

**IN THE SUPREME COURT
STATE OF ARIZONA**

DAVID FRANCISCO, et al.,

Plaintiffs/ Appellants/ Respondents,

v.

AFFILIATED UROLOGISTS LTD., et al.,

Defendants/ Appellees/ Petitioners.

Supreme Court No. CV-
23-0152-PR

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

Maricopa County
Superior Court
No. CV2020-010470

**AMICUS CURIAE BRIEF OF BANNER HEALTH, DIGNITY HEALTH,
HONORHEALTH, PHOENIX CHILDREN'S HOSPITAL, THE ARIZONA
MEDICAL ASSOCIATION, AND THE AMERICAN MEDICAL
ASSOCIATION**

**This Brief is filed with the written consent of the parties pursuant to
ARCAP 16(b)(1)(A)**

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American Medical Association

INTEREST OF AMICI CURIAE

Banner Health, headquartered in Phoenix, is one of the largest nonprofit hospital systems in the country. It operates 30 hospitals, including three academic medical centers, and other related health entities, and provides services in six states. With more than 50,000 employees, Banner Health is the largest private employer in Arizona. Banner provides emergency and hospital care, hospice, long-term/home care, outpatient surgery, labs, rehabilitation services, pharmacies, and primary care services.

Dignity Health is a California-based not-for-profit public-benefit corporation that operates more than 40 hospitals in Arizona, California, and Nevada. In February 2019, Dignity Health aligned with Catholic Health Initiatives, becoming CommonSpirit Health, a nonprofit health system with more than 1,000 medical care sites in 21 states. In Arizona, Dignity Health employs approximately 8,000 individuals, including hundreds of doctors and advanced practice clinicians, and credentials more than 2,500 physicians who support patient care, medical education and research at seven hospitals, numerous clinics, and other medical care sites.

HonorHealth is a locally-owned, non-profit, integrated health system that resulted from a merger between John C. Lincoln Health Network and

Scottsdale Healthcare. It has 3,700 expert physicians and 14,000 employees who serve six hospitals, 157 primary and specialty care clinics, a cancer care network, plus research and community services in Phoenix and Scottsdale.

Phoenix Children's Hospital, Inc. is one of the nation's largest pediatric health systems and has provided inpatient, outpatient, trauma, emergency and urgent care to children and families for over 38 years. The health system is comprised of Phoenix Children's Hospital—Main Campus, Phoenix Children's Hospital—East Valley at Dignity Health Mercy Gilbert Medical Center, four pediatric specialty and urgent care centers, 11 community pediatric practices, 20 outpatient clinics, two ambulatory surgery centers and six community-service-related outpatient clinics throughout the state of Arizona. Phoenix Children's employs more than 400 pediatric physicians and more than 1,300 FTEs on its nursing staff. Phoenix Children's Care Network includes more than 850 pediatric primary care providers and specialists who deliver care across more than 75 subspecialties.

The Arizona Medical Association ("ArMA") is a voluntary membership organization for Arizona physicians. It currently represents nearly 4,000 physicians and physicians in training from all specialties and practice settings. ArMA's vision is to make Arizona the best place to practice

medicine and receive care. It is the foremost advocate and resource in the state for economically sustainable medical practices, the freedom to deliver care in the best interests of patients, and health for all Arizonans. ArMA has frequently represented its membership at the state capitol on issues affecting physicians and patients and has provided amicus support in appellate matters regarding the same.

The American Medical Association (“AMA”) is the largest professional association of physicians, residents, and medical students in the United States. Through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all United States physicians, residents, and medical students are represented in the AMA’s policymaking process. The AMA, founded in 1847, promotes the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every state, including Arizona, and every medical specialty.

The AMA and ArMA both appear as separate entities speaking for their members and the AMA Litigation Center. The Litigation Center is a coalition among the AMA and medical societies of every state and the District of Columbia. The Litigation Center is the voice of America’s medical

profession in legal proceedings across the country. The mission of the Litigation Center is to represent the interests of the medical profession in the courts. It brings lawsuits, files amicus briefs, and otherwise provides support or becomes actively involved in litigation of general importance to physicians.

The foregoing entities and organizations have a strong interest in how medical negligence lawsuits are handled in Arizona. In fact, Amici will be directly impacted by the issues here – (a) whether expert testimony is required to prove medical negligence based on lack of informed consent; and (b) whether FDA warnings alone may establish the standard of care. The former issue seemed to be well settled in Arizona in that every lack of informed consent case decided thus far has required expert testimony to establish the standard of care and breach thereof. But the court of appeals Decision now questions those cases ostensibly based on the narrow and rarely utilized exception that expert testimony in medical negligence cases is not required if the alleged negligence is “so grossly apparent that a layman would have no difficulty recognizing it.” *Riedisser v. Nelson*, 111 Ariz. 542, 544 (1975). The only way this exception applies here is if the latter issue – whether FDA warnings alone establish the standard of care – is decided in

the affirmative. In other words, the FDA inserts and included warnings are synonymous with the standard of care such that if a physician does not strictly adhere to those inserts and inform their patients of every FDA warning, they may be found guilty of medical negligence, without expert testimony. This is what the Decision stands for and is in direct contrast to established Arizona law and the precedent of most jurisdictions. The Decision must be reviewed.

The Decision supplants the medical judgment of Arizona physicians – including those employed by the hospital amici and members of ArMA and the AMA – by imposing a nonexistent requirement to strictly adhere to FDA inserts and warnings or face liability for medical negligence even if there is no expert medical testimony that the physician was negligent. Amici curiae therefore respectfully request the Court to grant review and relief.

No person or entity other than the amici curiae identified herein prepared or provided financial resources for this brief.

REASONS REVIEW SHOULD BE GRANTED

1. Review is necessary to confirm Arizona’s long-standing precedent that expert medical testimony is required to establish the standard of care and breach thereof in medical negligence cases based on lack of

informed consent and to redefine the narrow and rare exception to the general rule that expert testimony is required to prove medical negligence.

Here, the court of appeals correctly defined what Appellants' claim was for – medical negligence based on a lack of informed consent. Mem. Dec., ¶ 7; *see also Duncan v. Scottsdale Medical Imaging, Ltd.*, 205 Ariz. 306, 310 (2003) (“true ‘informed consent’ claims, i.e., those involving the doctor’s obligation to provide information, must be brought as negligence actions.”). But they incorrectly analyzed how that claim must be proven. Without citation to any precedent, the court of appeals noted, “evidence of custom, while usually important, is not determinative in all cases; there is no legal rule requiring that expert testimony *always* exists to define the standard of care.” Mem. Dec., ¶ 8. In cases based on lack of informed consent, Arizona courts have consistently held that expert testimony is required to prove the standard of care, including:¹

- *Riedisser v. Nelson*, 111 Ariz. 542, 544-545 (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

¹ *See also* AB, pg. 10 – 11.

established by expert medical testimony.” (citing *Shetter v. Rochelle*, 2 Ariz. App. 358, 370 (1965) (emphasis added)).

- *Duncan v. Scottsdale Medical Imaging, Ltd.*, 205 Ariz. 306, 310 (2003): Holding that a lack of informed consent claim must be supported by “expert testimony in accordance with the applicable standard of care.” (citing *See Hales v. Pittman*, 118 Ariz. 305, 311 n. 4 (1978)).

Based on this precedent, expert testimony is required to prove the standard of care and breach thereof in lack of informed consent cases without exception.² Review is necessary to confirm this established and long-standing precedent to avoid confusion in future cases involving medical negligence based on a lack of informed consent.

Further, while entirely unclear in their Decision, the court of appeals note that expert testimony is not “*always*” required, is likely alluding to the narrow and rarely utilized exception: “Negligence on the part of a physician **must** be established by expert medical testimony **unless** the negligence is so grossly apparent that a layman would have no difficulty in recognizing it.”

² Indeed, most jurisdictions require expert testimony to establish the standard of care and breach thereof for medical negligence cases based on a lack of informed consent. *Ketchup v. Howard*, 543 S.E. 2d 371, Appendix (Ct. App. Ga. 2000) (providing a state-by-state overview of informed consent law).

Riedisser, 111 Ariz. at 543. Appellants argue that this is “simply one of those rare cases.” [PR Resp., pg. 1.] Review is necessary to determine whether the “grossly apparent” exception applies in cases like this one where a doctor allegedly failed to provide the patient with an FDA imposed warning. For the reasons below, this is not the rare case or situation where the “grossly apparent” exception applies.

As a preliminary matter, the court of appeals failed to mention the “grossly apparent” exception. Instead, they simply state – without citation to any authority – “there is no legal rule requiring that expert testimony *always* exist to define the standard of care.” Mem. Dec. ¶ 8. This in and of itself is a problem because it suggests that there are other scenarios – besides the “grossly apparent” exception – where expert testimony may not be required in medical negligence cases. This is simply not true. “A plaintiff in a medical malpractice action must present expert testimony to establish (1) the general standard of care exercised by physicians in the defendant’s field of practice under similar circumstances, and (2) that the defendant deviated from that standard of care in the present case.” *Potter v. H. Kern Wisner, M.D., P.C.*, 170 Ariz. 331, 333 (App. 1991) (citing *Bell v. Maricopa Medical Center*, 157 Ariz. 192, 194-95, (App.1988)). The **only** exception established in Arizona is

the “grossly apparent” exception. That’s it. The only way for a plaintiff to forgo the requirement of expert testimony is to show that a medical professional did something so obviously egregious that no medical explanation is required because anyone could see that they were negligent.

This is simply not a “grossly apparent” case. The “doctrine of informed consent provides that physicians . . . have a duty to inform patients of the known material risks of a proposed treatment or procedure and to inform patients of available treatment alternatives.” *Ketchup v. Howard*, 543 S.E. 2d 371, 372 (Ct. App. Ga. 2000). This necessarily involves medical knowledge and judgment that is beyond the common knowledge of a lay person. Contrast this to situations where the negligence was “grossly apparent,” which typically involve surgeons leaving foreign objects inside a patient. *See, e.g., Revels v. Pohle*, 101 Ariz. 208, 210-11, 418 (1966) (involving a surgeon who left a metal suture inside a patient during a hysterectomy); *Tiller v. Von Pohle*, 72 Ariz. 11, 15 (1951) (involving a surgeon who left a cloth sack inside patient during an abdominal procedure).

In this case, whether Dr. Art was required via the standard of care to provide the FDA warnings to Mr. Francisco is beyond the knowledge of any common juror. Only a qualified medical expert could explain whether the

standard of care required such warnings.³ The court of appeals Decision otherwise was error.

2. While the court of appeals may not have directly held that FDA inserts establish the standard of care, that proposition is the only logical conclusion of the Decision. Amici implore this Court to review the Decision and bring Arizona into the majority view that FDA warnings alone do not establish the standard of care.

³ Appellants claim that Dr. Art's "board" the AUA "simply recommends blasting all surgical urology patients with Cipro . . ." and that, because of this, they could not find "a board-certified urologist willing to testify against the urology board's recommendations." [PR Resp. pg. 9.] First, the AUA is not Dr. Art's "board" and there is no indication that any board-certified urologist must adhere to its guidance. [AB, pg. 4, FN 1.] Second, the sole article Appellants rely on for this claim does not recommend "blasting" all patients with Cipro and does not "instruct its members to ignore one of the FDA's direst warnings regarding the use of Cipro." [PR Resp. pgs. 9 - 10.] The cited article specifically acknowledges the FDA's Cipro warning and notes "due to the side effect warning consider switching to a different antibiotic in surgery or prior to a procedure on case-by-case basis." [OB, Appendix, Ex. 7, pg. 31.] In fact, according to the article, the prophylactic antibiotic recommendation for procedures involving implanted prosthesis - like the UroLift - are Aminoglycosides, not fluorouinolones, like Cipro. [*Id.*, at pg. 47.] As such, the fact that Appellants could not secure an expert does not demonstrate an "untenable and unconstitutional 'conspiracy of silence' whereby board-certified urologists in American are free to disregard important FDA warnings . . .," it simply means that Appellants do not have a viable medical negligence claim. [PR Resp., pgs. 9 - 10.]

A plaintiff in a medical malpractice case must prove negligence with expert opinion testimony establishing the standard of care and explaining how the healthcare provider fell below that standard of care. A.R.S. § 12-563; *Seisinger v. Siegal*, 220 Ariz. 85, 94 (2009) (noting that the standard of care must be established by expert medical testimony); *Bell v. Maricopa Medical Center*, 157 Ariz. 192, 194-195 (App. 1988). An Arizona “jury cannot consider whether a medical malpractice defendant acted negligently until it has determined the standard against which the defendant’s conduct is to be measured. There is a difference between the evidence the jury considers in determining the standard and the standard itself. Only a deviation from the standard itself constitutes evidence of negligence.” *Id.* As analyzed above, the only exception to the expert requirement is the “grossly apparent” exception. So, for the Decision to fit into established Arizona precedent, the FDA warnings must be synonymous with the standard of care such that failure to provide those warnings is “grossly apparent.” This proposition undercuts established Arizona law and is in direct contrast to most jurisdictions that have analyzed the issue.

The court of appeals essentially holding that the FDA insert is synonymous with the standard of care seems based on a fundamental

misunderstanding of the purpose of the FDA inserts and warnings. The FDA neither “directs physicians to advise patients of all risks” nor does it “instruct[] the doctor to give certain warnings to patients.” Mem. Dec. ¶ 12. In fact, the FDA does not mandate physician compliance with drug labeling guidance:

In general, the FDA has elected not to interfere with a physician’s right to practice medicine according to his own lights and the dictates of state law, the FDA reasoning that only health care providers who are familiar with all aspects of a patient’s unique and personal situation can properly determine the circumstances under which a given drug should be used.

* * *

In addition to permitting the use of a prescription drug for non-indicated purposes, compliance with the drug’s labeling, package insert and the corresponding *PDR* information related to other phases of a drug’s use is not made mandatory by the FDA, even though the FDA requires that the drug manufacturer provide guidance for the physician as to how to safely use the drug.

Glen Bradford & Charles C. Elben, *The Drug Package Insert and the PDR as Establishing the Standard of Care in Prescription Drug Liability Cases*, 57 J. Mo. B. 233, 235 (2001).

Because compliance with FDA guidelines is not mandatory and “courts have recognized that a practicing physician is not limited in her prescribing to the FDA-approved package insert information,” most jurisdictions that

have analyzed the issue hold that FDA inserts do not establish the standard of care without corresponding expert testimony. *Id.* at pgs. 236 & 239.⁴ Indeed, “[a]llowing the admission of PDR warnings without accompanying expert testimony could transform drug manufacturers into judges of acceptable medical care. The effect would be to force doctors to follow the PDR’s recommendations or run the risk of liability for malpractice.” *Morlino v. Medical Center*, 706 A.2d 721, 730 (N.J. 1998). This Court should accept review and adopt the rule as followed in most jurisdictions that FDA inserts and warnings, while admissible, do not establish the standard of care without the requisite expert testimony.

This rule would not only comport with Arizona precedent requiring expert testimony on the standard of care, but it is also in line with the statutory intent of A.R.S. § 12-2603: “[T]o curtail the filing of frivolous lawsuits against health care professionals.” *Rasor v. Northwest Hosp. LLC*, 244 Ariz. 423, 426 - 427 (App. 2018) (*citing* 2004 Ariz. Sess. Laws, ch. 4, § 2). Should the Decision stand, Arizona physicians – including those employed by the hospital amici and members of ArMA and the AMA – could be subject

⁴ PR. pgs. 12 - 13.

to countless frivolous lawsuits if they fail to strictly adhere to FDA inserts and warnings. Not only would physicians be obligated to disclose every single FDA warning – which would usurp the medical judgment of the physician and likely make informed consent discussions too tedious and time-consuming to undertake – they would also be obligated to strictly adhere to all other FDA guidance, including only prescribing a medication for its FDA approved use. This is an untenable result. Doctors routinely prescribe medications off-label and legal cases which analyze the issue “are essentially unanimous in reaching the conclusion that a licensed physician is entitled to use his or her best medical judgment regarding the appropriate, including off-label, use of FDA-approved prescription drugs.” Bradford & Elben, *supra*, at 235.⁵

⁵ Indeed, because new uses and indications can only be added to FDA-approved labeling after a drug manufacturer submits specific evidence for the new indication to the FDA, that FDA-approved labeling often temporally lags advances in medical care. *See generally* 21 C.F.R § 314.70. As a result, often well-supported treatments can become part of the standard of care before they are added as new indications for an existing drug. If the Decision becomes the rule, and if physicians are not permitted to use a drug for even well-supported indications which have not yet been through the FDA labeling approval process, patients will necessarily be deprived of the best care.

Taking the Decision to its logical conclusion, practitioners could be subject to lawsuits for the standard practice of prescribing an off-label medication because the FDA “directed” them to only prescribe a medication for its intended use and they failed to do so. Based on the Decision, plaintiffs will argue that “specialized knowledge is not needed to evaluate whether the FDA instructed” a physician to only prescribe a medication for its intended use and they will be able to skirt the requirements of a preliminary expert affidavit under A.R.S. § 12-2603. Mem. Dec. ¶ 12. Of course, as argued by Appellants, it is ultimately up to the jury to decide the issue of standard and breach and, as noted in the Decision, a defendant can always offer responsive expert testimony to refute the FDA inserts. However, such a consequence not only directly contradicts the requirement of a plaintiff to offer expert testimony, it also impermissibly shifts the burden to defendant. *Seisinger*, 220 Ariz. at 94, ¶ 32 (holding that a plaintiff claiming medical malpractice possesses the burden of proof on each element of the claim).

3. Finally, despite Appellants claims otherwise, the Decision is not “only applicable to its narrow set of facts.” [PR Resp., pg. 1.] On the contrary, it has wide reaching implications that will not only negatively impact the

practice of Arizona medical practitioners, but will shape future medical negligence lawsuits in a way that improperly impacts medical negligence defendants. The Petition and this Amicus Brief more than satisfy the requirements of ARCAP 23(d)(3) by showing that (1) no Arizona decision analyzes and/or controls the issue of whether FDA inserts may establish the standard of care without expert testimony; and (2) that the court of appeals incorrectly decided and important issue of law. It makes no difference that the Decision is unpublished. Rule 111(c), Ariz. R. Sp. Ct., allows the citation of an unpublished decision for its “persuasive value” if “no opinion adequately addresses the issue before the court.” There are no Arizona opinions addressing the issues analyzed in the Decision. As such, even if it is not technically precedential, attorneys will cite to it and trial court judges will rely on it in future cases to the detriment of Arizona medical practitioners and their patients.

CONCLUSION

For the foregoing reasons, amici curiae Banner Health, Dignity Health, HonorHealth, Phoenix Children’s Hospital, the Arizona Medical Association, and the American Medical Association respectfully request the Court to grant review and relief.

RESPECTFULLY SUBMITTED this 24th day of August, 2023.

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