IN THE SUPREME COURT

STATE OF ARIZONA

David Francisco, DDS and Kimberley Francisco, husband and wife, Plaintiffs/Appellants, v. Affiliated Urologists, Ltd., an Arizona Corporation; Kevin Art, M.D. and Jane Doe Art, husband and wife; Doe Entities I-X; and Roes I-X; Defendants/Appellees.	No. CV-23-0152-PR Court of Appeals, Division One No. 1 CA-CV-21-0701 Maricopa County Superior Court No. CV2020-010470

SUPPLEMENTAL BRIEF

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I. INTRODUCTION

The underlying issue in this appeal is whether a claim for "lack of informed consent" presents a claim for medical negligence or negligent non-disclosure. All parties agree that informed consent is required for any medical or surgical intervention. All parties further agree that the doctor's duty to provide "informed consent" is the doctor's duty to provide the patient with sufficient material information so as to make an informed decision. If this Court frames the issue as one of medical negligence to be supported with expert testimony, then doctors are the sole and final arbiters of what patients should be told. If this Court frames the issue as one of negligent non-disclosure, then jurors get to decide what material information doctors should give to their patients. Underpinning the legal analysis is a crucial public policy question – "Who gets to decide what the public is told?"

In addressing "who gets to decide," this Court must also consider this: "What is the logical end to allowing a reasonable, objective patient be the arbiter of what a doctor ought to tell him?" David submits that the result he seeks is the desirable outcome – if public policy seeks: (1) to respect the autonomy of medical patients and (2) to allow patients to make their own decisions as to (a) what drugs enter their bodies and (b) what risk each patient considers acceptable. To be sure, doctors must

disclose only material risks; the question presented is who is to be the arbiter of what "material risk" means.[1]

There are three alternate reasons why David is entitled to a jury made up of citizens from a cross-section of society – and not a group of doctors – deciding his case. First, jurors can easily determine for themselves whether a reasonable person in David's shoes would have wanted to know about this particularized FDA "Black Box" warning. Second, David submits that "lack of informed consent" cases are ones of negligent non-disclosure, not medical negligence, thus not requiring[2] expert medical testimony in most circumstances. Third, if this Court is going to require expert medical testimony in all informed consent cases, the application of A.R.S. §§ 12-2603 and 12-2604 to the facts in this case unconstitutionally abrogates David's access to justice and right to seek compensation.

II. ORDINARY PERSONS DO NOT NEED MEDICAL EXPERTS TO DECIDE THE FACT ISSUES DAVID PRESENTS

The question presented in this section is whether jurors of ordinary intelligence can determine, without medical experts, whether Dr. Art should have told David about the particularized the Black Box warnings at issue.

[1] Any concern about "frivolous" claims can be handled by Rules 11, 12, and 56 – just like any other lawsuit.

[2] Although expert testimony may be admissible.

Expert testimony is not necessary where, as here, the acts complained of are something that unskilled persons of ordinary intelligence are able to understand. (*See* Response to Petition for Review, filed on September 13, 2023, at pp. 4-6). Page 13 of David's Reply Brief (filed on April 29, 2022) would be an easy PowerPoint slide (or two) for the jury to follow. The FDA warnings for Cipro say:

- "The risk of … tendon rupture is increased in patients over 60 [and] in patients taking corticosteroid drugs," and
- "Geriatric patients [over 60] are at an increased risk for developing severe tendon disorders…. This risk is further increased in patients receiving concomitant corticosteroid therapy," and
- "Caution should be used when prescribing CIPRO to elderly patients especially those on corticosteroids," and
- "Patients should be advised of this potential adverse reaction …"

As this Court is aware, David was over 60 and using corticosteroids when Dr. Art prescribed him Cipro; David further alleges (in an affidavit) that Dr. Art never gave him this warning.

Of the potential adverse consequences of Cipro, tendon rupture is the worst. Dr. Art performed a non-essential, elective procedure to reduce David's symptoms of a benign enlarged prostate. If David had been informed that Dr. Art's choice of post-surgical antibiotic presented him with a risk (much less a high risk) of tendon

rupture, then David would have been able to make an informed choice between (*i*) waking often in the middle of the night to urinate or (*ii*) potentially spending the rest of his waking hours in leg, arm, and back braces.[3]

The Hospital Amicus brief supporting Dr. Art's Petition for Review throws up a straw-man argument suggesting that David argues that the FDA warnings conclusively establish the standard of care. (*See* Hospital Amicus Brief at p. 10). However, David is not arguing that he should have been granted Rule 56 relief on liability given these warnings. One can imagine any number of scenarios in which violation of a regulation would be required to render aid. For example, law enforcement officers may violate red light traffic laws, so long as they do so with reasonable care. *See,* A.R.S. § 28-624. This is why the Court of Appeals held that Dr. Art was free to introduce testimony as to why he did not give David these Black Box warnings. (*See* Memorandum Decision at ¶ 12). Consistent with Arizona law, David merely suggests that the FDA warnings are admissible and that the jury need not have specialized medical training to be able to determine whether they were material to David's condition.

Similarly, the Hospitals' concern about a chilling effect on off-label uses is unfounded. (*See*, Hospital Amicus Brief at p. 14). Certainly, if a doctor is prescribing

[3] Or, if medically indicated, David could have been given the option of a different antibiotic that did not carry a risk of tendon rupture.

a drug for something other than that which the FDA has approved, the doctor should disclose that to his patient. The Amici cannot seriously be arguing that doctors should not be required to inform their patients they are prescribing drugs for uses not approved by the FDA.

Cipro is a broad-spectrum antibiotic – with a broad spectrum of both desirable and undesirable consequences. Certainly, David did not want to suffer a post-surgical infection, but he also would never volunteer to suffer a series of ruptured tendons throughout his body. David was entitled to be informed of that potential outcome, and he was certainly entitled to be informed of his exponentially increased risk of that outcome given his medical history – at least the FDA thinks that Dr. Art should have told David. Jurors of average intelligence can certainly decide this case for themselves.

III. PATIENTS SHOULD BE THE ONES TELLING DOCTORS WHAT PATIENTS BELIEVE ARE MATERIAL RISKS

The question presented in this section is whether a group of doctors can decide what they think patients should know without input from the patients they are treating.

Again – and to cut off any doomsday, slippery slope arguments – David speaks only of material risks. Suffering a headache after undergoing a life-saving intervention is not a material risk that should have been disclosed. Similarly, a small risk of serious injury from an emergency procedure designed to prevent certain death

is not material. David submits that tendon rupture, especially compared to the elective, non-essential procedure at issue, is a material risk of ingesting Cipro.

Defendants and the Hospital Amicus rely on *Duncan v. Scottsdale Medical Imaging, Ltd.*, 205 Ariz. 306, 310, ¶ 13 (2003), for the proposition that a claim for "lack of informed consent" is a medical negligence case and that the "'parameters of the required disclosure for any particular [informed consent] case [is] to be established by expert testimony.'" (citing a footnote from *Hales v. Pittman*, 118 Ariz. 305, 311, n. 4 (1978) (*citing Cobbs v. Grant*, 502 P.2d 1 (1972)). This holding in *Duncan* is *dictum*,[4] and the footnote cited to by *Duncan* from *Hales* is problematic in that the *Hales* footnote failed to properly cite the case to which it cited – the California case of *Cobbs v. Grant*, 502 P.2d 1 (Cal.1972). Paragraph 13 of *Duncan* is therefore dictum based on a footnote in *Hales* that mis-cited the source, *Cobbs*.

Duncan, citing to *Cobbs*, differentiates between (1) battery (intentional tort) cases in which the doctor performed a procedure without consent (or outside of the consent) and (2) negligence where the doctor performs a procedure or provides treatment but "failed to meet his due care duty to disclose pertinent information." *Duncan* at ¶ 11 (*citing Cobbs*, 502 P.2d at 8).

[4] *Duncan* decided that the case before it presented a case of battery, not negligence. *Id*. at ¶ 14. Therefore, discussion of the evidence required in a negligence case was unnecessary to the holding.

Cobbs, citing to *Canterbury v. Spence*, 464 F.2d 772, 786 (D.C.Cir.1972), holds that the test as to whether information should be provided is the information's "materiality to the patient's decision." *Cobbs*, 502 P.2d at 11. *Cobbs* holds that allowing the medical community alone to decide that which should be disclosed (as opposed to the patients receiving the treatment) would vest the doctors with "virtual absolute discretion," and such discretion "is irreconcilable with the basic right of the patient to make the ultimate informed decision." *Id*. at 10. The "ultimate decision" is a "**nonmedical** judgment reserved to the patient alone." *Id*. (emphasis added). Indeed, *Cobbs* is entirely at odds with both Dr. Art and the Hospital Amici.

Cobbs, endorsed in numerous reported Arizona decisions, holds:

> Even if there can be said to be a medical community standard as to the disclosure requirement for any prescribed treatment, it appears so nebulous that doctors become, in effect, vested with virtual absolute discretion. (See Note, *Physicians and Surgeons* (1962) 75 Harv.L.Rev. 1445; Waltz and Scheuneman, *Informed Consent to Therapy* (1970) 64 Nw.U.L.Rev. 628.) The court in *Canterbury v. Spence*, supra, 464 F.2d 772, 784, bluntly observed: 'Nor can we ignore the fact that to bind the disclosure obligation to medical usage is to arrogate the decision on revelation to the physician alone. Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.' ***Unlimited discretion in the physician is irreconcilable with the basic right of the patient to make the ultimate informed decision regarding the course of treatment to which he knowledgeably consents to be subjected***.

Cobbs v. Grant, 502 P.2d 1, 10 (1972) (emphasis added)

Canterbury rejected the notion that custom and practice among a medical community should control what ought to be disclosed to the patient; rather, "Any definition of scope [of disclosure] in terms of purely **a professional standard is at odds with the patient's prerogative** to decide on the projected therapy himself." *Canterbury*, 464 F.2d at 786 (emphasis added). *Canterbury* further holds, "Respect for the patient's right of self-determination … demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves." *Id*. at 784. Both *Cobbs* and *Canterbury* hold that requiring medical expert testimony in all informed consent lawsuits would necessarily remove a patient's say in the matter. To disagree with *Cobbs* and *Canterbury* – and to find against David Francisco – would be a public policy edict declaring a physician's discretion is superior to, and takes precedence over, a patient's free will.

The Arizona Trial Lawyers Amicus Brief filed with the Court of Appeals, citing to Professor Dobbs and many others, refers to this as a "'patient-oriented' materiality standard." (*See* Amicus Brief at 8). This patient-oriented standard is in line with the AMA and good public policy.

The AMA recognizes the problems with allowing the community of doctors to set the standard of disclosure. *See*, Murray, Bryan, AMA Journal of Ethics, *Informed Consent: What Must a Physician Disclose to a Patient?* 2012;14(7):563-566 (2012). The "community disclosure" standard "creates an incentive for

physicians to protect themselves by collectively limiting the standard disclosure, which is not in the patients' best interests." (https://journalofethics.ama-assn.org/article/informed-consent-what-must-physician-disclose-patient/2012-07; *see also*, Appendix to Supplemental Brief at Exhibit 1). This is the long recognized "Conspiracy of Silence" discussed more thoroughly in David's Opening Brief at pp. 19, 23, 30, 35-37. In this lawsuit, the FDA issued its most dire warning based on years of data. (*See* Opening Brief at pp. 26-27). Therefore, under a "patient-oriented materiality standard," a reasonable jury could find in David's favor without the need of any expert testimony.

IV. ALLOWING UROLOGISTS TO BE THE SOLE ARBITERS OF THE MATERIALITY OF RISKS IS UNCONSTITUTIONAL AS APPLIED TO THE FACTS OF THIS CASE

The question presented in this section is whether urologists in the United States can set a standard of care and insulate themselves from liability by simply ignoring the mounds of available scientific evidence.

Pharmacological professionals from around the globe would have wanted David to be warned about the risks of Cipro. (*See* Appendix to Opening Brief at Exhibits 1 through 7).[5] Further, Cipro prescriptions by urologists is particularly

[5] In addition to the materials previously cited, in 2023 the European Medicines Agency issued this warning: https://www.ema.europa.eu/en/news/fluoroquinolone-antibiotics-reminder-measures-reduce-risk-long-lasting-disabling-and-potentially-irreversible-side-effects (*see also*, Appendix to Supplemental Brief at Exhibit 2). As of 2021, Australia restricts use of drugs from the same family as Cipro "to infections

important because of the age of urology patients; a 2021 survey indicated that the median age of all UroLift patients is 69 years old, and only 3.7% are below the age of 50. (*See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8028737/; *see also*, Appendix to Supplemental Brief at Exhibit 4).

The Multidisciplinary Digital Publishing Institute provides open access journals and performed a retrospective study from India on antibiotics from the fluoroquinolone family (such as Cipro). The findings include: (1) patients taking fluoroquinolones had double the adverse health effects as patients taking no antibiotic treatment (8.5% compared to 4.1%); (2) a higher incidence rate of adverse health reactions related to flouroquinolones than other antibiotics; (3) that flouroquinolones "are not safe compared to other antibiotics; and (4) "the use of FQs [flouroquinolones] ***should be limited to conditions where no other alternatives are available.***" (emphasis added). (*See* Exhibit 5 to Appendix to Supplemental Brief, at p. 1, "Abstract").

Against this mountain of evidence, however, urologists in America are told to give Cipro to every patient who undergoes a UroLift surgical procedure designed to reduce the incidences of waking in the night to urinate. Discovery will bear out why

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resistant to all other recommended drugs." https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8542490/ (*see also*, Appendix to Supplemental Brief at Exhibit 3). These are in addition to the previously cited warnings from the European Urologists, the Canadian Urologists, the FDA, and the National Center for Biotechnology Information previously cited.

Dr. Art prescribed Cipro without giving David a warning, and the jury will be able to hear all that evidence. However, application of A.R.S. §§ 12-2603 and 12-2604 to the facts of this case would unconstitutionally abrogate David's ability to seek recourse by preventing David from presenting evidence to the jury from those scientists around the world who are, in fact, the leading experts on Cipro. (*See* Opening Brief at pp. 29-37).

V. CONCLUSION

All the legal arguments presented by both sides sit atop a crucially-important, and very pertinent, public policy decision – *i.e.*, do the patients get a say in what they are told about pharmaceuticals? If the answer is "no," then Dr. Art wins this appeal, and a small group of surgeons can decide what pharmacological information is disseminated to their patients regardless of what the rest of the scientific community says.

RESPECTFULLY SUBMITTED this 2nd day of February, 2024.

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