ARIZONA SUPREME COURT
ORAL ARGUMENT CASE SUMMARY

DAVID FRANCISCO, et al. v. AFFILIATED UROLOGISTS, LTD., et al.
CV-23-0152-PR

PARTIES AND AMICI :

Petitioners/Defendants:	Affiliated Urologists, Ltd., and Dr. Kevin Art (collectively, "the Practice")
Respondent/Plaintiffs:	David and Kimberley Francisco (collectively, "the Franciscos")
Amicus Curiae:	Arizona Association for Justice/Arizona Trial Lawyers Association
Amici Curiae:	Banner Health, Dignity Health, HonorHealth, Phoenix Children's Hospital, the Arizona Medical Association, and the American Medical Association

FACTS:

The Injury and the Lawsuit. In 2018, Dr. Art performed a urological procedure on David Francisco. After surgery, Dr. Art prescribed Cipro as a prophylactic antibiotic. About two days after starting to take the drug, Francisco "began to feel certain tingling and itching sensations that he believed might be an allergic reaction, along with mild joint pain." Over the next several days, Francisco began to experience significant pain in his ankles, knees, hips, elbows, and right shoulder. Francisco's joint pain continued over several months, and he also developed peripheral neuropathy, a form of nerve damage. Two experts have determined that Francisco's condition is consistent with Cipro toxicity.

In August 2020, the Franciscos filed a lawsuit against the Practice. The lawsuit alleged that Dr. Art failed to inform Francisco of the potential risks associated with Cipro. The Cipro prescription included the manufacturer's 52-page "package insert" that warned about the drug's possible side-effects, including a "black box" direction from the Federal Drug Administration ("FDA") stating that physicians "should" warn patients of certain adverse reactions. Dr. Art did not do so.

In June 2021, the Practice filed a motion to compel the Franciscos to file a preliminary expert opinion affidavit from a qualified medical expert under A.R.S. § 12-2603, which says that in a malpractice action, a plaintiff "shall certify in a written statement . . . whether or not expert opinion testimony is necessary to prove the health care professional's standard of care or liability for the claim." In turn, A.R.S. § 12-563 requires a malpractice plaintiff to show that the defendant "health care provider failed to exercise that degree of care, skill and learning expected of a reasonable, prudent health care provider in the profession or class to which he belongs within the state acting in the same or similar circumstances."

In response, the Franciscos argued that expert testimony was not necessary here to prove the standard of care because a jury could read and understand the FDA "black box" warning without the assistance of medical expert testimony. The superior court ruled that expert testimony was required and dismissed the case with prejudice. The Franciscos then appealed.

The Court of Appeals' Decision. The Court of Appeals reversed the superior court's

decision. The Franciscos' central argument was that "expert testimony is not necessary to prove their lack of informed consent claims given the particularized FDA warnings and David [Francisco's] medical history." The court noted that "the medical profession's custom to warn must usually be established by expert testimony and depends 'upon the circumstances of the particular case.'" (Quoting *Riedisser v. Nelson*, 111 Ariz. 542, 544-45 (1975).) It went on to say, however, that custom is "not determinative in all cases; there is no legal rule requiring that expert testimony *always* exist to define the standard of care." In support, it noted that A.R.S. § 12-2603 itself indicates expert testimony is not always required because it asks "*whether or not* expert opinion testimony is necessary," suggesting that there are instances in which it is not required.

The court explained that the superior court relied on the Arizona Supreme Court's decision in *Riedisser* in ruling that Dr. Art's possible duty to warn of a specific risk hinged on medical knowledge. The Court of Appeals, however, distinguished that case on the ground that "[m]edical knowledge was necessary [there] 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" after having a hysterectomy. (Citing *Riedisser*, 111 Ariz. at 544-45.)

It noted, however, that *Riedisser* also went on to say that "the duty to warn of specific risk depends 'upon the circumstance of the particular case and upon the general practice followed by the medical profession,' and 'there is . . . no clear rule as to what information must be disclosed in what circumstances; medical judgment is primarily involved.'" (Quoting *Riedisser*, 111 Ariz. at 544-45.) From that, the Court of Appeals concluded that "[c]ustom 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." (Citing *Rodriguez v. Jackson*, 118 Ariz. 13, 18 (App. 1977), as "recognizing that although a package insert is not conclusive evidence of the standard of care, it is admissible into evidence.")

The court therefore held that the absence of expert testimony on the "custom of the medical profession does not mandate dismissal under A.R.S. § 12-2603 if, 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." It stated that, in this case, "specialized knowledge is not needed to evaluate whether the FDA instructed the doctor to give certain warnings to patients." "In such circumstances," the court explained, "a layperson is well able to determine whether, in the context of all evidence from both sides, the failure to warn constituted negligence."

ISSUE:

The petitioner has asked the Supreme Court to address the following issue:

> 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?