

**COURT OF APPEALS
STATE OF ARIZONA
DIVISION ONE**

DAVID FRANCISCO and KIMBERLY
FRANCISCO, husband and wife,

Plaintiffs/Appellants,

v.

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

Defendants/Appellees..

Case No. 1 CA-CV 21-0701

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

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

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Legal Argument

- 1. In an informed-consent case, the plaintiff must prove two kinds of causation. The first requires expert testimony; the second does not.**

A patient will have a claim for failure to obtain informed consent if the healthcare provider did not adequately disclose material risks about a proposed medical treatment. *Duncan v. Scottsdale Medical Imaging, Ltd.*, 205 Ariz. 306, 310 ¶ 11 (2003). “Material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient’s position when deciding to accept or reject the recommended medical procedure.” *Truman v. Thomas*, 611 P.2d 902, 905 (Cal. 1980).

It is violation of the “duty to disclose all material risks a patient would need to determine his or her course of treatment, and the breach’s causation of physical injury, that give rise to an action for informed consent.” *Ditto v. McCurdy*, 510 F.3d 1070, 1078 (9th Cir. 2007). Some cases suggest that the required disclosure of material information to the patient must “be established by expert testimony in accordance with the applicable standard of medical care.” *Hales v. Pittman*, 118 Ariz. 305, 311 n. 4 (1978).

More recently and more precisely, however, this Court has explained that a patient alleging a lack of informed consent must show two things: *First*, that the patient would have declined the treatment with adequate disclosure. *Second*, that the treatment proximately injured the patient. *Rice v. Brakel*, 233 Ariz. 140, 146 ¶

23 (App. 2013). Expert testimony is *not* needed for the first type of causation since that “is plainly a matter to which plaintiffs themselves could testify and is within the knowledge of the average layperson.” *Gorney v. Meaney*, 214 Ariz. 226, 231 ¶ 15 (App. 2007).

2. Patients have a right to receive material information about proposed treatments from their healthcare providers.

The American Medical Association has explained that:

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.

AMA Code of Medical Ethics § 2.1.1 (2001).

A physician should therefore inform the patient not only about the diagnosis (when known) and the nature and purpose of recommended interventions, but also about “the burdens, risks, and expected benefits of all options,” including not getting treatment. *Id.* at § 2.1.1(b).

In the area of drug prescription, in particular, as discussed in the final part of this brief, under the learned-intermediary doctrine a doctor prescribing a drug that may potentially be dangerous for the patient had a duty to communicate the drug maker’s product warnings to the patient, so the patient can in turn give informed consent to using the drug. *See Watts v. Medicis Pharmaceutical Corp.*, 239 Ariz. 19 (2016) (explaining and applying the learned-intermediary doctrine).

In general, because a healthcare provider has a duty to disclose all material information that the provider could “reasonably expect a patient would want to consider in determining whether to undergo the medical procedure,” a “medical standard is not involved in the materiality test”—and “expert testimony is not required.” Dan B. Dobbs, Paul T. Hayden & Ellen M. Bublick, 2 *The Law of Torts* § 309 at 224 (2nd ed. 2011). After all, “the duty to inform a patient of all reasonable options is a standard of care well within the understanding of a lay jury and requires no expert testimony.” *Kimmel v. Dayrit*, 693 A.2d 1287, 1297 (N.J. App. Div. 1997).

That sort of “patient-oriented” materiality standard recognizes that, while a patient needs medical information to understand the proposed treatment, the choice of what is best for the patient “is a personal, not a medical, decision. Unlike the traditional standard, expert testimony is not required to prove what is material.” Wendy K. Mariner, *Informed Consent in the Post-Modern Era*, 13 *Law & Social Inquiry* 385, 387 n. 6 (1988).

In cases like the present one, where a patient has testified that, if he had been reasonably informed about the risks, he would not have agreed to take a drug highly dangerous for someone of his age and medical condition, the patient’s testimony is “sufficient to present a question of fact requiring the jury to assess the risks and benefits” of the proposed treatment, and then to decide if a reasonably

provident person would have agreed to the treatment. *Osorio v. Brauner*, 662 N.Y.S.2d 488, 489 (App. Div. 1997).

A patient is “not required to adduce expert medical testimony to the effect that a reasonably prudent person in plaintiff’s position would not have undergone” the proposed treatment “if he or she had been fully informed of such a risk.” *Id.*

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

“Once it is determined that a duty of disclosure applies,” in fact, “breach of that duty ought to be judged not by the standards of expert behavior but by the standards appropriate to protection of patient autonomy.” Marjorie Maguire Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 Yale L.J. 219, 286 (Dec. 1985).

Under a patient-oriented materiality standard for informed consent, which is the standard Arizona implicitly uses, “the physician must disclose the risks and alternatives that a reasonable person in the patient’s circumstances would find material in making a medical decision.” Evelyn M. Tenebaum, *Revitalizing Informed Consent and Protecting Patient Autonomy: An Appeal to Abandon*

Objective Causation, 64 Okla. L. Rev. 697, 737 (2012). Expert testimony is not required to establish if a healthcare provider disclosed “all risks that a reasonable person would consider significant regardless of whether such disclosure is required accepted practice in the medical profession.” Note, *Medical Malpractice: Expert Opinion Unnecessary to Establish Claim Based on Doctrine of Informed Consent*, Minn. L. Rev. 695, 698 (1979).

A “patient standard focuses on what the reasonable patient would want to know” and “avoids the necessity of using expert testimony to prove that the disclosure standard has not been met.” *Revitalizing*, 64 Okla. L. Rev. at 738-39. And so, although some expert testimony might be needed “to explain the medical procedures involved and the risks and alternatives” to the trier of fact, no expert testimony is needed “with respect to the patient disclosure standard itself. Deciding what a reasonable person would want to know does not require technical expertise.” *Id.* at 739.

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

3. Jurors are capable of deciding whether a healthcare provider has given the needed material information to the patient.

Letting juries decide whether a healthcare provider gave relevant, material information about foreseeable risks of a proposed treatment to the patient—and what the patient would have chosen to do if made aware of the foreseeable risks—is consistent with Arizona caselaw that, even in a medical-negligence case, expert testimony is not required when “the negligence is so grossly apparent that a layman would have no difficulty in recognizing it.” *Revels v. Pohle*, 101 Ariz. 208, 210 (1966) (quoting *Boyce v. Brown*, 51 Ariz. 416, 421 (1938)).

Indeed, it is the rule in Arizona that, absent unusual facts requiring expertise, “the jury is permitted to decide what is reasonable from the common experience of mankind.” *Rossell v. Volkswagen of America*, 147 Ariz. 160, 166-67 (1985).

For Arizona negligence cases, the “decisive consideration in determining the admissibility of expert opinion evidence is whether the subject of inquiry is one of such common knowledge that men of ordinary education could reach a conclusion as intelligently as the [expert] witness.” *Woodward v. Chirco Const. Co.*, 141 Ariz. 520, 521 (App. 1984) (quoting *People v. Cole*, 301 P.2d 854, 856 (Cal. 1956)). That approach will work as well in medical-negligence, informed-consent cases as it does in other negligence cases.

In the final analysis, where the facts can be placed before the jurors, “and are of such a nature that jurors generally are just as competent to form opinions in

reference to them and draw inferences from them as witnesses, then there is no occasion to resort to expert or opinion evidence.”” *Lee Moor Contracting Co. v. Blanton*, 49 Ariz. 130, 144 (1937) (quoting *Ferguson v. Hubbell*, 97 N.Y. 507, 513-14 (1884)).

4. There is nothing enigmatic about the material information a healthcare provider must give the patient to allow for informed consent.

As for what material information a healthcare provider must disclose to allow for informed consent, in 2021, the California Court of Appeal distilled the relevant principles and usefully explained that the “minimal disclosures” in every informed-consent case would include:

- (1) a reasonable explanation of each recommended procedure;
- (2) the likelihood of success for each recommended procedure;
- (3) the risks involved in accepting and rejecting each proposed procedure, particularly the potential of death or serious harm and the complications that might possibly occur; and
- (4) the physician’s personal interests that may affect his judgment, even if unrelated to the patient’s health.

Flores v. Liu, 274 Cal.Rptr.3d 444, 455 (App. 2021) (cleaned up; citations omitted).

The standard for what is material “focuses on what an objective, reasonable ‘prudent person’ in the patient’s shoes would want to know, and is therefore not

dictated by whatever ‘custom’ physicians in the relevant medical community follow when making disclosures.” *Id.* at 455. Stated in slightly different form, in an informed-consent case, “material information” is information that the healthcare provider knows or should know would be regarded as significant by a reasonable person in the patient’s position when deciding to accept or reject a recommended medical procedure. *Arato v. Avedon*, 858 P.2d 598, 608 n. 9 (Cal. 1993).

Since “the focus of informed consent is on what the reasonable patient needs to know to make an intelligent choice among the available options, a physician:

- (1) “need not give the patient a ‘mini-course in medical science’ or a ‘lengthy polysyllabic discourse on all possible complications’ and their statistical probabilities” *Id.* (quoting *Cobbs v. Grant*, 502 P.2d 1, 11 (Cal. 1972));
- (2) “need not disclose information that is ‘commonly appreciated’” *Id.* (quoting *Truman v. Thomas*, 611 P.2d 902, 905 (Cal. 1980)); and
- (3) “need not disclose information regarding the non-medical effects of a medical procedure.” *Id.* (citing *Arato*, 858 P.2d 598 at 608).

That returns us to the jury’s role. Because “the duty to obtain informed consent is pegged to what a ‘reasonable person’ in the patient’s position would deem to be ‘material’ to her medical decision-making (rather than being pegged to customs for disclosure in the profession), the decision as to what information

should be disclosed is entrusted chiefly to the trier of fact, and *not* to medical experts.” *Flores*, 274 Cal.Rptr.3d at 455 (emphasis in original).

5. A.R.S. § 12-2603 does not nullify the principle that there need not be a medical expert in every medical-malpractice case.

Litigants rely on experts too much. In fact, the “expertization of civil law is a major reason for the complexity, expense, and delay that limit access to the justice system and make trials so rare.” Gregg J. Costa, *Nine Tips for Civil Trials from a Prosecutor Turned Judge*, 44(1) Litig. 43, 44 (Fall 2017).

On one point, there is universal agreement. A medical expert is not needed on every issue in every medical-malpractice case. For instance, in the 1983 *Carranza* case, this Court held that it was unnecessary for the plaintiff to offer expert medical testimony to show that the burn a child sustained on her leg while undergoing heart surgery could not have occurred without negligence because that was within the realm of common knowledge. *Carranza v. Tucson Medical Center*, 135 Ariz. 490, 492 (App. 1983). *See also* Answering Brief at 8-9 (citing medical-malpractice cases where no medical experts were needed).

In a medical-malpractice case, a “claimant”¹ may certify to the trial court that “expert testimony is not required for the claim” or for the designation of a nonparty as being at fault for causing or contributing to causing the malpractice.

¹ The term “claimant” refers to “the claimant or the party designating [a] nonparty at fault or its attorney.” A.R.S. § 12-2603(D).

A.R.S. § 12-2603(D). But if the defendant healthcare professional or a designated nonparty at fault “disputes that certification in good faith,” either one “may apply by motion to the court for an order requiring the claimant “to obtain and serve a preliminary expert opinion affidavit.” A.R.S. § 12-2603(D).

In the motion seeking that order, the defendant healthcare professional or the designated nonparty at fault the following:

1. The claim for which it believes expert testimony is needed.
2. The prima facie elements of the claim.
3. The legal or factual basis for its contention that expert opinion testimony is required to establish the standard of care or liability for the claim.

A.R.S. § 12-2603(D)(1), (2) & (3).

The trial court erred by concluding this is a case where lay jurors cannot, without the expert guidance outlined in A.R.S. § 12-2603, determine liability for failure to provide the information reasonably needed for informed consent. *Minute Entry* at 2 (Aug. 3, 2021). That is an error that echoes in other similar cases.

Under a patient-centered materiality approach, lay jurors can evaluate the testimony concerning what the healthcare provider disclosed about the risks of the proposed treatment. Then, the jury can hear from the patient whether the patient would have regarded that information as material and decide whether the patient would have rejected the proposed treatment if the patient had received from the

healthcare provider the needed material information on the risks associated with the proposed treatment. What weight and credibility to assign to the informed-consent testimony is a matter for the jury to determine. *Sandretto v. Payson Healthcare Mgmt., Inc.*, 234 Ariz. 351, 359 ¶ 24 (App. 2014).

6. In an informed-consent case, the jury must evaluate the credibility and weight to give the healthcare provider's and the patient's testimony.

Armed with expert testimony about whether the harm the patient received was the result of a risk about the patient was not informed, a jury can decide if the patient's consent was informed. The jury will need to evaluate the weight and credibility of the testimony on what the healthcare provider communicated about potential risks, on what the patient understood, and on what the patient would have done if armed with the nondisclosed material information.

The facts in the present case provide a paradigm of uninformed consent. Here, the healthcare provider prescribed Cipro to David Francisco, although he was a geriatric patient taking corticosteroids. *Minute Entry* at 1 (Aug. 3, 2021). Before then, the Food and Drug Administration had published a strong, clear warning that prescribing Cipro was dangerous for geriatric patients taking corticosteroids, because they could develop severe tendon disorders. *Id.* But the healthcare provider failed to inform Francisco about that material risk. And so, he took the Cipro and developed severe tendon disorders. *Id.*

The important point in the present case is the avowal to the trial court that:

“If [the healthcare provider] had advised David [Francisco] of the potential complications, David would have opted for a different antibiotic.” *Id.* Whether Francisco would have opted for a different antibiotic is a question of fact requiring jury evaluation of the credibility and weight of Francisco’s testimony. The jury is free to believe or disbelieve Francisco’s testimony that, if he had received the material information about possible complications associated with Cipro, he would have chosen a different antibiotic and not suffered severe damage to his tendons.

Here, and in the many cases like it that have occurred and are sure to occur in the future throughout Arizona, lay jurors can:

- (1) consider what a healthcare provider told and failed to tell a patient about a proposed medical treatment and its risks;
- (2) decide whether there was an adverse result arising from the medical treatment; and
- (3) evaluate a patient’s testimony that, if the patient had received the material information about the risks of the proposed medical treatment, the patient would have refused to undergo that treatment, and would have avoided the adverse result.

Lay jurors need no expert guidance on what a healthcare provider told the patient. That is a question of fact. And lay jurors need no expert guidance on whether a patient is telling the truth about what the patient would have done if the

patient had received the material information needed for informed consent. That is also a question of fact for the jury to resolve based on the credibility and weight the jurors decide to give to the patient's testimony.

“No rule is better established than that the credibility of the witnesses and the weight and value to be given to their testimony are questions exclusively for the jury.” *State v. Cox*, 217 Ariz. 353, 357 ¶ 27 (2007) (quoting *State v. Clemons*, 110 Ariz. 555, 556-57 (1974)). “A trial judge’s gatekeeping role is not intended to displace the jury’s fact-finding role, which includes assessing the weight and credibility of testimony and resolving any evidentiary conflicts.” *State v. Rojo-Valenzuela*, 237 Ariz. 448, 451 ¶ 11 (2015). Credibility is for the jury—“the jury is the lie detector in the courtroom.” *United States v. Barnard*, 490 F.2d 907, 912 (9th Cir. 1973), *cert. denied*, 416 U.S. 959 (1974).

Expert guidance, of course, would be needed on the causation question of whether the adverse result that the patient actually experienced arose from a risk for which the healthcare provider failed to provide material information. And expert guidance would be needed about the nature, extent, and duration of the medical harm that the patient suffered as a result of the medical treatment the patient says would have been refused if the patient had received the needed material information.

But no expert guidance is needed on what a healthcare provider discloses

and fails to disclose and on what the patient says that he or she would have done if armed with the material information. Those are questions of fact in the present case and in other medical-negligence, informed-consent cases across Arizona. For those questions of fact, no expert testimony is needed.

7. The learned-intermediary doctrine complements the informed-consent rule—and inherently imposes a duty on a prescribing doctor to provide needed information to the patient about a prescribed drug to ensure the patient can provide informed consent.

The opening brief suggested that the learned-intermediary doctrine had a role in this informed-consent situation. *Opening Brief* at 28 n. 9. It does. In fact, the relationship between informed consent and the learned-intermediary doctrine is an issue that merits close attention. Indeed, that relationship may be dispositive for this case and for other cases concerning whether informed consent was given to prescription of a hazardous drug.

Under the learned-intermediary doctrine, a drug manufacturer can satisfy its duty to warn end users of its drugs by giving suitable warnings to doctors who prescribe or administer drugs to their patients. *Watts v. Medicis Pharmaceutical Corp.*, 239 Ariz. 19, 22 ¶ 1 (2016). If the drug maker gives complete, accurate, and proper warnings about its drug to a learned intermediary, such as a prescribing doctor, the drug maker has fulfilled its duty to warn the patient, because the drug maker can assume the doctor will pass along the needed warnings to the patient. *Id.* at 24 ¶ 13.

The learned-intermediary doctrine's premise is that some 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." *Id.*

The learned-intermediary doctrine has a logical and profound connection with the informed-consent rule. After all, if a drug manufacturer's warning is adequate, the prescribing doctor may be liable if the doctor fails to disclose the information needed for the patient to make an informed decision about treatment choices. See Charles J. Walsh, Steven R. Rowland & Howard L. Dorfman, *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 Rutgers L. Rev. 821, 845-47 (1996).

The learned-intermediary doctrine encourages the physician to engage in the informed-consent process with the patient when choosing prescription medications. Jerica L. Peters, *State v. Karl: An Unreasonable Rejection of the Learned Intermediary Doctrine*, 48 Jurimetrics 285, 299 (2008). Indeed, the doctrine tasks the physician "with informing a patient of the various risks and benefits associated with the drug so that the patient can exercise informed consent." Max Roberts, *Weaning Drug Manufacturers off Their Painkiller: Creating an Exception to the Learned Intermediary Doctrine in Light of the Opioid Crisis*, 46 Fordham Urb.

L.J. 683, 692 (2019).

Since physicians must get a patient's informed consent before administering dangerous drugs, courts that apply the learned-intermediary doctrine "usually find that it is unnecessary and counter-productive for manufacturers to warn patients about prescription drugs and medical devices because it is physicians who make prescribing decisions on behalf of their patients." Nancy K. Plant, *The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment*, 81 Iowa L. Rev. 1007 (1996).

For prescription drugs, the learned-intermediary doctrine complements the informed-consent rule since, like the learned-intermediary doctrine, the informed-consent rule requires the prescribing doctor to act as a conduit for facts that the doctor has learned about a potentially hazardous drug and that the patient needs to know to make an informed decision on whether to take the drug. Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 Iowa L. Rev. 261, 269-72 (1999).

A corollary to the duty of disclosure that the learned-intermediary doctrine imposes on a prescribing physician is that the content of the disclosure to the patient would not require expert testimony if the content of the information to be disclosed is imposed by a higher authority. For instance, if, as was the case here, the Food and Drug Administration has actually mandated the information that must

accompany the risky prescribed drug, because the duty of disclosure has shifted to the prescribing doctor under the learned-intermediary doctrine, then the FDA-specified warnings constitute the information the prescribing doctor has a duty to convey to the patient to ensure that the patient's consent is actually informed.

No independent expert is needed to elucidate for the jury the terms and meaning of the FDA black-box danger warnings that accompany the drug. Any such elucidation can come from testimony of the learned-intermediary who has the duty to transmit the black-box danger warnings to the patient, namely, from the prescribing doctor. Having said that, little elucidation would be needed here, since the average juror could understand most of the short and startling FDA black-box warnings, which stated that the Cipro could cause disabling and potentially serious adverse reactions, including tendinitis, tendon rupture, peripheral neuropathy, and a central nervous system effect, and that the risk of tendinitis and tendon rupture is greater in patients over the age of 60 and in patients taking corticosteroid drugs. *Opening Brief* at 8.

Indeed, in the learned-intermediary context, the FDA black-box warning in this case also specifically told prescribing doctors that they should inform geriatric patients about the potential adverse reaction of an increased risk of developing severe tendinitis and tendon disorders, including tendon rupture—a risk further increased in those geriatric patients that are also receiving corticosteroid drugs.

Opening Brief at 8.

In this particular case, the prescribing doctor could translate “tendinitis,” “peripheral neuropathy,” “central nervous system effect,” and “corticosteroid drugs” for the patient thinking of taking the Cipro—and for a jury—although the shockingly unpleasant term “tendon rupture” needs no explanation. There would be no need for an independent expert to explain those terms to a jury, as long as the prescribing doctor is available to testify about the drug warnings that, under the learned-intermediary doctrine, an Arizona doctor has the duty to provide to the patient. There should be a similar result in other cases where the FDA has provided one of its usually clear set of black-box warnings.

On the learned-intermediary point, in summary, Amicus submits that a reasonable approach is that no expert is needed to “educate” the jury concerning:

(1) whether a doctor acting as the learned intermediary actually transmitted a drug manufacturer’s warnings to the patient (a question of fact),

(2) whether the prescribing doctor’s warnings to the patient reasonably matched the warnings the drug manufacturer provided to the prescribing doctor (a question of fact),

(3) whether the patient would have understood the warnings if the prescribing doctor had given them to the patient (a question of fact requiring jury evaluation of the patient’s testimony and credibility), and

(4) whether the patient would have still agreed to take the drug if the manufacturer's warning had been passed on to the patient (another question of fact requiring jury evaluation of the patient's testimony and credibility).

All in all, there is little to no role for an expert to play in the intersection of the informed-consent rule and the learned-intermediary doctrine.

Conclusion

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

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

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

DATED this 8th day of May, 2022.

AHWATUKEE LEGAL OFFICE, P.C.

/s/ David L. Abney, Esq.
David L. Abney, Counsel for Amicus Curiae

Certificate of Compliance

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