1

David Francisco, et al., Plain tiffs/Appellants,
v.
Affiliated Urologists Ltd, et al.
Defendants/Appellees.

No. CV-23-0152-PR

Supreme Court of Arizona

August 16, 2024

Appeal from the Superior Court in Maricopa County The Honorable James D. Smith, Judge (Ret.) No. CV2020-010470

Memorandum Decision of the Court of Appeals, Division One No. 1 CA-CV 21-0701 Filed May 23, 2023 **VACATED**

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2

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JUSTICE MONTGOMERY authored the opinion of the Court, in which CHIEF JUSTICE TIMMER, VICE CHIEF JUSTICE LOPEZ and JUSTICES BRUTINEL, BEENE, and BERCH (RETIRED) joined. [*]

MONTGOMERY, JUSTICE

¶1 To prevail on a negligence claim concerning medical malpractice, a plaintiff must prove that the defendant doctor failed to meet the standard of care required of a health care professional in the doctor's field of practice. Pursuant to A.R.S. § 12-2603, a plaintiff is required to certify whether expert testimony is necessary to establish the standard of care and, if it is, serve a preliminary expert opinion affidavit. In this case, we consider whether a warning required by the Food and Drug Administration ("FDA") regarding the use of prescription medication can serve to establish the standard of care and obviate the need for expert testimony. Given the facts of this case, we hold that Arizona law does not permit such warnings to substitute for the required testimony and independently establish the standard of care.

I. FACTUAL AND PROCEDURAL BACKGROUND[1]

¶2 Following his retirement as an endodontist in 2016, David Francisco moved to Sedona with his wife. In the summer of 2018, he sought treatment from Kevin Art, M.D. ("Dr. Art"), an employee of Affiliated Urologists, Ltd. (collectively, the "Practice"). Aside from the need for

3

treatment, Francisco was a very fit and physically active sixty-six-year-old. His medical history included approximately forty years of taking corticosteroids, an allergy to the antibiotic doxycycline, and hypothyroidism. In August, Dr. Art performed a urological procedure on Francisco and prescribed the antibiotic Ciproflaxin ("Cipro") to prevent post-surgery infection. Dr. Art did not discuss the use of Cipro with Francisco before prescribing it.

¶3 The packaging for Cipro contained an insert providing information about the drug and its use, which included an FDA "black box" warning. A black box warning is the gravest warning the FDA can issue and warns of serious

adverse consequences that can result from taking a particular medication. The warning here advised that Cipro may cause "disabling and potentially irreversible serious adverse reactions," including tendinitis and tendon rupture, peripheral neuropathy, and central nervous effects. Additionally, the warning included an admonition to "[s]ee full prescribing information for complete boxed warning," which indicated that geriatric patients with a history of corticosteroid use were at an increased risk of experiencing complications from taking Cipro, including ruptured tendons. The insert separately instructed prescribing physicians to warn such patients of the noted risks and discontinue using Cipro if any symptoms of tendinitis or tendon rupture occur.

¶4 Two days after beginning to take Cipro, Francisco reported symptoms consistent with an allergic reaction to the drug, including tingling and itching sensations and mild joint pain. After taking five of the six prescribed tablets, his symptoms worsened. Eventually, Francisco suffered numerous ruptured tendons throughout his body, and he suffered significant pain in his ankles, knees, hips, elbows, and right shoulder. The symptoms intensified over several months, and he eventually developed peripheral neuropathy, a form of nerve damage, in his limbs. Two expert witnesses retained by Francisco determined that his condition was consistent with Cipro toxicity.

¶5 Francisco and his wife sued the Practice, alleging that he suffered possibly permanent injuries due to taking Cipro and that if he had known of the black box warnings, he would have requested a different antibiotic or refused the urological procedure. The Franciscos additionally alleged that Dr. Art negligently failed to warn Francisco of any risks

4

associated with taking Cipro.

¶6 Along with their complaint, the Franciscos filed a certification regarding the need for expert testimony, citing A.R.S. §§ 12-2603 and -2604, the latter statute establishing the qualifications of expert witnesses. However, the certification did not address whether expert testimony was needed regarding the standard of care as it related to their claim against Dr. Art. Instead, it "certifie[d] that expert testimony will be necessary for *Defendants* to provide the applicable standard of care and liability as to [the] Defendants in the . . . matter." (Emphasis added.)[2]

¶7 The Franciscos thereafter sought partial summary judgment regarding Dr. Art's alleged breach of the standard of care based on the black box warnings and Francisco's medical history. In turn, the Practice filed a motion to dismiss, arguing that the Franciscos were required to establish the standard of care for their claims with expert medical testimony. The Franciscos objected to the Practice's motion to dismiss because the Practice had not first sought an order to determine whether expert testimony was necessary. *See* § 12-2603(D) (providing that a "health care professional . . . may apply by motion to the court for an order requiring the claimant . . . to obtain and serve a preliminary expert opinion affidavit"). Ultimately, the superior court struck the pending motions and ordered the Practice to file a motion pursuant to § 12-2603(D).

¶8 In response to the Practice's § 12-2603(D) motion, the Franciscos argued that an expert opinion affidavit was not necessary for two main reasons. First, the jury did not need expert testimony to understand the FDA warnings. Second, a jury was likewise capable, without expert testimony, of determining if information in the FDA warnings would have been material to Francisco in deciding whether to take Cipro.

¶9 The Franciscos further asserted that, if ordered by the court to provide an expert affidavit, they would not be able to comply because guidance provided by the American Urological Association ("AUA") to its

5

physician members authorized the use of Cipro for elderly patients with a history of

corticosteroid use. Therefore, according to the Franciscos, the guidance made it impossible for them to find a board-certified urologist willing to testify that prescribing Cipro to Francisco under these circumstances violated the standard of care. In support of this conclusion, the Franciscos' counsel stated that he had contacted two potential experts who said they would not testify that Dr. Art acted below the standard of care. The Franciscos consequently argued that §§ 12-2603 and -2604 were unconstitutional as applied to them under the anti-abrogation clause of Arizona's Constitution. *See* Ariz. Const. art. 18, § 6.

¶10 The superior court granted the Practice's motion to compel. The Franciscos filed a motion for reconsideration, which the court denied. The Practice then moved to dismiss the case pursuant to § 12-2603(F), which the court granted, dismissing the case with prejudice.[3]

¶11 The court of appeals reversed the superior court's judgment and remanded for further proceedings. *Francisco v. Affiliated Urologists Ltd*, No. 1 CA-CV 21-0701, 2023 WL 3589654, at *3 ¶ 13 (Ariz. App. May 23, 2023) (mem. decision). The court first rejected the Franciscos' argument that their claim was not a medical malpractice claim and that the expert testimony requirements of § 12-2603 did not apply. *Id.* at *2 ¶¶ 6-7. Next, the court considered whether, in light of Cipro's black box warning and Francisco's medical history, expert testimony was required to prove that Dr. Art's failure to warn Francisco of Cipro's risks fell below the standard of care. *Id.* ¶ 8. The court reasoned that although expert testimony is *usually* required to establish the medical profession's standard to inform patients of risks, no legal rule *requires* expert testimony in every case. *Id.* Rather, a duty to warn "depends 'upon the circumstances of the particular case and upon the general practice followed by the medical profession.'" *Id.* at *3 ¶ 10 (quoting *Riedisser v. Nelson*, 111 Ariz. 542, 544-45 (1975)).

¶12 Accordingly, 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." *Id.* ¶ 11. The court then further concluded that evaluating whether the FDA instructed physicians to give a specific warning, and whether a physician gave the specific warning, does not require expert testimony. *Id.* ¶ 12. Thus, § 12-2603 did not mandate dismissal of the case. *Id.*

¶13 We granted review because whether an FDA black box warning can substitute for expert testimony to establish the standard of care under Arizona law in medical malpractice cases is an issue of statewide importance and likely to recur. We have jurisdiction pursuant to article 6, section 5(3) of the Arizona Constitution.

II. DISCUSSION

A. Standard Of Review

¶14 Before turning to the arguments presented, we first address the applicable standard of review. Although nearly all appellate courts that have considered a trial court's dismissal for failure to comply with § 12-2603's preliminary expert affidavit requirements have concluded that the standard for review is de novo, the reasons have varied. Some courts have relied on the fact that a motion to dismiss is subject to de novo review. *See, e.g.*, *Romero v. Hasan*, 241 Ariz. 385, 386 ¶ 6 (App. 2017). Others have focused on the application of § 12-2603's statutory requirements to conclude that statutory construction calls for a de novo review. *See, e.g.*, *Gorney v. Meaney*, 214 Ariz. 226, 228 ¶ 4 (App. 2007); *Sanchez v. Old Pueblo Anesthesia, P.C.*, 218 Ariz. 317, 319 ¶ 5 (App. 2008), *disapproved on other grounds by Rasor v. Nw. Hosp., LLC*, 243 Ariz. 160 ¶¶ 17-19 (2017). Finally, one court engaged in a de novo review after concluding that the failure to comply with § 12-2603 is a pleading failure. *See Boswell v. Fintelmann*, 242 Ariz. 52, 54 ¶ 5 (App. 2017). Only one case involving a failure to comply with

a preliminary expert affidavit requirement has applied an abuse of discretion standard. *See Warner v. Sw. Desert Images, LLC*, 218 Ariz. 121, 128 ¶ 14 (App. 2008) (concluding that the same standard that applies to a trial court's exercise of discretion in admitting expert testimony should apply to a decision whether expert testimony is required pursuant to § 12-2602, which deals generally with claims against licensed professionals).

7

¶15 After we heard oral argument in this case, the court of appeals considered the standard of review issue in *Fong v. City of Phoenix*, No. 1 CA-CV 23-0520, 2024 WL 2855191 (Ariz. App. June 6, 2024). The case involved the dismissal of a plaintiff's claim for failing to present expert testimony regarding the standard of care, albeit in the context of § 12-2602. *Id.* at *2 ¶ 8. In concluding that a de novo standard of review applied, the court addressed *Warner* and declined to follow it for two reasons.

¶16 First, the court noted that *Warner's* discussion of the abuse of discretion standard of review concerning expert testimony was unnecessary. *Id.* ¶ 11. The basis for the appellate court's reversal of the trial court's judgment in *Warner* was the trial court's failure to adhere to statutory procedural requirements. *Id.* The case did not involve a determination of whether expert testimony was required in the first place. *Id.* Therefore, the discussion of the standard of review was dictum and non-binding. *Id.*

¶17 Second, the court of appeals concluded that "*Warner* erroneously conflated the standard of review that applies to a determination that expert evidence is admissible with the standard that applies to a determination that a claim is not viable without expert support." *Id.* at *3 ¶ 12. Thus, *Warner's* reliance on this Court's discussion in *State v. Mosley*, 119 Ariz. 393, 400 (1978), regarding the discretion a trial court has in determining whether to allow expert testimony at trial was misplaced. *Id.* We agree with the distinction made by the *Fong* court that "whether expert testimony is *admissible* and whether it is *required* 'are meaningfully different questions.'" *Id.* ¶ 13 (quoting *KS Condo, LLC v. Fairfax Vill. Condo. VII*, 302 A.3d 503, 508 n.1 (D.C. 2023)).

¶18 With respect to the former question, the *Fong* court noted that "the admissibility of expert testimony is reviewed for abuse of discretion." *Id.* However, with respect to the latter question, the court observed that "the majority of courts that have addressed the issue have held that whether expert testimony is required to prove a plaintiff's claim is a question of law that is reviewed [de novo]." *Id.* ¶ 15 (collecting cases). Accordingly, the court held that "whether a plaintiff's failure to present expert testimony is fatal to [a] claim is a question of law that is reviewed [de novo]." *Id.* at *4 ¶ 17. We concur and hold that, because determining whether evidence, without expert testimony, can establish the standard of care in a medical

8

malpractice action is a question of law, dismissal of a case based on the failure to comply with § 12-2603 is subject to de novo review.

B. Nature Of The Franciscos' Claim

¶19 We next turn to the Franciscos' initial argument that the statutory requirements for expert testimony do not apply to their claim against Dr. Art. The Franciscos argue that this is an "informed consent" case involving a "negligent disclosure" claim and not a "medical negligence" or medical malpractice claim. Therefore, according to the Franciscos, because the expert testimony requirements of §§ 12-2603 and -2604 only apply to medical malpractice claims, they do not apply here. The Practice argues that a lack of informed consent case falls within the definition of a medical malpractice action, which requires expert testimony to establish the standard of care.[4]

¶20 We begin by considering the text of the relevant statutes. "Absent ambiguity, we interpret statutes according to their plain language." *In re Drummond*, 543 P.3d 1022,

1025 ¶ 5 (Ariz. 2024).

¶21 Section 12-2603(A) addresses the need for preliminary expert opinion testimony to prove the standard of care in instances where "a claim against a health care professional is asserted in a civil action." Section 12-2603(H) defines a "claim" as "a legal cause of action against a health care professional under [A.R.S.] §§ 12-561 through 12-563." Section 12-561(2) defines a "[m]edical malpractice action" as "an action for injury . . . against a licensed health care provider based upon such provider's alleged negligence . . . in the rendering of health care . . . or other health-related services." Section 12-2604(A) establishes the requirements for expert testimony "[i]n an action alleging medical malpractice."

9

¶22 The Franciscos allege that Dr. Art failed to provide sufficient information regarding the risks of Cipro. The claim therefore falls within the class of "true 'informed consent' claims, i.e., those involving the doctor's obligation to provide information," which "must be brought as negligence actions." *See Duncan v. Scottsdale Med. Imaging, Ltd.*, 205 Ariz. 306, 310 ¶ 13 (2003). But even if we characterized the claim as a "negligent disclosure" claim, as the Franciscos assert, it is still based on a health care provider's alleged negligence in rendering health care or health-related services, which falls squarely within the definition of a medical malpractice action. *See* § 12-561(2); *see also Jeter v. Mayo Clinic Ariz.*, 211 Ariz. 386, 403-05 ¶¶ 76-84 (App. 2005) (explaining medical malpractice requires negligent acts in "the rendering of medical or health care-related services" and "depends on a number of factors, including whether the wrong involved the exercise of professional judgment in the treatment of the patient by health care providers"). We conclude that the Franciscos' claim is a medical malpractice claim and, therefore, the provisions of §§ 12-2603 and -2604 apply.

¶23 Our interpretation of § 12-2603 as requiring expert testimony in lack of informed consent cases is consistent with this Court's previous reading of the statute. *See, e.g.*, *Seisinger v. Siebel*, 220 Ariz. 85, 94 ¶ 33, 95 ¶ 39 (2009) ("Arizona courts have long held that the standard of care normally must be established by expert medical testimony."); *Duncan*, 205 Ariz. at 310 ¶ 13 ("[T]he 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." (cleaned up) (quoting *Hales v. Pittman*, 118 Ariz. 305, 311 n.4 (1978))); *Riedisser*, 111 Ariz. at 544-45 (explaining that "the custom of the medical profession to warn must be established by expert medical testimony" but it "depends upon the circumstances of the particular case") (citation omitted).

C. Exception To Requirement For Expert Testimony

¶24 The Franciscos alternatively argue that "[t]his lawsuit is simply one of those rare cases" in which expert testimony to establish the standard of care is not required. Specifically, they assert that Dr. Art's failure to warn Francisco of Cipro's potential adverse effects described in the black box warning is something "that unskilled persons of ordinary intelligence are able to understand." Although the Practice does not

10

dispute that there are cases in which expert testimony is not required, it argues that this is not such a case. Furthermore, the Practice argues that because the degree of disclosure required under these circumstances involves the exercise of medical judgment, this case is distinguishable from those where expert testimony was not required to establish the standard of care.

¶25 Assuming that the black box warning for Cipro is admissible, an issue not explicitly before us, the pertinent question is whether the warning may be used instead of testimony from an expert witness to establish the standard of care. The only exception to the statutory

requirement for expert testimony lies within the common-law doctrine of res ipsa loquitur. *See Sanchez*, 218 Ariz. at 321 ¶ 14 (noting that "neither [§§ 12-2603 nor -2604] expressly requires expert testimony in those res ipsa cases where none was previously required"); *see also Seisinger*, 220 Ariz. at 94 ¶ 33 n.8 ("Section 12-2604(A) does not purport to abolish the common-law res ipsa loquitur doctrine. Rather, the statute applies only to those cases in which expert testimony is otherwise required.").

¶26 The res ipsa loquitur doctrine applies where "the negligence is so grossly apparent that a layman would have no difficulty in recognizing it." *Riedisser*, 111 Ariz. at 544. In such circumstances, no expert testimony is generally required. *Id.* In other words, courts do not require expert testimony "where the lack of skill or care is such as to be within the comprehension and common knowledge of laymen to understand and judge it." *Faris v. Drs. Hosp., Inc.*, 18 Ariz.App. 264, 270 (1972); *see also Seisinger*, 220 Ariz. at 94 ¶ 33.

¶27 Circumstances constituting grossly apparent negligence include an instance where "a cloth sack approximately ten inches wide by sixteen or eighteen inches long" was removed from a patient's abdomen after a previous abdominal surgery. *Tiller v. Von Pohle*, 72 Ariz. 11, 14-15 (1951). Another instance arose from a physician leaving steel sutures in a patient for months after an operation and ignoring her complaints regarding the pain. *Revels v. Pohle*, 101 Ariz. 208, 208-11 (1966) (stating further that "expert testimony is not required where 'the negligence is so grossly apparent that a layman would have no difficulty in recognizing it'" (quoting *Boyce v. Brown*, 51 Ariz. 416, 421 (1938))). In yet another case, a six-inch metal clamp was left in a patient's abdomen following surgery for

gallstones. *Landgraff v. Wagner*, 26 Ariz.App. 49, 52 (1976). The *Landgraff* court had no trouble concluding that "[t]he error [was] so self-evident that a jury [could] determine the question of negligence without reliance upon the opinion of an expert." *Id.* at 57*; see also Carranza v. Tucson Med. Ctr.*, 135 Ariz. 490, 491-92 (App. 1983) (concluding expert testimony was not required where a child suffered a burn on her leg after heart surgery). The facts of this case, though, are very different.

¶28 In prescribing Cipro, Dr. Art had to evaluate the concomitant risks and benefits of prescribing the drug to determine what information to disclose. This evaluation considered, among other things, Francisco's health, which included a history of hypothyroidism, corticosteroid use, and allergies to other antibiotics. Although the black box warning indicated significant risks for older patients with a history of corticosteroid use, it could not account for Francisco's individual situation, including his presentation as a vigorous and active older adult.

¶29 In such a circumstance, "only health-care professionals are 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." *Watts v. Medicis Pharm. Corp.*, 239 Ariz. 19, 24 ¶ 12 (2016) (quoting Restatement (Third) of Torts: Prod. Liab. § 6 cmt. b (Am. L. Inst. 1998)); *see also Riedesser*, 111 Ariz. at 545 ("There is, of course, no clear rule as to what information must be disclosed in what circumstances; medical judgment is primarily involved."); *McGrady v. Wright*, 151 Ariz. 534, 537 (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."). Therefore, "we leave the precise parameters of the required disclosure for any particular case to be established by expert testimony in accordance with the applicable standard of medical care." *Hales*, 118 Ariz. at 311 n.4; *see also Sampson v. Surgery Ctr. of Peoria, LLC*, 251 Ariz. 308, 312 ¶ 19 (2021) (stating that "[i]n a case where the standard of care or the cause of death is disputed on a matter requiring medical knowledge to resolve, it is difficult, if not impossible, to imagine a situation where lay jurors, untrained in medicine or medical

procedure, could properly determine liability absent expert guidance").

¶30 Consequently, a layperson would not know, as a matter of "common knowledge," whether Dr. Art's alleged failure to warn Francisco

12

of certain risks associated with Cipro constitutes a departure from the relevant standard of care. Therefore, reliance on the res ipsa loquitur doctrine under these facts is misplaced. When the standard of care consists of a duty to warn that requires medical judgment, "the custom of the medical profession to warn must be established by expert medical testimony." *Riedisser*, 111 Ariz. at 545 (citation omitted).

¶31 Likewise, the Franciscos' reliance on *Rodriguez v. Jackson*, 118 Ariz. 13 (App. 1977), is misplaced. The Franciscos cite *Rodriguez* for the proposition that "FDA warnings are admissible evidence that a jury may consider when determining the standard of care, but the ultimate decision remains with the jury." While it may be true that, in appropriate cases, FDA warnings may be admissible, the *Rodriguez* court concluded that a manual for "The Tuberculosis Control Program in Arizona, March 1969," was insufficient to establish the standard of care. *Id*. at 17-18. The court further noted that the plaintiff had "presented no testimony by a medical doctor as to the custom of the medical profession relative to these warnings." *Id*. at 18. In short, although FDA warnings may be admissible in conjunction with expert testimony, they are not conclusive on their own. *See id.* ("While the package insert is admissible into evidence, it does not establish conclusive evidence of the standard or accepted practice in the use of the drug by physicians and surgeons, nor that a departure from such directions is negligence."); *see also Ramon v. Farr*, 770 P.2d 131, 135 (Utah 1989) ("[W]e think the better rule is that manufacturers' inserts and parallel P.D.R. entries do not by themselves set the standard of care, even as a prima facie matter. A manufacturer's recommendations are, however, some evidence that the finder of fact may consider along with expert testimony on the standard of care."), *overruled in part on other grounds by Miller v. Utah Dept. of Transp.*, 285 P.3d 1208 (Utah 2012). Thus, aside from issues regarding admissibility, an FDA warning is not competent evidence, on its own, to establish the standard of care in an Arizona medical malpractice case.[5]

13

¶32 Other jurisdictions have also concluded that package-insert warnings are insufficient to establish the standard of care and we find their reasoning compelling. First, medication manufacturers write the warnings "for many reasons including compliance with FDA requirements, advertisement, the provision of useful information to physicians, and an attempt to limit the manufacturer's liability." *Morlino v. Med. Ctr. of Ocean Cnty.*, 706 A.2d 721, 729 (N.J. 1998); *see also Spensieri v. Lasky*, 723 N.E.2d 544, 548 (N.Y. 1999); *Ramon*, 770 P.2d at 135-36 ("The American Medical Association . . . has repeatedly alleged that inserts are an inadequate standard for medical practice, pointing to the inconsistent purposes served by the document[s] - advertising for the manufacturer, regulation by the government, and information for the doctor-and to the poor quality of past inserts." (citation omitted)).

¶33 Second, the FDA has previously stated, in a rulemaking proposal, that "labeling is not intended either to preclude the physician from using his best judgment in the interest of the patient, or to impose liability if he does not follow the package insert." *Legal Status of Approved Labeling for Prescription Drugs; Prescribing for Uses Unapproved by the Food and Drug Administration*, 37 Fed.Reg. 16503, 16504 (proposed Aug. 15, 1972); *see also Labeling Requirements for Systemic Antibacterial Drug Products Intended for Human Use*, 68 Fed.Reg. 6062, 6071 (same). It has even suggested that "off-label" practices "may . . . constitute a medically[-]recognized standard of care." *See United States v. Caronia*, 703 F.3d 149, 153 (2nd Cir. 2012) (second alteration in original) (quoting U.S. Food &Drug Admin., *Draft Guidance, Good Reprint Practices for the*

Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices 3 (2009)).

¶34 Third, "the FDA-required labeling . . . may not be easily understood by the jury without expert assistance because these materials are written for the medical profession, not the general public." *Richardson v. Miller*, 44 S.W.3d 1, 16 (Tenn. Ct. App. 2000); *see also Watts*, 239 Ariz. at 24 ¶ 13 (discussing premise for the learned intermediary doctrine and noting that "certain types of 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").

14

¶35 Furthermore, relying on FDA black box warnings as a substitute for expert testimony, as the Franciscos urge, may result in drug manufacturers and the FDA determining the standard of care for Arizona medical malpractice cases. *See Richardson*, 44 S.W.3d at 16; *Spensieri*, 723 N.E.2d at 548. This directly contravenes the requirement in Arizona law that the standard of care be determined by the custom of "the profession or class" to which the physician "belongs *within the state*." *See* § 12-563(1) (emphasis added); *see also Riedisser*, 111 Ariz. at 544 (recognizing that "in [medical] malpractice, the duty of disclosure of the risks by the physician . . . *is measured by the usual practices of the medical profession*" (emphasis added)).

¶36 Given all the foregoing, we decline to equate a failure to disclose a black box warning in a case involving medical judgment with incidents constituting grossly apparent negligence, thereby expanding the application of the res ipsa loquitur doctrine to excuse the statutory requirement for expert testimony pursuant to § 12-2603. We therefore conclude that expert witness testimony was necessary to establish the standard of care in this case. The trial court correctly dismissed the Franciscos' claim for failure to provide a preliminary expert opinion affidavit as required. The court of appeals erred in finding otherwise.

D. The Anti-Abrogation Clause

¶37 The Franciscos argue that §§ 12-2603 and -2604 violate the anti-abrogation clause of Arizona's Constitution as applied to them. *See* Ariz. Const. art. 18, § 6. Specifically, they argue that because board-certified urologists "refus[e] to comply with the FDA's warnings" and would be unwilling to testify against the AUA's guidance authorizing physicians to prescribe Cipro to patients like Francisco, requiring the expert testimony of a board-certified urologist prevents them from prosecuting this case and unconstitutionally abrogates the right to recover in this negligence action.

¶38 The Practice counters that the preliminary affidavit and expert qualification requirements in §§ 12-2603 and -2604, respectively, do not abrogate the Franciscos' right of action. The Practice maintains that the statutes were designed to help weed out frivolous cases before significant resources are wasted on fruitless litigation, and that here they are simply serving their intended purpose. *See Gorney*, 214 Ariz. at 229 ¶ 8. The

15

Practice concludes by asserting that "[i]t is not the statute that is preventing Plaintiffs from finding a qualified urologist to testify. It is the invalidity of their claim."

¶39 Article 18, section 6 of the Arizona Constitution states: "The right of action to recover damages for injuries shall never be abrogated . . . ." The provision prohibits the "abrogation of all common law actions for negligence," including medical malpractice. *See Baker v. Univ. Physicians Healthcare*, 231 Ariz. 379, 388 ¶ 34 (2013) (internal quotation mark omitted) (quoting *Cronin v. Sheldon*, 195 Ariz. 531, 538 ¶ 35 (1999)). However, the legislature may "regulate the cause of action for negligence so long as it leaves a claimant reasonable

alternatives or choices which will enable him or her to bring the action." *Id.* (quoting *Barrio v. San Manuel Div. Hosp. for Magma Copper Co.*, 143 Ariz. 101, 106 (1984)).

¶40 Sections 12-2603 and -2604 are part of a statutory framework intended "to curb frivolous medical malpractice lawsuits by imposing a stricter standard of pleading and setting deadlines for the early involvement of the plaintiff's expert witness." *Gorney*, 214 Ariz. at 229 ¶ 8. Section 12-2603 "defines specific tasks that must be completed by specific deadlines to prosecute claims against health care professionals, along with specific procedures whereby plaintiffs may obtain extensions of time and opportunities to cure deficiencies." *Passmore v. McCarver*, 242 Ariz. 288, 292 ¶ 9 (App. 2017). The record before us reflects that the Franciscos' counsel only contacted two experts to offer the requisite opinion. Furthermore, the record is unclear as to what aspects of Dr. Art's alleged negligence the experts were asked to offer an opinion about (whether *prescribing* Cipro was negligence or *the failure to warn* of Cipro's risks was negligence), and to what degree the AUA guidance may have affected their willingness to testify that Dr. Art acted negligently. Thus, the record does not support a conclusion that § 12-2603 prevented the Franciscos from securing the requisite affidavit.

¶41 We rejected a similar constitutional challenge to § 12-2604 in *Baker*, 231 Ariz. at 388 ¶¶ 36-37. There, the plaintiff argued that § 12-2604 violated the anti-abrogation clause because it limited the class of qualified experts to persons who are board certified in the same specialty as the defendant-physician, and the plaintiff could therefore not have his expert of choice who was not certified as required. *See id.* at 387 ¶ ¶ 31-32. This

16

Court held that "[a]lthough the statute might deny a plaintiff his expert of choice, the record [did] not show that [plaintiff] lack[ed] 'reasonable alternatives or choices which [would] enable him or her to bring the action.'" *Id.* at 388 ¶ 35 (quoting *Barrio*, 143 Ariz. at 106). Importantly, the Court explained that "[a]lthough plaintiffs might face greater difficulties in finding a qualified expert because of a smaller expert pool, § 12-2604 does not bar medical malpractice lawsuits or preclude plaintiffs from recovery in such actions." *Id.* ¶ 37. Accordingly, § 12-2604 permissibly regulated the plaintiff's right to bring a medical malpractice suit. *Id.* ¶ 35.

¶42 We acknowledge that, unlike in *Baker*, the Franciscos claim they cannot present *any* expert because no board-certified urologist will testify due to the guidance issued by the AUA. Nevertheless, given the previous discussion regarding the need for expert testimony concerning medical judgment, *see* Part II(C) ¶¶ 28-30, and our previous analysis and holding in *Baker*, we conclude that the provisions of §§ 12-2603 and -2604 constitute permissible regulation of medical negligence causes of action. Accordingly, we hold that §§ 12-2603 and -2604 do not violate the Arizona Constitution's anti-abrogation clause as applied to the Franciscos.

III. CONCLUSION

¶43 For the reasons stated, we vacate the court of appeals' memorandum decision and affirm the trial court's judgment.

17

BOLICK, J., concurring in part and dissenting in part:

¶44 I join the majority opinion except for Part II(C). I dissent from that portion of the opinion because I believe that the failure to follow the black box warning under the facts presented here presents a prima facie case of negligent failure to warn leading to a lack of informed consent, and therefore agree with the court of appeals that dismissal inappropriately deprived the Franciscos of their day in court.

¶45 Arizona Revised Statutes § 12-2603(A) requires a plaintiff in a case against a health care professional to certify "whether or not

expert opinion testimony is necessary to prove the health care professional's standard of care or liability." The statute does not provide a substantive standard for that determination. If a plaintiff certifies that expert opinion testimony is necessary, or if the court deems it necessary upon motion by the defendant, the plaintiff must serve a preliminary expert opinion affidavit. *See* § 12-2603(B), (D), (E). Subsection (C) provides a procedural option short of dismissal-an extension of time for compliance-but subsection (F) directs the court to dismiss the case without prejudice if the plaintiff fails to comply. Ultimately, A.R.S. § 12-563(1) establishes as a necessary element of proof in a negligence claim that "[t]he 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."

¶46 The statutes do not mandate a particular outcome in this case. Rather, it is the Court that has spelled out when a preliminary expert opinion affidavit is necessary to move a case forward. The majority's reasoning is not inconsistent with our precedents in this context, but the courts have repeatedly noted that the point of § 12-2603 is to curb frivolous lawsuits by imposing stricter standards of pleading and setting deadlines for the involvement of the plaintiff's expert witnesses. *See, e.g.*, *Rasor v. Nw. Hosp., LLC*, 243 Ariz. 160, 164-65 ¶ 22 (2017); *Rasor v. Nw. Hosp. LLC*, 244 Ariz. 423, 426-27 ¶ 13 (App. 2018). This case, on its face, is not frivolous. For the reasons below, I conclude that the rationale underlying our precedents supports allowing this case to proceed without expert testimony on the standard of care.

18

¶47 I agree with the majority that our decisions dictate that where medical judgment is required and the circumstances are beyond an ordinary layman's grasp, expert testimony is required. *See, e.g.*, *Sampson v. Surgery Ctr. of Peoria, LLC*, 251 Ariz. 308, 311 ¶ 16 (2021) (noting that "in most instances the applicable standard of care, and the probable consequences of failing to meet that standard, are beyond ordinary lay knowledge"). But as the majority points out, *supra* ¶¶ 25-26, neither our statutes nor case law eliminated the common law doctrine of res ipsa loquitor, which provides that no expert testimony is necessary where negligence is grossly apparent.

¶48 This appears to be a case of first impression. I agree with the majority that most of the copious, small-print warnings contained in prescription drug package inserts, which are drafted by drug companies and not subject to FDA approval, are inadequate to establish a standard of care. [6] But I am aware of no case determining whether a black box warning, mandated and approved by the FDA, may state a prima facie case in a failure to warn case. I believe that in this case, it should.

¶49 As the majority acknowledges, "[a] black box warning is the gravest warning the FDA can issue and warns of serious adverse consequences that can result from taking a particular medication." *Supra* ¶ 3. As the FDA's most significant cautionary statement, the black box warning appears in bold print at the beginning of the package insert under "Highlights of Prescribing Information," and then again under "Full Prescribing Information." Andrew T. Georgi, *The FDA Black Box Warning System: The Utmost in Drug and Patient Safety?* 7 (Sept. 27, 2010) (M.D. thesis, Yale University School of Medicine) (available at https://elischolar.library.yale.edu/cgi/viewcontent.cgi?article=1199&con text=ymtdl). It is issued only for "the most serious warnings necessary to ensure the safe use of the product." *Id.* (Citation omitted). It is based, among other things, on evidence of an adverse reaction that is serious in proportion to the potential benefit of using the drug, including life threatening or potentially disabling adverse reactions. *Id.* at 9; *see also* 21 C.F.R. § 201.57(c)(1) (providing that "[c]ertain . . . serious warnings,

19

particularly those that may lead to death or serious injury, may be required by the FDA to be presented in a box"). Unlike learned treatises, of

course, the black box warnings accompany all of the drugs for which they are mandated.

¶50 I agree with the majority that by mandating black box warnings for a particular medication, the FDA does not purport to preempt determinations regarding negligence or standard of care, which are matters of state law. *See supra* ¶¶ 33-35. But in the context of establishing an applicable standard of care, FDA black box warnings bear indicia of reliability and clarity such that expert testimony may be unnecessary for a plaintiff to move forward with his or her negligent failure to warn claim. *See City of Glendale v. Farmers Ins. Exch.*, 126 Ariz. 118, 120 (1980) (holding that "in order to avoid a directed verdict, the non-movant must establish a prima facie case," that is, "there must be evidence sufficient to justify, although not necessarily compel, an inference of liability").

¶51 I pause to note circumstances here that are particularly relevant. This case involves the negligent failure to warn of Cipro's dangers, which is precisely within the scope of the FDA's expertise and the exact purpose of the black box warnings. Relatedly, and in light of the fact that expert medical testimony here would necessarily have to be provided by a licensed health care professional in the same specialty as the defendant, *see* A.R.S. § 12-2604(A)(1), the black box warning pertains primarily to pharmacology, not urology; that is, it is a warning provided to *all* physicians who might prescribe the medication, so that a urologist would not possess any specialized knowledge pertaining to the medication at issue. To the extent that specific circumstances pertaining either to the particular patient or procedure here would negate the need to heed the black box warning, the defendant would be free, as the court of appeals pointed out, to present expert testimony to that effect. *Francisco v. Affiliated Urologists Ltd*, No. 1 CA-CV 21-0701, 2023 WL 3589654, at *3 ¶ 12 (Ariz. App. May 23, 2023) (mem. decision).

¶52 At the same time, although black box warnings are addressed to medical professionals, the one at issue here is clearly written and intelligible to a layperson in a way that would flash bright danger lights. As the majority recites, *supra* ¶ 3, the warning stated "that Cipro may cause 'disabling and potentially irreversible serious adverse reactions,' including

tendinitis and tendon rupture, peripheral neuropathy, and central nervous effects." It referred to the full prescribing information for a complete warning, "which indicated that geriatric patients with a history of corticosteroid use were at an increased risk of experiencing complications . . . including ruptured tendons." *Supra* ¶ 3. The insert "instructed prescribing physicians to warn such patients of the noted risks and [to] discontinue using Cipro if any symptoms of tendinitis or tendon rupture occur." *Supra* ¶ 3. The warning thus identified not only the risks but also the most at-risk patients, and instructed physicians to warn such patients of the risks *and* to discontinue using the medication if the symptoms occurred. Dr. Art failed to give any Cipro-related warning to Francisco.

¶53 In my view, this objective instruction, directed to *all* prescribing physicians by the federal agency that monitors and regulates prescription drugs, is at least sufficient to require the defendants to explain why Dr. Art did not provide such a warning, or why it was reasonable to not do so. And, as the majority observes, *supra* ¶ 4, Francisco took the prescribed medication, developed symptoms, and later suffered ruptured tendons and peripheral neuropathy (nerve damage) that, according to expert witnesses, were consistent with Cipro toxicity.

¶54 Defendants articulate numerous reasons why it was appropriate for Dr. Art to fail to heed the black box warning and inform Francisco of Cipro's dangers. Those explanations may well be sufficient to deny liability-but not to prevent Francisco from presenting his case. Indeed, the preliminary expert opinion affidavit requirement set forth in § 12-2603 is a procedural requirement-not a necessary element of a prima facie case for the standard of care. *See Rasor*, 243 Ariz. at 164 ¶ 22 (characterizing § 12-2603's requirement as "a threshold

procedural requirement for a plaintiff" (emphasis added)).

¶55 Although there are no cases precisely on point, the one I find most instructive is *Revels v. Pohle,* 101 Ariz. 208 (1966), which the majority cites, *supra* ¶ 27. There, a physician performed a hysterectomy, after which the patient complained about pain around the incision for about nine months. *Revels*, 101 Ariz. at 209. The doctor prescribed pills and urged the patient to gain weight, but did not conduct an x-ray or other examination, and the pain persisted. *Id.* Eventually a different physician discovered steel

21

sutures inside the patient, removed them, and the pain dissipated. *Id.* Because the plaintiff failed to provide expert testimony regarding the defendant physician's failure to more carefully examine the patient, the trial court directed judgment against the plaintiff. *Id.* at 209-10.

¶56 This Court reversed, not because of the presence of the sutures, but rather because the failure to more carefully examine the patient was sufficient to establish a prima facie case of negligence under the res ipsa loquitor doctrine. *Id.* at 210-11. Certainly, diagnosis and treatment of pain involves skill and judgment on the part of a medical professional and would therefore ordinarily require expert testimony. *Id.* at 210. But the Court concluded that "laymen can say that in all cases where there [are] continual complaints of pain from a patient over a substantial period of time, that it is a departure from standard medical practice for the doctor to fail to examine the patient in any manner." *Id.* at 211.

¶57 Both *Revels* and this case involve situations that *ordinarily* require the exercise of medical judgment. But *Revels*' facts removed that case from the ordinary. So too do the facts presented here. A layperson reading the black box warning could readily conclude that a failure to warn a patient in the circumstances presented would amount to a departure from standard medical practice. *See, e.g.*, *Natale v. Camden Cnty. Corr. Facility*, 318 F.3d 575, 580 (3rd Cir. 2003) ("While laypersons are unlikely to know how often insulin-dependent diabetics need insulin, common sense-the judgment imparted by human experience-would tell a layperson that medical personnel charged with caring for an insulin-dependent diabetic should determine how often the diabetic needs insulin."); *Brouwer v. Sisters of Charity Providence Hosps.*, 763 S.E.2d 200, 204 (S.C. 2014) (holding that plaintiff did not need to provide expert testimony where patient with known latex allergy was exposed to latex during surgery); *Sanzari v. Rosenfeld,* 167 A.2d 625, 633 (N.J. 1961) (observing that "it is within the common knowledge of laymen that a reasonable man . . . who knows a drug is potentially harmful to a certain type of patient should take adequate precaution before administering the drug or deciding whether to administer it"). Granted, in *Revels* the conclusion would be based on a juror's experience, whereas here it would be based on reading a warning; but in both cases it would be grounded in common sense and in neither case would expert testimony be necessary to discern a baseline professional standard.

22

¶58 I agree with the majority that the statutes on their face do not violate the anti-abrogation clause of Arizona's Constitution, as this Court has expansively interpreted it. *See, e.g.*, *Torres v. JAI Dining Servs. (Phx.), Inc.*, 256 Ariz. 212 (2023). But the circumstances here suggest that the more stringent we are in requiring expert medical testimony to establish a prima facie case, the more likely that such a constitutional violation will occur. As the majority observes, *supra* ¶ 9, the Franciscos assert that the American Urological Association has provided guidance to its members authorizing the use of Cipro for elderly patients with a history of corticosteroid use. Urologists following that guidance are unlikely to provide contrary expert testimony. The Franciscos reported that they unsuccessfully sought testimony from two (but only two) urologists. *Supra* ¶ 9. And because § 12-2604 allows

testimony only from medical professionals in the same area of specialty, they could not provide such testimony through a pharmacologist, even though a pharmacologist might be equally or more competent than a urologist to articulate a standard of care in a failure to warn case.

¶59 The Court has held that no anti-abrogation violation occurs so long as "the record does not show that [plaintiff] lacks 'reasonable alternatives or choices which will enable him or her to bring the action.'" *Baker v. Univ. Physicians Healthcare*, 231 Ariz. 379, 388 ¶ 35 (2013) (quoting *Barrio v. San Manuel Div. Hosp. for Magma Copper Co.*, 143 Ariz. 101, 106 (1984)). If we require expert testimony and no experts within the area of specialization are willing to testify, and if we are unwilling to allow highly probative alternative methods to establish a prima facie case, that confluence of statutory and judicial constraints may indeed amount to an as-applied violation of the anti-abrogation clause, for it may foreclose a cause of action recognized at common law.

¶60 Moreover, and relatedly, I agree with the court of appeals that "[c]ustom alone is not the standard." *Francisco*, 2023 WL 3589654, at *3 ¶ 11; *see* § 12-563(1) (defining the appropriate standard of care as "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*" (emphasis added)). We recently held in the criminal context that rendering incorrect advice regarding a plea agreement constituted ineffective assistance of counsel "even if other attorneys were giving similarly incorrect advice at the time." *State v. Anderson*, 547 P.3d 345, 352 ¶ 31

(Ariz. 2024); *see also id*. ¶ 30 (noting that "[l]egal community standards 'may be valuable measures of the prevailing professional norms of effective representation,' but they are not 'inexorable commands'" (quoting *State v.* Miller, 251 Ariz. 99, 103 ¶ 14 (2021))). Here, too, viewing custom as dispositive could bode constitutional ramifications.

¶61 For the foregoing reasons, I conclude that a black box warning may establish a prima facie showing of standard of care in a failure to warn case. I would reverse the trial court and allow the matter to proceed. With great respect to my colleagues, I concur in part and dissent in part, including from the disposition.

Notes:

[*] Justice Kathryn H. King is recused from this matter. Pursuant to article 6, section 3 of the Arizona Constitution, Justice Rebecca White Berch (Ret.) of the Arizona Supreme Court was designated to sit in this matter.

[1] When reviewing a motion to dismiss, we treat the complaint's alleged facts as true. *See Summerfield v. Superior Court*, 144 Ariz. 467, 470 (1985).

[2] The Franciscos later filed an amended certification stating that expert testimony was not necessary for them "to prove the applicable standard of care and liability."

[3] Section 12-2603(F) provides that such a dismissal shall be without prejudice. However, nothing in the record indicates this was brought to the superior court's attention or subsequently challenged.

[4] The Practice also argues that this argument was waived because it is not the underlying issue, was not the question presented in the petition for review, and that we granted review on how to prove the standard of care, not what the standard of care is. To the extent waiver is an issue, we exercise our discretion to consider the argument because it is inherent to the analysis for resolving the issues before us. *See, e.g.*, *City of Phoenix v. Fields*, 219 Ariz. 568, 574 ¶ 23 (2009) (exercising discretion to consider an issue arguably waived).

[5] The resolution of this issue moots the Franciscos' argument that we should determine the disclosure of information from the patient's point of view. As § 12-563(1) and our caselaw

make clear, the perspective for assessing what should be disclosed is from the healthcare professional's point of view.

[6] For those reasons, the opinions rejecting the use of generic drug package insert warnings as a basis for setting a standard of care, *see supra* ¶¶ 31-32, 34, although correctly decided, are largely irrelevant to the question here.
