reason that cases across the country hold that an FDA label or "black box warning" does not establish the medical standard of care or eliminate the need for expert testimony in an informed consent case.

These points are further explained below. Suffice it to say here that the court of appeals' decision is erroneous, ill-considered, and should be vacated. Defendants Affiliated Urologists, Ltd. and Dr. Kevin Art therefore urge the Court to grant review and relief.

I. FACTS

Plaintiffs' complaint alleged that Dr. Art fell below the standard of care by failing to inform Plaintiff David Francisco of the risks of taking the antibiotic Cipro after his prostate procedure. [R. 1, ¶¶ 40, 41.] A.R.S. § 12-2603(A) and (B) require a medical malpractice claimant to certify whether

expert testimony is needed to prove his claim, and if so, to provide a preliminary expert affidavit in order to go forward. Here, Plaintiffs said they did not need expert testimony to prove their claim. [R. 48.] Defendants disagreed, and moved to compel Plaintiffs to provide the preliminary expert affidavit. [R. 50-51.]

In response, Plaintiffs conceded that the American Urological Association (AUA) recommends prescribing Cipro to patients like Plaintiff; that the urology expert they consulted would not testify that Dr. Art fell below the standard of care; and that they were unlikely to find any expert to testify for them. [R. 52-54, pp. 14, 17.] Left with no expert testimony to support their claim, Plaintiffs argued they did not need an expert because laypeople can decide whether Dr. Art was negligent in failing to warn about the risks of Cipro. [R. 52-54, p. 2.]

The trial court disagreed, granted Defendants' motion to compel, and ordered Plaintiffs to submit a preliminary expert affidavit within 30 days. [R. 67.] Plaintiffs did not submit the affidavit, and the court granted Defendants' motion to dismiss. [R. 73.]

The court of appeals reversed. As noted above, the court conclusorily held that in cases involving an FDA black box warning, "a layperson is well

able to determine whether . . . the failure to warn constituted negligence." Mem. Dec. ¶ 12.

II. ISSUE PRESENTED FOR REVIEW

Arizona law requires a medical malpractice plaintiff alleging lack of informed consent to prove with expert testimony that the defendant physician fell below the standard of care. Did the court of appeals err in ruling that the existence of an FDA black box warning on a prescription medication's insert relieved the plaintiff of the expert testimony requirement?

III. REASONS REVIEW SHOULD BE GRANTED

1. Review and relief are necessary to rectify the court of appeals' decision and outline the policy reasons why FDA inserts cannot establish the physician's standard of care without expert testimony:

a. First, the purposes of FDA inserts are to allow the manufacturer to comply with the FDA's regulations, to provide advertising and promotional material, and to limit the manufacturer's liability. They are not intended to equate with or supplant the medical providers' standard of care. *Richardson v. Miller*, 44 S.W.3d 1, 16 (Tenn. App. 2000); *see also Spensieri v. Lasky*, 701 N.Y.S.2d 689, 693 (1999) ("[t]he purposes behind [drug labeling]

render its content ill-suited to serve as prima facie evidence of a standard of care. . . they seek to cover a wide range of concerns not always directed at a diagnosis and course of treatment."); *Morlino v. Medical Center,* 706 A.2d 721, 729 (N.J. 1998) ("drug manufacturers do not design package inserts and PDR entries to establish a standard of medical care").[2]

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[2] "Manufacturers write drug package inserts and PDR warnings for many reasons including compliance with FDA requirements, advertisement, the provision of useful information to physicians, and an attempt to limit the manufacturer's liability. After a drug has been on the market for a sufficient period of time, moreover, physicians may rely more on their own experience and the professional publications of others than on a drug manufacturer's advertisements, inserts, or PDR entries.

Those considerations highlight the reasons expert testimony must accompany the introduction of PDR warnings to establish the applicable standard of care in prescribing a drug. Additionally, 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.

Accordingly, we hold that package inserts and PDR references alone do not establish the standard of care. It follows that a physician's failure to adhere to PDR warnings does not by itself constitute negligence. Reliance on the PDR alone to establish negligence would both obviate expert testimony on an issue where it is needed and could mislead the jury about the appropriate standard of care."

Id. at 729-730.

b. Indeed, the foregoing differences in standards underscore why we have a Learned Intermediary Doctrine. That doctrine absolves drug manufacturers of liability if they provide complete, accurate, and appropriate warnings about a prescription drug to the "learned intermediary" physician. Why? Because "the 'learned intermediary' is best suited to weigh the patient's individual needs in conjunction with the risks and benefits of the prescription drug." *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 25 (2016), adopting the RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6.[3] To hold physicians liable as a matter of law for not disclosing black box

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[3] *See* cmt b: "The obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider's prescription traditionally has required warnings directed to health-care providers and not to patients. 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).

See also cmt. d: "When prescribing health-care providers are adequately informed of the relevant benefits and risks associated with various prescription drugs and medical devices, they can reach appropriate decisions regarding which drug or device is best for specific patients."

warnings would remove the treating physician's expertise from the analysis and eliminate the basis for having a Learned Intermediary Doctrine.

c. Second, allowing FDA materials to supplant expert testimony would improperly permit the drug manufacturer, rather than the medical profession, to establish the standard of care. *Richardson*, 44 S.W.3d at 16; *Spensieri*, 701 N.Y.S.2d at 693.

d. Third, as exemplified by this case, FDA materials are written for the medical profession, not the general public. Expert testimony is needed to explain the materials. *Richardson, supra*, at 16; *Spensieri, supra*, at 693.

e. And finally, FDA labels cannot be cross-examined. *Richardson, supra*, at 17; *Spensieri, supra*, at 693.

2. In light of the foregoing policy reasons explaining why the court of appeals' decision is not sustainable, review and relief are necessary to confirm that this lack of informed consent case, like other lack of informed consent cases in Arizona,[4] requires expert testimony to establish the

[4] *See, e.g.*, *Duncan v. Scottsdale Med. Imaging Ltd.*, 205 Ariz. 306, 309–10 (2003); *Riedisser v. Nelson*, 111 Ariz. 542, 544–45 (1975); *Gorney v. Meaney*, 214

physician's standard of care and breach—regardless of whether an FDA black box warning exists.

The only time expert testimony is not required for medical negligence cases is where the alleged negligence is "so grossly apparent that a layman would have no difficulty in recognizing it." *Riedisser v. Nelson*, 111 Ariz. 542, 544 (1975). This is not a "grossly apparent" case. Whether Cipro was or was not an appropriate (or the only viable) antibiotic to prescribe for David Francisco, and whether the risk for this particular patient under these particular circumstances was great enough to have required a reasonable physician in the defendant's position to have mentioned it, was a matter of medical judgment that required expert testimony. [5] The fact that Plaintiff could not find one urologist who agreed with his claim of negligence is telling.

Ariz. 226, 230 (Ct. App. 2007); *McGrady v. Wright*, 151 Ariz. 534, 537 (Ct. App. 1986); *Gurr v. Willcutt*, 146 Ariz. 575 (Ct. App. 1985).

[5] Indeed, further complicating the medical judgment here was the fact that David had a reported allergy to doxycycline and a history of hypothyroidism, which meant the two other antibiotics that penetrate the prostate were contraindicated. [*See* R. 50-51, p. 6.]

3. Review and relief are necessary to bring Arizona into conformance with the great majority of cases across the country which hold that FDA inserts, while admissible, do not establish the standard of care without the requisite expert testimony. *See, e.g.*, *Richardson v. Miller*, 44 S.W.3d 1, 16 (Tenn. Ct. App. 2000) ("a majority of jurisdictions have determined that a prescription drug's labeling or parallel PDR reference is admissible to prove the standard of care, but only if the plaintiff also introduces other expert testimony regarding the standard of care."); *Doctors Co. v. Plummer*, 210 So. 3d 711, 719 (Fla. Dist. Ct. App. 2017); *Anderson v. Eli Lilly & Co.*, 2015 WL 8773795, at *3-4 (Ohio App. Dec. 15, 2015); *Ngo v. Queen's Medical Center*, 358 P.3d 26, 41 (Haw. 2015), and *Craft v. Peebles*, 893 P.2d 138, 151-52 (Haw. 1995); *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 114 (Ky. 2008); *Chandler v. Simpson*, 2000 WL 426441, at *9 (Wash. App. April 18, 2000); *Spensieri v. Lasky,* 94 N.Y.2d 231, 238 (1999); *Morlino v. Medical Center*, 706 A.2d 721, 728 (N.J. 1998); *Bissett v. Renna*, 710 A.2d 404, 407 (N.H. 1998); *Grayson v. State*, 838 P.2d 546, 548-49 (Okla. App. 1992); *Ramon v. Farr*, 770 P.2d 131, 135-36 (Utah 1989), *abrogated on other grounds, Miller v. Utah Dep't of Transp.*, 285 P.3d 1208, 1212, n.1 (Utah 2012); *Garvey v. O'Donoghue*, 530 A.2d 1141, 1146 (D.C. 1987); *Thompson v. Carter*, 518 So.2d 609, 613 (Miss.

1987); *Nolan v. Dillon*, 276 A.2d 36, 49 (Md. 1971); *Crouch v. Most*, 432 P.2d 250, 252 (N.M. 1967); *Salgo v. Leland Stanford, Jr. University Board of Trustees*, 317 P.2d 170, 180 (Cal. App. 1st Dist. 1957).

4. Finally, review and relief are necessary to correct the court of appeals' incorrect statement of law. To justify its ruling, the court of appeals said a lay jury can evaluate "whether the FDA instructed the doctor to give certain warnings to patients." Mem. Dec., ¶ 12. But a lack of informed consent claim does not hinge on what the "FDA instructed the doctor," for an FDA insert's suggestion that a physician should give his patient certain warnings does not establish either the standard of care for the physician, *see Ramon v. Farr*, *supra*, or his alleged negligence. *Grayson v. State*, *supra*. Even the Arizona case the court cited, *Rodriguez v. Jackson*, 118 Ariz. 13, 18 (Ct. App. 1977), recognizes that a package insert, while admissible, is not conclusive evidence of the standard of care. As such, Plaintiff does not make out a prima facie case of negligence by pointing to a black box warning. Nor does the plaintiff's case hinge on what the jury finds or does not find about the FDA insert, as the court of appeals suggested. The case hinges on the jury's finding, based on expert testimony, that the defendant did or did not

act as a reasonable physician in the community would act under the same or similar circumstances. A.R.S. § 12-563(1).

CONCLUSION

For the foregoing reasons, Defendants Affiliated Urologists, Ltd. and Dr. Kevin Art urge the Court to grant review and relief.

RESPECTFULLY SUBMITTED this 19th day of June, 2023.

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IN THE
ARIZONA COURT OF APPEALS
DIVISION ONE

DAVID FRANCISCO, et al., *Plaintiffs/Appellants*,

v.

AFFILIATED UROLOGISTS LTD, et al., *Defendants/Appellees*.

No. 1 CA-CV 21-0701
FILED 5-23-2023

Appeal from the Superior Court in Maricopa County
No. CV2020-010470
The Honorable James D. Smith, Judge (Retired)

REVERSED AND REMANDED

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MEMORANDUM DECISION

Presiding Judge Maria Elena Cruz delivered the decision of the Court, in which Judge Angela K. Paton and Judge Jennifer M. Perkins[1] joined.

C R U Z, Judge:

¶1 David Francisco and his wife, Kimberley Francisco, appeal the superior court's dismissal with prejudice of their medical negligence claim against Kevin Art, M.D. ("Dr. Art") and Affiliated Urologists, Ltd. (collectively, "the Practice") based on non-compliance with Arizona Revised Statutes ("A.R.S.") section 12-2603. We reverse and remand for further proceedings consistent with this decision.

FACTUAL AND PROCEDURAL HISTORY

¶2 The Franciscos filed a lawsuit against the Practice alleging medical negligence.[2] The Franciscos alleged Dr. Art failed to inform David of the potential risks of taking ciprofloxacin ("Cipro"), a drug Dr. Art prescribed for David following a 2018 urological procedure. The Franciscos allege David had a reaction to Cipro that caused him permanent pain and injury. The Franciscos asserted that, had Dr. Art offered adequate information or prescribed a reasonable alternative, David would have requested a different antibiotic.

¶3 The Franciscos certified that expert witness testimony was not necessary to prove the applicable standard of care and liability. The Practice filed a motion to compel a preliminary expert opinion affidavit

[1] Judge Jennifer M. Perkins replaced Judge Peter B. Swann, who was originally assigned to this panel but has since retired. Judge Perkins has read the briefs, watched the recorded oral argument, and reviewed the record.

[2] In their complaint, the Franciscos alleged three causes of action: lack of informed consent, negligence, and negligence per se. All three claims are premised on the Franciscos' allegation that Dr. Art failed to warn or inform David of the increased risk of harm based on the FDA warnings and David's particular patient profile. The Franciscos do not raise any issue regarding their negligence per se claim, and thus it is waived. *See Ramos v. Nichols*, 252 Ariz. 519, 523, ¶ 11 (App. 2022).

required under A.R.S. § 12-2603(D). In response, the Franciscos argued that, as recently as 2016, the Food and Drug Administration ("FDA") warned in its Cipro medication insert that Cipro can cause "disabling and potentially irreversible serious adverse reactions," and instructed doctors prescribing Cipro to use caution "when prescribing CIPRO to elderly patients especially those on corticosteroids," to inform patients of this potential adverse reaction, and to give instructions "to discontinue CIPRO use and contact their healthcare provider if any symptoms of tendinitis or tendon rupture occur." At the time of the surgery, David was 66 years old and had been taking corticosteroids for about 40 years. The Franciscos argued jurors could decide for themselves whether the FDA warnings would have been material to David's decision-making process, and the FDA warnings at issue did not require experts for the jury to understand them. Ultimately, the Franciscos conceded they were unable to find an expert to provide a preliminary expert opinion affidavit. The superior court granted the Practice's motion to compel a preliminary expert opinion affidavit as to the claims of negligent prescription of Cipro and failure to inform of the risks of taking the drug, as well as denied the Franciscos' motion for reconsideration.

¶4 The Practice moved to dismiss pursuant to A.R.S. § 12-2603(F). The superior court granted the motion and entered final judgment dismissing the case with prejudice. The Franciscos timely appealed, and we have jurisdiction pursuant to Article 6, Section 9, of the Arizona Constitution and A.R.S. §§ 12-120.21(A)(1) and -2101(A)(1).

DISCUSSION

¶5 The Franciscos argue the superior court erred in requiring a preliminary expert opinion affidavit as to their lack of informed consent claim and in dismissing the same. We review an order requiring a preliminary expert opinion affidavit under A.R.S. § 12-2603 for abuse of discretion. *See Warner v. Sw. Desert Images, LLC*, 218 Ariz. 121, 128, ¶ 14 (App. 2008) (reasoning that the abuse of discretion standard should apply to the superior court's decision whether expert testimony is required under A.R.S. § 12-2602, the companion statute to A.R.S. § 12-2603, because the determination at trial of areas of expert testimony is discretionary).

¶6 The Franciscos argue that A.R.S. § 12-2603 only applies to medical malpractice claims and that, because a lack of informed consent claim is not a medical malpractice claim, expert testimony is not required. As relevant here, a "claim" for purposes of § 12-2603 means a legal cause of action under the Medical Malpractice Act, A.R.S. §§ 12-561 through 12-563, when "[t]he claim is based on the health care professional's alleged breach

of contract, negligence, misconduct, errors or omission in rendering professional services," and when expert testimony is necessary to prove the standard of care or liability. A.R.S. § 12-2603(H).

¶7 It is undisputed that the Franciscos alleged a medical negligence action against healthcare provider Dr. Art for lack of informed consent. A lack of informed consent claim is a negligence action. *Duncan v. Scottsdale Med. Imaging, Ltd.*, 205 Ariz. 306, 309-10, ¶¶ 11-13 (2003) (lack of informed consent claim involves the physician's duty to inform the patient of inherent risks in surgery or treatment to which he has consented and should be pled in negligence); *Rice v. Brakel*, 233 Ariz. 140, 144, ¶ 12 (App. 2013) (duty to disclose relevant risks exists under the informed consent theory of medical malpractice); *Gorney v. Meaney*, 214 Ariz. 226, 230, ¶ 11 (App. 2007) (lack of informed consent claim falls within definition of claim for medical malpractice); *Gurr v. Willcut*, 146 Ariz. 575, 581 (App. 1985) (same). Moreover, this court has expressly rejected the argument that A.R.S. § 12-2603 excepts lack of informed consent claims from its reach. *Gorney*, 214 Ariz. at 230, ¶ 9.

¶8 The Franciscos next argue expert testimony is not necessary to prove their lack of informed consent claims given the particularized FDA warnings and David's medical history. The Arizona Supreme Court has made clear that the medical profession's custom to warn must usually be established by expert medical testimony and depends "upon the circumstances of the particular case." *Riedisser v. Nelson*, 111 Ariz. 542, 544-45 (1975) (citation omitted); *see also Potter v. H. Kern Wisner, M.D., P.C.*, 170 Ariz. 331, 333 (App. 1991); *Seisinger v. Siebel*, 220 Ariz. 85, 95, ¶ 39 (2009) ("[E]xpert testimony is *usually* required to establish the standard of care.") (emphasis added) (citation omitted). But evidence of custom, while usually important, is not determinative in all cases; there is no legal rule requiring that expert testimony *always* exist to define the standard of care. Notably, § 12-2603(A) requires a plaintiff to file a written statement as to "*whether or not* expert opinion testimony is necessary to prove the health care professional's standard of care or liability for the claim." (Emphasis added.)

¶9 Here, relying on *Riedisser*, the superior court held that Dr. Art's possible duty to warn of a specific risk hinged on medical knowledge. 111 Ariz. at 545. But *Riedisser* is distinguishable. In that case, the plaintiff suffered a rare, adverse result after undergoing a hysterectomy for which she gave her informed consent. *Id.* at 543-44. Medical knowledge was necessary to explain to the jury whether the physician breached his duty of disclosure in failing to inform her of the unlikely possibility of the rare complication she experienced. *Id.* at 544-45. The court reasoned that

because Ms. Riedisser gave her informed consent, any liability of the physician must be from malpractice and must be measured by the usual practices of the medical profession. *Id.* In other words, a medical expert would be required to explain to the jury the standard of disclosure for that surgical procedure within the medical community.

¶10 As *Riedisser* notes, the duty to warn of a specific risk depends "upon the circumstances of the particular case and upon the general practice followed by the medical profession," and "[t]here is . . . no clear rule as to what information must be disclosed in what circumstances; medical judgment is primarily involved." *Id.* (citation omitted).

¶11 Custom alone is not the standard. All relevant circumstances should be considered, including whether the FDA has specified in a medication's package insert that the prescriber should give a warning. *Cf. Rodriguez v. Jackson*, 118 Ariz. 13, 18 (App. 1977) (recognizing that although a package insert is not conclusive evidence of the standard of care, it is admissible into evidence).

¶12 The absence of expert testimony on the custom of the medical profession does not mandate dismissal under § 12-2603 when, as here, the FDA directs physicians to advise patients of all risks associated with prescribed medications, provides physicians with a specific "black box" warning, and the physician does not advise the patient of the specific warning Here, specialized knowledge is not needed to evaluate whether the FDA instructed the doctor to give certain warnings to patients. The Franciscos should be permitted to present evidence that the FDA warnings for Cipro directed prescribers to inform their patients of the potential adverse reaction and give them instructions for further follow up. Should the Practice wish to offer responsive expert testimony that physicians are free to ignore such a directive, it may do so. In such circumstances, a layperson is well able to determine whether, in the context of all evidence from both sides, the failure to warn constituted negligence.

CONCLUSION

¶13 We reverse and remand for further proceedings consistent with this decision. The Franciscos are awarded their costs on appeal, upon compliance with ARCAP 21.

AMY M. WOOD • Clerk of the Court
FILED: AA