IN THE SUPREME COURT OF TEXAS

NO. 13-1014

RANDOL MILL PHARMACY, KVG ENTERPRISES, INC., GARY G. DALEY, JOHN WAYNE BAILEY, JAMES ROBERT FORSYTHE, KEVIN LYNN HEIDE, JULIE KNOWLTON LUBBERT, AND CARA MORRELL, PETITIONERS,

v.

STACEY MILLER AND RANDY MILLER, RESPONDENTS

ON PETITION FOR REVIEW FROM THE
COURT OF APPEALS FOR THE SECOND DISTRICT OF TEXAS

Argued January 14, 2015

JUSTICE LEHRMANN delivered the opinion of the Court.

After suffering a severe adverse reaction to a compounded drug administered by her physician, Stacey Miller sued the compounding pharmacy and several of its licensed-pharmacist employees. We are asked whether Miller's claims against these defendants are health care liability claims subject to the requirements of the Texas Medical Liability Act. If they are, then Miller's failure to serve them with an expert report pursuant to the Act requires dismissal of her suit. Holding that Miller's causes of action are not health care liability claims, the trial court denied the defendants' motion to dismiss, and the court of appeals affirmed. We disagree and reverse the court of appeals' judgment.

I. Background

In 2011, Dr. Ricardo Tan treated Miller for symptoms related to her previously diagnosed Hepatitis C. He prescribed and administered weekly intravenous injections of 200 mg/ml lipoic acid, an antioxidant supplement. According to Miller's petition, she underwent nine weeks of treatment without incident. However, she suffered a severe adverse reaction while receiving a lipoic-acid treatment on December 5, 2011. She alleged that, as a result, she was hospitalized for several weeks, received multiple blood transfusions, and is now permanently blind in both eyes. Randol Mill Pharmacy, a licensed compounding pharmacy in Arlington, compounded the particular vial of lipoic acid to which Miller reacted. It was prepared as part of an order Dr. Tan had placed with Randol Mill for twenty-three 30-ml vials of lipoic acid for office use, without reference to any particular patient.

Miller and her husband sued Dr. Tan, Randol Mill, and several licensed pharmacists in Randol Mill's employ.[1] The claims against Dr. Tan were dismissed and severed. As to Randol Mill and the individual pharmacists (collectively, the pharmacist defendants), Miller alleged that, "because of negligence in compounding, inadequate and inappropriate warnings and instructions for use, the compounded Lipoic Acid was defective, ineffective and unreasonably dangerous." Miller also alleged that the pharmacist defendants "breached their implied warranties in the design, manufacture, inspection, marketing, and/or distribution" of the lipoic acid. Miller more specifically alleged that they: failed to confirm the identity, strength, and sterility of the lipoic acid prior to its

[1] The individual defendants are Gary G. Daley, John Wayne Bailey, James Robert Forsythe, Kevin Lynn Heide, Julie Knowlton Lubbert, and Cara Morrell. Defendant KVG Enterprises, Inc. is the corporation doing business as Randol Mill.

release; failed to implement a reasonably safe design; failed to manufacture the lipoic acid in a reasonably safe condition; and failed to accompany the lipoic acid with proper warnings regarding possible adverse side effects and with adequate information to medical care providers regarding appropriate use.

Taking the position that Miller had asserted health care liability claims governed by the Texas Medical Liability Act, *see* TEX. CIV. PRAC. & REM. CODE §§ 74.001–.507, the pharmacist defendants moved to dismiss Miller's claims with prejudice for failure to serve an expert report within 120 days of her filing suit, *see id.* § 74.351. The trial court denied the motion, and a divided court of appeals affirmed,[2] holding that the pharmacist defendants were not health care providers, that the claims against them were not health care liability claims, and that the Medical Liability Act therefore did not apply. 413 S.W.3d 844 (Tex. App.—Fort Worth 2013). We granted the pharmacist defendants' petition for review.

II. Analysis

This case presents issues of statutory interpretation, which we review de novo. *Zanchi v. Lane*, 408 S.W.3d 373, 376 (Tex. 2013). In construing statutes, we start with the "ordinary meaning of the statutory text." *In re Ford Motor Co.*, 442 S.W.3d 265, 271 (Tex. 2014). We analyze that language in context, considering the specific sections at issue as well as the statute as a whole. *CHCA Woman's Hosp. v. Lidji*, 403 S.W.3d 228, 231–32 (Tex. 2013).

[2] Although a court of appeals' judgment is generally final in an interlocutory appeal, we have jurisdiction when that court's justices "disagree on a question of law material to the decision." TEX. GOV'T CODE § 22.225(b)(3), (c).

A. Relevant Provisions of the Texas Medical Liability Act

The Texas Medical Liability Act provides a comprehensive statutory framework governing health care liability claims. *Id.* at 232. It is intended to strike "a careful balance between eradicating frivolous [health care liability] claims and preserving meritorious ones." *Leland v. Brandal*, 257 S.W.3d 204, 208 (Tex. 2008). A key component of the Act's framework is its requirement that the plaintiff serve expert reports early in the litigation process "for each physician or health care provider against whom a [health care] liability claim is asserted." TEX. CIV. PRAC. & REM. CODE § 74.351(a).[3] Failure to comply with this requirement results in dismissal of the claim with prejudice upon the health care provider's motion. *Id.* § 74.351(b). Miller and the pharmacist defendants dispute whether her claims constitute health care liability claims such that the Medical Liability Act generally, and the expert-report requirement specifically, applies.[4]

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[3] The version of the statute applicable to this case required the reports to be served "not later than the 120th day after the date the original petition was filed." Act of May 18, 2005, 79th Leg., R.S., ch. 635, § 1, sec. 74.351(a), 2005 Tex. Gen. Laws 1590, 1590. The statute has since been amended to require service of the reports "not later than the 120th day after the date each defendant's original answer is filed." Act of May 26, 2013, 83d Leg., R.S., ch. 870, § 2, sec. 74.351(a), 2013 Tex. Gen. Laws 2217, 2217.

[4] Miller's live pleading alleges that notice was sent to the pharmacist defendants pursuant to section 74.051 of the Act, which requires a person asserting a health care liability claim to send written notice "to each physician or health care provider against whom such claim is being made at least 60 days before" suit is filed. Citing our opinion in *Horizon/CMS Healthcare Corp. v. Auld*, 34 S.W.3d 887 (Tex. 2000), the pharmacist defendants argue that this allegation constitutes a judicial admission that they are health care providers and that no proof thereof is necessary. A judicial admission "occurs when an assertion of fact is conclusively established in live pleadings." *Id.* at 905. The consequence of a judicial admission is that "jury questions concerning the fact need not be submitted." *Id.* (holding that the live pleading's assertion that the plaintiff had complied with both the notice and expert-report provisions of the Medical Liability Act's predecessor constituted a judicial admission that the defendant was a health care provider and relieved the defendant of the burden to offer evidence at trial or obtain a jury finding). The issue here is not whether a jury finding is required; the case is at its preliminary stages and the sole issue in dispute is whether Miller has asserted health care liability claims. At this stage of the litigation, we decline to hold that Miller's allegation that she provided notice under the Act, by itself, constitutes a dispositive judicial admission.

The Act defines "health care liability claim" as

> a cause of action against a health care provider or physician for treatment, lack of treatment, or other claimed departure from accepted standards of medical care, or health care, or safety or professional or administrative services directly related to health care, which proximately results in injury to or death of a claimant, whether the claimant's claim or cause of action sounds in tort or contract.

Id. § 74.001(13). Thus, only claims brought against physicians or health care providers may qualify as health care liability claims. A "health care provider" is "any person, partnership, professional association, corporation, facility, or institution duly licensed, certified, registered, or chartered by the State of Texas to provide health care, including . . . a pharmacist." *Id.* § 74.001(12)(A)(iv). Employees and independent contractors of health care providers who are acting within the scope of the employment or contractual relationship also qualify as health care providers. *Id.* § 74.001(12)(B)(ii). Finally, the Act defines "pharmacist" as

> one licensed under Chapter 551, Occupations Code, who, for the purposes of this chapter, performs those activities limited to the dispensing of prescription medicines which result in health care liability claims and does not include any other cause of action that may exist at common law against them, including but not limited to causes of action for the sale of mishandled or defective products.

Id. § 74.001(22).

B. General Definition of Health Care Provider vs. Specific Definition of Pharmacist

As an initial matter, we address the pharmacist defendants' argument that they qualify as health care providers under the term's general definition irrespective of the more specific definition of pharmacist. The argument is as follows: (1) As a licensed Class A pharmacy, Randol Mill is a "facility . . . duly licensed . . . by the State of Texas to provide health care," *id.* § 74.001(12)(A); (2) Randol Mill thus meets the definition of health care provider under the Act; and (3) as employees

of Randol Mill, the individual defendants are also health care providers regardless of whether they meet the Act's definition of pharmacist, *id.* § 74.001(12)(B)(ii).

This argument has appeal when the Act's definitions are viewed in isolation, but our well-settled rules of statutory interpretation require us to "examine the entire act to glean its meaning" and to "presume that 'the entire statute is intended to be effective.'" *Meritor Auto., Inc. v. Ruan Leasing Co.*, 44 S.W.3d 86, 90 (Tex. 2001) (quoting TEX. GOV'T CODE § 311.021(2)). Further, we may not interpret a statute in a way that renders any part of it meaningless. *Crosstex Energy Servs., L.P. v. Pro Plus, Inc.*, 430 S.W.3d 384, 390 (Tex. 2014). When analyzed in this manner, the statute cannot have the meaning Randol Mill proposes.

More specifically, Randol Mill's interpretation renders the definition of pharmacist wholly superfluous because defendants who are licensed under chapter 551 of the Occupations Code—the first requirement to meet the pharmacist definition—automatically fall within the broader definition of health care provider. But the remainder of the pharmacist definition expressly narrows the circumstances in which such defendants may be considered health care providers, principally by limiting the qualifying activities to "the dispensing of prescription medicines that result in health care liability claims." TEX. CIV. PRAC. & REM. CODE § 74.001(22). And the referenced chapter 551 of the Occupations Code, which is the first chapter of the Texas Pharmacy Act, encompasses the licensing of both pharmacies like Randol Mill and individual pharmacists. *See* TEX. OCC. CODE §§ 551.002(c), .003(3)–(7), (28). Accordingly, both Randol Mill and the individual defendants in this case qualify as health care providers under the Medical Liability Act only if they meet the Act's definition of pharmacist.

C. The Defendants Are Pharmacists

This is our first opportunity to examine the Medical Liability Act's application to claims against pharmacists in general and compounding pharmacists in particular. In the typical case against a pharmacy involving claims of misfilled prescriptions, the courts of appeals are generally in agreement—and often the parties do not dispute—that the Act applies and an expert report is required. *See, e.g.*, *Walgreen Co. v. Hieger*, 243 S.W.3d 183, 185–86 (Tex. App.—Houston [14th Dist.] 2007, pet. denied) (analyzing the sufficiency of an expert report in a claim alleging the pharmacy incorrectly filled a prescription with the wrong medication); *HEB Grocery Co. v. Farenik*, 243 S.W.3d 171, 173 (Tex. App.—San Antonio 2007, no pet.) (same); *see also Gingrich v. Scarborough*, No. 09-09-00211-CV, 2010 WL 1711067, at *5 (Tex. App.—Beaumont April 29, 2010, no pet.) (mem. op.) (holding that the plaintiff's expert report was insufficient as to a claim that the pharmacy negligently filled a prescription for "excessive" medications that led to drug toxicity). Unlike those cases, this case implicates a pharmacy's compounding services, and so we begin with a discussion of that practice.

1. Pharmacy Compounding

Generally, drug compounding is the process by which a pharmacist mixes or alters drugs to create a medication that is tailored to the needs of an individual patient and that is not otherwise commercially available. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 360–61 (2002). Pharmacists engaging in this process may customize a drug's dose, delivery vehicle, binding agents, or flavor. Jesse M. Boodoo, Note and Comment, *Compounding Problems and Compounding Confusion: Federal Regulation of Compounded Drug Products and the FDAMA Circuit Split*, 36

AM. J.L. & MED. 220, 223 (2010). Common recipients of compounded drugs include hospice patients who require higher doses and alternate delivery vehicles, children who require lower doses in liquid rather than tablet form, and patients who are allergic to a drug's inactive ingredient. *Id.* Further, compounding is "constantly used" in the hospital setting "to prepare intravenous mixtures 'ranging from simple fluid replacement to the delivery of complicated, individualized chemotherapy regiments.'" *Id.* at 224 (quoting *Federal and State Role in Pharmacy Compounding and Reconstitution: Exploring the Right Mix to Protect Patients: Hearing Before the S. Comm. on Health, Educ., Labor and Pensions*, 108th Cong. 54 (2003) (statement of Daniel A. Herbert, President-elect, American Pharmaceutical Association)). Compounded medications "are traditionally created only upon receiving a prescription from a physician or other authorized prescriber." Michael Snow, Note, *Seeing Through the Murky Vial: Does the FDA Have the Authority to Stop Compounding Pharmacies from Pirate Manufacturing?*, 66 VAND. L. REV. 1609, 1611 (Oct. 2013); *see also Thompson*, 535 U.S. at 361 ("Pharmacists may provide compounded drugs to patients only upon receipt of a valid prescription from a doctor . . . ." (citing state pharmacy regulations)).

Texas is one of "[m]any States" that "specifically regulate compounding practices as part of their regulation of pharmacies." *Thompson*, 535 U.S. at 361. To that end, both the Texas Pharmacy Act and the associated regulations governing compounding services define compounding as

> the preparation, mixing, assembling, packaging, or labeling of a drug or device:
>
> > (A) as the result of a practitioner's prescription drug order based on the practitioner–patient–pharmacist relationship in the course of professional practice;

> (B) for administration to a patient by a practitioner as the result of a practitioner's initiative based on the practitioner–patient–pharmacist relationship in the course of professional practice;
>
> (C) in anticipation of a prescription drug order based on a routine, regularly observed prescribing pattern; or
>
> (D) for or as an incident to research, teaching, or chemical analysis and not for selling or dispensing, except as allowed under Section 562.154 or Chapter 563 [of the Occupations Code].

TEX. OCC. CODE § 551.003(9); 22 TEX. ADMIN. CODE §§ 291.131(b)(3), .133(b)(14). Pertinent to this case, the Pharmacy Act permits a pharmacy to "dispense and deliver a reasonable quantity[5] of a compounded drug to a practitioner for office use,"[6] requiring the pharmacy to verify the source of the raw materials, comply with applicable United States Pharmacopoeia guidelines,[7] and comply with the State Board of Pharmacy's applicable standards and rules. TEX. OCC. CODE §§ 562.152, .153. In turn, the Pharmacy Board has enacted detailed regulations governing pharmacy compounding for a practitioner's office use. *See* 22 TEX. ADMIN. CODE §§ 291.131(f), .133(f). Notably, the Pharmacy Act also defines "manufacturing" and expressly states that "[t]he term does

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[5] A "reasonable quantity" of a compounded drug "does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date," "is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice," and does not exceed "an amount the pharmacy is capable of compounding in compliance with [applicable] pharmaceutical standards for identity, strength, quality, and purity" of the drug. TEX. OCC. CODE § 562.151(3).

[6] "Office use" is defined in pertinent part as the "administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting." *Id.* § 562.151(1); 22 TEX. ADMIN. CODE § 291.133(b)(32).

[7] The U.S. Pharmacopoeia is "an independent compendium of drug standards." *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388 (5th Cir. 2008).

not include compounding." TEX. OCC. CODE § 551.003(23). With this background in mind, we turn to the issues at hand.

2. Randol Mill Was Dispensing Prescription Medicines

As noted above, licensed pharmacists and pharmacies are health care providers for purposes of the Medical Liability Act with respect to "those activities limited to the dispensing of prescription medicines which result in health care liability claims." TEX. CIV. PRAC. & REM. CODE § 74.001(22). They are not considered health care providers with respect to "any other cause of action that may exist at common law against them, including but not limited to causes of action for the sale of mishandled or defective products." *Id.* The parties dispute whether the pharmacist defendants' act of compounding the injectable lipoic acid that Dr. Tan administered to Miller constituted "the dispensing of prescription medicines." We hold that it did.

The Medical Liability Act does not define the word "dispense," but the Pharmacy Act does: "'Dispense' means to prepare, package, compound, or label, in the course of professional practice, a prescription drug or device for delivery to an ultimate user or the user's agent under a practitioner's lawful order." TEX. OCC. CODE § 551.003(16). An "ultimate user" is "a person who obtains or possesses a prescription drug . . . for the person's own use." *Id.* § 551.003(43). The court of appeals recognized that a doctor or nurse administering the drug to the ultimate user, such as Dr. Tan, may qualify as the "user's agent." 413 S.W.3d at 851. However, the court held that Randol Mill did not compound the lipoic acid "for delivery to an ultimate user or the user's agent" because Dr. Tan's order did not specify the particular patient or patients for whom the drug was intended. *Id.* at 849. We disagree.

As noted above, a pharmacist may "dispense and deliver a reasonable quantity of a compounded drug to a practitioner for office use." TEX. OCC. CODE § 562.152. Because a "reasonable quantity" is an amount that the practitioner "anticipates may be used" before the drug's expiration date, the Pharmacy Act specifically contemplates that a pharmacist may "dispense" a compounded drug to a practitioner without knowing the specific identity of the ultimate user. Further, and importantly, when a drug is dispensed for office use, it means that the *practitioner* will be administering the drug to the patient. *Id.* § 562.151(1) (defining "office use"). The limitations on this practice are thus designed to ensure that the compounded drug is administered in a health care setting directly to the patient to whom the drug is ultimately prescribed. We cannot agree with the effect of the distinction drawn by the court of appeals, which effectively held that "a pharmacist who is compounding prescription drugs *for individuals* does fall within the [Medical Liability Act's] statutory definition of a pharmacist," while a pharmacist who is compounding prescription drugs for a practitioner's office use does not. 413 S.W.3d at 850–51 (emphasis partially omitted). Accordingly, we hold that a pharmacist who compounds a drug for office use pursuant to a practitioner's lawful order, as authorized by the Pharmacy Act, is "dispensing" the drug whether or not the order identifies the patients to whom the drug will be administered.

Miller alternatively argues that the pharmacy defendants do not fall within the Medical Liability Act's definition of pharmacist because the compounded lipoic acid that Randol Mill delivered to Dr. Tan is not a prescription medicine. TEX. CIV. PRAC. & REM. CODE § 74.001(22) (defining "pharmacist" to extend to "activities limited to the dispensing of prescription medicines").

As with the term "dispense," the Medical Liability Act does not define "prescription medicines." Neither does the Pharmacy Act, although that Act does define the term "prescription drug" as

> (A) a substance for which federal or state law requires a prescription before the substance may be legally dispensed to the public;
>
> (B) a drug or device that under federal law is required, before being dispensed or delivered, to be labeled with the statement:
>
> (i) "Caution: federal law prohibits dispensing without prescription" or "Rx only" or another legend that complies with federal law; or
>
> (ii) "Caution: federal law restricts this drug to use by or on the order of a licensed veterinarian"; or
>
> (C) a drug or device that is required by federal or state statute or regulation to be dispensed on prescription or that is restricted to use by a practitioner only.

TEX. OCC. CODE § 551.003(36). The ordinary meaning of prescription drug—"a drug that can be bought only as prescribed by a physician"—is similar to subsection (A) of the statutory definition. WEBSTER'S THIRD NEW INT'L DICTIONARY 1792 (2002). Miller argues that no evidence shows that lipoic acid, in any form, qualifies as a prescription drug.

We first note that the Legislature's choice of the term "medicine" rather than "drug" in the Medical Liability Act likely will not affect the statute's application in most circumstances. The dictionary definition of medicine is "a substance or preparation used in treating disease." *Id.* at 1402. The Pharmacy Act's definition of drug is broader, but includes "a substance intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease." TEX. OCC. CODE § 551.003(18)(B). The parties do not argue that the injectable lipoic acid at issue meets the definition of drug but not medicine, or vice versa. They dispute only whether a prescription is required for patient use.

To that end, the Pharmacy Act's provisions governing compounding confirm that compounded drugs may not be given to a patient absent a doctor's order. Unless incident to research, "compounding" occurs only (1) as the result of a prescription drug order, (2) in anticipation of a prescription drug order, or (3) "for administration to a patient by a practitioner as the result of a practitioner's initiative." *Id.* § 551.003(9). The first two categories expressly require a prescription drug order,[8] and as to the third category, only "prescription drugs" are "administer[ed]." *Id.* § 551.003(1) ("'Administer' means to directly apply a prescription drug to the body of a patient by any means, including injection, inhalation, or ingestion, by: (A) a person authorized by law to administer the drug, . . . or (B) the patient at the direction of a practitioner."). The language of the above-discussed provisions governing compounding for office use is also instructive; specifically, the Pharmacy Act allows a pharmacy to "dispense and deliver" a compounded drug to a practitioner for office use in accordance with certain requirements. *Id.* § 562.152. Turning to the definitions of "dispense" and "deliver," only a "prescription drug or device" is dispensed, and only a "prescription drug or device or controlled substance" is delivered. *Id.* § 551.003(13), (16).

The requirement that a compounded drug be prescribed by a practitioner is consistent with the purpose served by the practice, which is to supply a drug in a form or dose that is not commercially available, but that the practitioner has concluded will best meet her patient's needs.[9]

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[8] "Prescription drug order" is defined in pertinent part as "an order from a practitioner or a practitioner's designated agent to a pharmacist for a drug or device to be dispensed." TEX. OCC. CODE § 551.003(37)(A).

[9] The regulations do allow compounding of commercially available products at a practitioner's request under narrow circumstances when the "product is not reasonably available from normal distribution channels in a timely manner to meet the patient's needs." 22 TEX. ADMIN. CODE §§ 291.131(d)(1)(C), .133(d)(1)(C).

Thompson, 535 U.S. at 360–61. In this case, Dr. Tan, in the exercise of his professional medical judgment, prescribed some of his patients, including Miller, a particular dose and form of lipoic acid that required compounding. He ordered a specific quantity of the compounded drug from Randol Mill for office use and administered the drug to Miller in his office, as contemplated by the Pharmacy Act. We hold that the injectable lipoic acid compounded by Randol Mill and administered to Miller was a prescription medicine under the Medical Liability Act. Accordingly, in compounding the lipoic acid for Dr. Tan's office use, the pharmacist defendants were engaged in "activities limited to the dispensing of prescription medicines." TEX. CIV. PRAC. & REM. CODE § 74.001(22).

3. Miller's Claims Are Health Care Liability Claims

Finally, we determine whether the pharmacist defendants' complained-of "activities . . . result[ed] in health care liability claims." *Id.* We thus consider whether Miller has asserted causes of action "for treatment, lack of treatment, or other claimed departure from accepted standards of medical care, or health care, or safety or professional or administrative services directly related to health care, which proximately result[ed] in injury to [Miller]."[10] *Id.* § 74.001(13) (defining "health care liability claim"). The Medical Liability Act broadly defines "health care" as "any act or treatment performed or furnished, or that should have been performed or furnished, by any health care provider for, to, or on behalf of a patient during the patient's medical care, treatment, or confinement." *Id.* § 74.001(10).

[10] The statutory language is somewhat circular because one of the elements of a health care liability claim is that it is asserted against a health care provider, and one of the requirements for a defendant to qualify as a pharmacist—and thus as a health care provider—is that the conduct for which it is sued results in a health care liability claim. TEX. CIV. PRAC. & REM. CODE § 74.001(13), (22).

In this case, Dr. Tan ordered compounded injectable lipoic acid for office administration to his patients, and the pharmacist defendants compounded the lipoic acid for that purpose. Dr. Tan administered the lipoic acid to Miller in the course of her treatment for Hepatitis C symptoms. Miller asserts that the pharmacist defendants' negligence in compounding the drug and their inclusion of inadequate warnings and instructions regarding its use proximately caused her injuries. Whether stated as negligence or breach of warranty, these claims rather clearly allege that the pharmacist defendants departed from accepted standards of health care. *See Marks v. St. Luke's Episcopal Hosp.*, 319 S.W.3d 658, 665–66 (Tex. 2010) ("Determining whether a pleading states a health care liability claim . . . depends on its underlying substance, not its form.").

Miller asserts, however, that her claims are in the nature of product-liability claims and are excluded from the Medical Liability Act's umbrella because, while the Act defines pharmacist to include "activities limited to the dispensing of prescription medicines which result in health care liability claims," it "does not include any other cause of action that may exist at common law against [pharmacists], including but not limited to causes of action for the sale of mishandled or defective products." TEX. CIV. PRAC. & REM. CODE § 74.001(22). We cannot construe this exclusion as broadly as Miller suggests because, so construed, it would swallow the Act's application to causes of action involving negligent compounding that otherwise qualify as health care liability claims.

We note that subsection 74.001(22) references the "sale" of defective products. Presumably this would extend to a pharmacy's liability as a "retailer or other member of the marketing chain" of a defective product, as well as its right to indemnity from the manufacturer where the pharmacy "is merely a conduit for the defective product." *Duncan v. Cessna Aircraft Co.*, 665 S.W.2d 414,

432 (Tex. 1984); *see also SSP Partners v. Gladstrong Invs. (USA) Corp.*, 275 S.W.3d 444, 446–47 (Tex. 2009) ("In Texas, the seller of a defective product is subject to strict liability for damages the product causes even though the defect was not his fault, but he is generally entitled to indemnity from the manufacturer by statute and by common law."). But the pharmacist defendants have not been sued merely as retailers of a defective product. Nor, importantly, have they been sued as manufacturers of a defective product, notwithstanding the petition's use of the "manufacturing" label to describe the pharmacist defendants' activity. *See Loaisiga v. Cerda*, 379 S.W.3d 248, 255 (Tex. 2012) (noting that, in analyzing whether a cause of action is a health care liability claim, courts must "focus[] on the facts underlying the claim, not the form of, or artfully-phrased language in, the plaintiff's pleadings"). As noted above, the Pharmacy Act and its associated regulations expressly distinguish between compounding and manufacturing. TEX. OCC. CODE § 551.003(23) ("The term [manufacturing] does not include compounding."). Unlike manufacturing, compounding qualifies as "dispensing prescription medicines."

At their core, Miller's claims call into question Randol Mill's compliance with professional standards of care applicable to pharmacies that perform compounding services, which implicates a host of complex regulations governing compounding practices in Texas. *See generally* 22 TEX. ADMIN. CODE §§ 291.131, .133. Determining whether the pharmacist defendants complied with these standards will inevitably require the testimony of experts in the field. *See Garland Cmty. Hosp. v. Rose*, 156 S.W.3d 541, 546 (Tex. 2004) (noting, in holding that a negligent credentialing claim against a hospital was a health care liability claim, that such a claim "involves a specialized standard of care" requiring expert testimony). We cannot allow Miller to "recast [her] malpractice

claim" as breach-of-warranty and products-liability claims to avoid the Medical Liability Act's strictures. *See, e.g.*, *Murphy v. Russell*, 167 S.W.3d 835, 839 (Tex. 2005) (per curiam) (holding that a plaintiff's DTPA claim stemming from an allegation that her physician misrepresented that he would not sedate her was a health care liability claim); *see also Yamada v. Friend*, 335 S.W.3d 192, 197 (Tex. 2010) ("[I]f the gravamen or essence of a cause of action is a health care liability claim, then allowing the claim to be split or spliced into a multitude of other causes of action with differing standards of care, damages, and procedures would contravene the Legislature's explicit requirements."). Accordingly, we hold that the pharmacist defendants are "pharmacists" under the Medical Liability Act for purposes of this lawsuit and that Miller has asserted health care liability claims against them.

III. Conclusion

In sum, we hold that the Medical Liability Act applies to Miller's claims against the pharmacist defendants. Under the applicable version of that Act, she was required to serve the defendants with an expert report within 120 days of filing suit. Because it is undisputed that she failed to do so, her claims must be dismissed. Accordingly, we reverse the court of appeals' judgment and remand the case to the trial court for further proceedings consistent with this opinion.

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Debra H. Lehrmann
Justice

OPINION DELIVERED: April 24, 2015