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

RESPONSE TO AMICUS BRIEF OF ARIZ. ASSOC. FOR JUSTICE/ARIZ. TRIAL LAWYERS' ASSOC.

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Notably, Amicus does not contend that review is unwarranted; indeed, it believes this case presents issues the Court could "profitably address" on review. That is true; but Amicus is entirely incorrect on the issues it poses.

First, Amicus misfocuses its arguments on causation, as it did below. [*See* Amicus, p. 7 (arguing no expert testimony needed to prove "a patient would have declined treatment" if informed; that "if he had been reasonably informed about the risks, he would not have agreed to take a drug . . ."; "whether a particular disclosure did or did not occur"; or "whether the plaintiff herself would have chosen a different treatment").] None of these causation points is at issue here. The issue is the legal standard of care to establish breach.[1]

Second, Amicus continues to improperly cite non-Arizona authority addressing a standard of care that differs from Arizona's. [Amicus, p. 8 (citing a New Jersey case for the idea that "the disclosure be viewed through

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[1] Amicus similarly errs in suggesting there is some question about duty here. [Amicus, p. 11.] Physicians obviously owe a duty of care to their patients.

the mind of the patient").] For nearly fifty years, Arizona courts have held that expert testimony is required to establish a physician's standard of care in informed consent cases. *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."). *See also*:

Riedisser v. Nelson, 111 Ariz. 542, 544–45 (1975) ("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).

Amicus thus errs in arguing 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." [Amicus, p. 8.] Not one Arizona case holds so, and Amicus has cited none.[2]

Third, Amicus incorrectly suggests that a prescribing doctor "has the duty to transmit the [FDA] warnings to the patient." [Amicus, p. 9; *see also* p. 10 (arguing "The duty to give 'black box warnings' and other warnings thus passes from the drug manufacturer to the doctor.").] The Learned Intermediary Doctrine does not impose a duty on the physician to "transmit

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[2] Amicus euphemistically calls its argument a "shift in emphasis." [Amicus, p. 8.] But Plaintiff neither asked this Court to overrule the well-established standard in Arizona, nor presented any such argument—here or below—on why the Court should do so. He only argued below (erroneously) that current Arizona law supports his argument for no expert testimony. [*See* OB, pp. 14-17 (arguing Arizona statutes do not require expert testimony); pp. 18-25 (arguing our cases rely on non-Arizona cases analyzing the informed consent issue "from the standpoint of a reasonable patient"); and pp. 26-29 (arguing expert testimony is simply not necessary).] None of this was correct; but the point here is that no one has asked the Court to overrule long-standing Arizona law, nor briefed the issue; and thus it is not appropriate for the Court's consideration here. The only issue before the Court is, given the requirement that a plaintiff must come forward with expert testimony to prove an informed consent claim, should the Court reject the court of appeals' new-found exception to that rule in this case.

the [FDA] warnings to the patient." To the contrary, the doctrine recognizes that only the patient's physician is "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." RESTATEMENT (THIRD) OF TORTS: PROD. LIAB. § 6, cmt. b (emphasis added), adopted in *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 25 (2016). Amicus's intimation that a physician has a "duty to transmit FDA warnings to the patient" would eliminate the physician's medical judgment that is the very rationale underlying the Learned Intermediary Doctrine.

Fourth, citing no authority, Amicus incorrectly suggests that when the FDA "says to do something," that is "what the law requires." [Amicus, pp. 5-6.] Amicus speculates (without citing any authority), "one would think that what the FDA says controls." [*Id*.] Not so. As Defendants explained at length in their Petition, FDA inserts do not set or supplant the medical providers' standard of care. Rather, the purpose of inserts and black box warnings is to allow the manufacturer to comply with the FDA's regulations,

to provide advertising and promotional material, and to limit the manufacturer's liability. [Petition, pp. 7-8, 10.] Defendants cited more than a dozen cases holding that while FDA inserts are admissible, they do not set the physicians' standard of care without expert testimony. [*Id*., pp. 7-8, 12-13.] Neither Plaintiff nor Amicus has cited one case to the contrary.

CONCLUSION

Amicus has not offered the Court any relevant consideration for this case; and certainly has not offered the Court a reason to deny review. Defendants/Petitioners Affiliated Urologists, Ltd. and Kevin Art, M.D again urge the Court to grant review and relief.

RESPECTFULLY SUBMITTED this 31st day of August, 2023.

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