



**COURT OF APPEALS
SECOND DISTRICT OF TEXAS
FORT WORTH**

NO. 02-12-00519-CV

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

APPELLANTS

V.

STACEY MILLER AND RANDY
MILLER

APPELLEES

FROM THE 348TH DISTRICT COURT OF TARRANT COUNTY

OPINION

I. INTRODUCTION

The primary issue we address in this appeal is whether a pharmacist's act—of filling a bulk phone order placed by a doctor for over twenty 30-milliliter vials of an injectable form of the antioxidant supplement lipoic acid for use in the

doctor's office—constitutes dispensing a prescription medicine as required for the pharmacist to qualify as a health care provider under the Texas Medical Liability Act (TMLA). See Tex. Civ. Prac. & Rem. Code Ann. § 74.001(a)(12)(A)(iv), (22) (West Supp. 2012). Because we hold that the answer to this question is no, we will affirm the trial court's order denying Appellants'¹ motion seeking dismissal of Appellees Stacey Miller and Randy Miller's suit based on the failure to file a chapter 74 expert report. See *id.* § 74.351 (West 2011).

II. FACTUAL AND PROCEDURAL BACKGROUND

Stacey was diagnosed with Hepatitis C. To treat Stacey's previously diagnosed Hepatitis C, Dr. Ricardo B. Tan began administering weekly injections of the antioxidant supplement lipoic acid. After nine weeks of treatment, Stacey began an episode of violent nausea and vomiting when Dr. Tan administered an injection of lipoic acid to Stacey on December 5, 2011. She was transported to the hospital where, according to her pleadings, she experienced "violent nausea, vomiting, tachycardia, severe back pain, neck and body pain, abdominal pain, diarrhea, a hematemesis/UGI bleed, acidosis, elevated CPK, electrolyte abnormality, fever, irritability, confusion, lethargy, muscle weakness, blurry vision with dark spots, hemorrhages in both eyes, right pleural effusion, hypotension, enlarged spleen, fluid in her gallbladder with surrounding fluids, a large amount

¹Appellants are Randol Mill Pharmacy; KVG Enterprises, Inc.; Gary G. Daley; John Wayne Bailey; James Robert Forsythe; Kevin Lynn Heide; Julie Knowlton Lubbert; and Cara Morrell.

of upper ABD ascites, periportal edema, and diverticulosis.” Stacey was hospitalized for several weeks and underwent multiple blood transfusions. As a result of this episode, she was rendered blind in both eyes.

Stacey and her husband Randy filed suit against Appellants alleging that Appellants had manufactured, distributed, and sold a defective product—injectable lipoic acid; failed to give physicians, as learned intermediaries, adequate and proper warning with respect to the risks associated with the use of lipoic acid; and breached implied warranties in the design, manufacture, inspection, marketing, and distribution of lipoic acid because it was not reasonably suited for the purposes and use for which it was intended and was not of merchantable quality. The Millers did not file an expert report under the TMLA. Appellants filed a motion to dismiss, claiming that the Millers’ suit against them was a health care liability claim governed by the TMLA. The Millers filed a response, attaching numerous documents generated through the investigation launched by the Texas Department of State Health Services (TDSHS) concerning Appellants’ manufacture of the injectable lipoic acid and Stacey’s injuries. After a hearing, the trial court signed an order denying Appellants’ motion to dismiss; Appellants perfected this appeal.

III. STANDARD OF REVIEW AND RULES OF STATUTORY CONSTRUCTION

The question of whether a cause of action is a health care liability claim under the TMLA is one of law, which we review de novo. See *Tex. W. Oaks Hosp., LP v. Williams*, 371 S.W.3d 171, 177 (Tex. 2012). When construing a

statute like the TMLA, our primary objective is to ascertain and give effect to the legislature's intent. Tex. Gov't Code Ann. § 312.005 (West 2013); *TGS-NOPEC Geophysical Co. v. Combs*, 340 S.W.3d 432, 439 (Tex. 2011); see *Tex. Dep't of Protective & Regulatory Servs. v. Mega Child Care*, 145 S.W.3d 170, 176 (Tex. 2004). To discern that intent, we begin with the statute's words. Tex. Gov't Code Ann. § 312.002 (West 2013); see *Tex. Dep't of Transp. v. City of Sunset Valley*, 146 S.W.3d 637, 642 (Tex. 2004). If a statute uses a term with a particular meaning or assigns a particular meaning to a term, we are bound by the statutory usage. *TGS-NOPEC*, 340 S.W.3d at 439; *Tex. Dep't of Transp. v. Needham*, 82 S.W.3d 314, 318 (Tex. 2002). Undefined terms in a statute are typically given their ordinary meaning, but if a different or more precise definition is apparent from the term's use in the context of the statute, we apply that meaning. *TGS-NOPEC*, 340 S.W.3d at 439; *In re Hall*, 286 S.W.3d 925, 928–29 (Tex. 2009) (orig. proceeding). Words and phrases shall be read in context and construed according to the rules of grammar and common usage, but words and phrases that have acquired a technical or particular meaning, whether by legislative definition or otherwise, shall be construed accordingly. Tex. Gov't Code Ann. § 311.011 (West 2013). We presume that the legislature selected statutory words, phrases, and expressions deliberately and purposefully. See *Tex. Lottery Comm'n v. First State Bank of DeQueen*, 325 S.W.3d 628, 635 (Tex. 2010); *In re M.N.*, 262 S.W.3d 799, 802 (Tex. 2008); *Shook v. Walden*, 304 S.W.3d 910, 917 (Tex. App.—Austin 2010, no pet.). We also presume that the

legislature was aware of the background law and acted with reference to it. See *Acker v. Tex. Water Comm'n*, 790 S.W.2d 299, 301 (Tex. 1990).

IV. APPELLANTS DO NOT MEET THE TMLA'S DEFINITION OF PHARMACIST, SO APPELLANTS ARE NOT HEALTH CARE PROVIDERS

The TMLA defines a 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.

Tex. Civ. Prac. & Rem. Code Ann. § 74.001(a)(13). According to this definition, a health care liability claim has three elements: (1) the defendant is a health care provider or physician; (2) the claimant's cause of action is for treatment, lack of treatment, or other claimed departure from accepted standards of medical care, health care, or safety or professional or administrative services directly related to health care; and (3) the defendant's alleged departure from accepted standards proximately caused the claimant's injury or death. *Loaisiga v. Cerda*, 379 S.W.3d 248, 255 (Tex. 2012); see *Marks v. St. Luke's Episcopal Hosp.*, 319 S.W.3d 658, 662 (Tex. 2010) (plurality opinion).

The first element is at issue here. The definition of a health care provider includes a pharmacist. Tex. Civ. Prac. & Rem. Code Ann. § 74.001(a)(12)(A)(iv), (22). Under the TMLA, a pharmacist is then further, more narrowly defined 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(a)(22).

The Millers attached numerous documents to their response to Appellants' motion to dismiss. The documents attached to the Millers' response to Appellants' motion to dismiss contain the information set forth below:²

- Injectable lipoic acid has not been granted marketing approval pursuant to a U.S. Food and Drug Administration New Drug Application or Abbreviated New Drug Application nor is it exempt from this requirement.
- Dr. Tan placed a “bulk” telephone order with Appellants on November 29, 2011 and on December 2, 2011 for an aggregate of twenty-three 30-milliliter vials of injectable lipoic acid for “office use.”
- Dr. Tan did not complete or call in a prescription for, nor did Appellants fill a prescription for, Stacey Miller or for any other specific individual user for injectable lipoic acid.
- Under Texas law, when a pharmacy distributes for office use and does not receive a prescription drug order for a specific patient, the pharmacy is “no longer exempt from being a manufacturer per Texas Food, Drug, and Cosmetic Act § 431.401 4-a.”³

²Appellants did not assert any objection to the trial court's consideration of these documents in connection with the trial court's ruling on their motion to dismiss.

³The Establishment Inspection Report issued by the TDSHS summarizes, “There is no evidence the compounded drug [lipoic acid] was distributed pursuant to a prescription drug order from a practitioner for a specific patient; therefore [the pharmacy or establishment was] manufacturing new prescription drugs [and that drug, injectable lipoic acid] lacked evidence of approval by the Food and Drug Administration.”

- Lipoic acid is compounded by mixing lipoic acid, sodium hydroxide, sterile water, and benzyl alcohol.

Appellants claim that they are health care providers and that, accordingly, the Millers were required to file an expert report under the TMLA. As set forth above, the TMLA's definition of a pharmacist is

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. (emphasis added). So, the question here is whether Appellants' compounding of an antioxidant supplement—injectable lipoic acid, Appellants' sale of that drug in bulk to a physician for office use to be injected into unknown users, and Appellants' sale of that drug in bulk in the absence of any prescription drug order for any specific person constitutes “dispensing prescription medicine” so that a pharmacist engaged in such activity is a health care provider under the TMLA.

Although the TMLA does not define the word “dispensing” that is used in its definition of a “pharmacist,” chapter 551 of the Texas Occupations Code—known as the Texas Pharmacy Act—defines “dispense” to mean “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.”⁴ Tex. Occ. Code Ann. § 551.003(16) (West 2012). Applying the rules of statutory construction recited above, the definition of the term “dispense” in the Texas Pharmacy Act applies to the same term—“dispensing”—used in defining a pharmacist in the TMLA. See Tex. Gov’t Code Ann. § 311.011(b) (“Words and phrases that have acquired a technical or particular meaning, whether by legislative definition or otherwise, shall be construed accordingly.”); *Sheshunoff v. Sheshunoff*, 172 S.W.3d 686, 692 (Tex. App.—Austin 2005, pet. denied) (explaining that court should give same meaning to same terms used in other statutory provisions on same or similar subjects unless something indicates different meaning was intended); *Guthery v. Taylor*, 112 S.W.3d 715, 721–22 (Tex. App.—Houston [14th Dist.] 2003, no pet.) (“When the same or a similar term is used in the same connection in different statutes, the term will be given the same meaning in one as in the other, unless there is something to indicate that a different meaning was intended.”); *Dickens v. Willis*, 957 S.W.2d 657, 659 (Tex. App.—Austin 1997, no pet.) (stating in absence of definition, court may look to similar area of law for guidance); *L & M–Surco Mfg., Inc. v. Winn Tile Co.*, 580 S.W.2d 920, 926 (Tex. Civ. App.—Tyler 1979, writ dismissed w.o.j.) (“Where the same or a similar term is used in the same connection in different statutes, it will be given the same meaning in one that it has in

⁴In fact, Appellants urge us to apply definitions—other than the definition of “dispense”—from the Texas Pharmacy Act in our construction of the definition of “pharmacist” set forth in the TMLA.

another, unless there is something to indicate that a different meaning was intended. This rule applies with particular force where the meaning of a word as used in one act is clear or has been judicially determined, and the same word is subsequently used in another act pertaining to the same subject.”); see *also* Tex. Occ. Code Ann. § 551.002 (West 2012) (explaining that legislative purpose of Texas Pharmacy Act is to regulate the practice of pharmacy). To hold otherwise would be to judicially rewrite the expressly limited definition of “pharmacist” set forth in the TMLA as one who is licensed and is “dispensing [] prescription medicines” to make it broader by including activities that the Texas Pharmacy Act does not define as “dispensing” and to judicially generate an unnecessary conflict between the actions constituting “dispensing” under the TMLA and the actions constituting “dispensing” under the Texas Pharmacy Act.

Utilizing the Texas Pharmacy Act’s definition of “dispense,” a pharmacist “dispenses” a drug when he or she prepares, packages, compounds, or labels 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 Ann. § 551.003(16). An “ultimate user” is defined in the Texas Pharmacy Act, in pertinent part, as a “person who obtains or possesses a prescription drug or device for the person’s own use.” *Id.* § 551.003(43).

Here, it is undisputed that Appellants did not compound the injectable lipoic acid for delivery to an ultimate user, i.e., for delivery to Stacey Miller or any other specific person. Appellants concede as much in their motion to dismiss

and in their appellate brief, arguing that they compounded the injectable lipoic acid for delivery to Dr. Tan for his office use based on Dr. Tan's bulk phone order. Dr. Tan was not an ultimate user because he did not obtain the injectable lipoic acid to use on himself. See *id.* Consequently, as a matter of law, because Appellants did not compound the lipoic acid for delivery to an ultimate user, they were not "dispensing" a prescription drug. See *id.* § 551.003(16) (defining dispensing). Because Appellants were not "dispensing," as that term is defined in the Texas Pharmacy Act, they do not meet the limited definition of a "pharmacist" under the TMLA.⁵ See Tex. Civ. Prac. & Rem. Code Ann. § 74.001(a)(22) (limiting definition of pharmacist to one dispensing prescription medication).

And because Appellants in this case do not fall within the TMLA's limited definition of "pharmacist," they are—by this limited definition—specifically excluded from the TMLA's statutory list of health care providers. See *id.* § 74.001(a)(12); *TGS-NOPEC*, 340 S.W.3d at 439 (explaining that if a statute assigns a particular meaning to a term—here "pharmacist"—we are bound by the

⁵We need not and do not decide whether lipoic acid is a prescription drug. If it is not, Appellants do not fall within the TMLA's definition of "pharmacist" because only a pharmacist dispensing *prescription* medications falls within the TMLA's definition of "pharmacist," and if it is—as Appellants contend—then Appellants still do not fall within the TMLA's definition of "pharmacist" because, as analyzed above, under the facts presented here they were not "dispensing" as the act of dispensing requires the existence of a practitioner's lawful order of the prescription drug for a specific person's use. See Tex. Civ. Prac. & Rem. Code Ann. § 74.001(a)(22) (defining pharmacist); Tex. Occ. Code Ann. § 551.003(16), (43) (defining dispensing and ultimate user, respectively).

statutory usage). Finally, because Appellants are not health care providers, the first element of a health care liability claim does not exist.⁶ See *Loaisiga*, 379 S.W.3d at 255 (setting forth elements of health care liability claim). Therefore, the Millers were not required to file an expert report under the TMLA, and the trial court did not err by denying Appellants' motion to dismiss. We overrule Appellants' sole issue.⁷

V. RESPONSE TO THE DISSENTING OPINION

The dissenting opinion muddles the issues⁸ and misunderstands our holding. The dissenting opinion states:

⁶The cases cited by Appellants are inapposite. The cases cited by Appellants do not involve the first element of a health care liability claim—whether the defendant is a health care provider; instead, they involve the second prong—whether the claimant's cause of action is for treatment, lack of treatment, or other claimed departure from accepted standards of medical care, health care, or safety or professional or administrative services directly related to health care. See, e.g., *Ruiz v. Walgreen Co.*, 79 S.W.3d 235, 238 (Tex. App.—Houston [14th Dist.] 2002, no pet.) (addressing whether, under prior version of the TMLA, plaintiffs' pleading stated a medical malpractice claim).

⁷Having overruled Appellants' sole issue on the ground that Appellants in this case are not health care providers under the TMLA, we need not address Appellants' other arguments concerning the nature of the Millers' claims; if Appellants are not health care providers, the Millers' claims are not health care liability claims. See, e.g., *Boulder Creek Acad. v. Kline*, 392 S.W.3d 752, 755 (Tex. App.—Dallas 2012, no pet.) (holding that because the defendant did not qualify as a health care provider, the plaintiffs' claim was not a health care liability claim).

⁸For example, the dissenting opinion notes that a pharmacist may compound a "drug" (defined differently than a "prescription drug") for a practitioner's office use, but it fails to recognize that the TMLA's definition of "pharmacist" applies only to pharmacists who are dispensing or compounding *prescription* drugs and that a prescription drug by definition requires a

The majority's interpretation would deny the many pharmacists who *compound drugs for individuals* that must be administered by nurses or physicians, intravenously or otherwise, of the protections afforded to them by the TMLA simply because the pharmacist did not personally *deliver the prescription to the recipient*.

Dissenting Op. at 7 (emphasis added). And further states:

According to the majority's interpretation, the difference between holding a pharmacist liable under the TMLA or ordinary tort law could be whether a nurse or physician administered the drug as opposed to the pharmacist directly *delivering the prescription to the patient*.

Id. at 17 (emphasis added). These statements in the dissenting opinion are wrong. Under our analysis set forth above, a pharmacist who is *compounding prescription drugs for individuals* does fall within the TMLA's statutory definition of a pharmacist. See Tex. Civ. Prac. & Rem. Code Ann. § 74.001(a)(22) (defining 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"); Tex. Occ. Code Ann. § 551.003(16) (defining "dispens[ing]" as prepar[ing], packag[ing], compound[ing], or label[ing] 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"); *id.* § 551.003(43) (defining "ultimate user" as a "person who obtains or possesses a

prescription, that is, a practitioner's lawful order of the prescription drug for a specific person's use. See Tex. Occ. Code Ann. § 562.152 (authorizing delivery of compounded drug—but not prescription drug—to practitioner for office use); Tex. Civ. Prac. & Rem. Code Ann. § 74.001(a)(22) (defining pharmacist); Tex. Occ. Code Ann. § 551.003(16), (18), (36), (43) (defining dispensing, drug, prescription drug, and ultimate user, respectively).

prescription drug or device for the person’s own use”). A pharmacist’s delivery of an injectable prescription drug to an “ultimate user’s agent,” i.e., to the doctor or nurse for administration to the specific person for whom the injectable drug was prescribed, does not exclude the pharmacist from the TMLA’s definition of “pharmacist,” and our opinion nowhere holds otherwise. See Tex. Civ. Prac. & Rem. Code Ann. § 74.001(a)(22); Tex. Occ. Code Ann. § 551.003(16), (43). Our holding is that Appellants here fail to meet the TMLA’s definition of pharmacist because the record before us conclusively establishes—in fact Appellants concede⁹—that they were not dispensing (or compounding) lipoic acid pursuant to a practitioner’s lawful order for any specific person, for any individual, or for any identifiable patient. They were filling a bulk phone order by Dr. Tan for his office use.

The dissenting opinion would hold—contrary to the controlling statutory definitions—that a pharmacist falls within the TMLA’s definition of pharmacist when he or she fills a telephone order for large quantities of a prescription drug for office-use administration to persons to be determined at a later date. *Cf.* Tex.

⁹During oral argument, the first question asked of Appellants’ counsel was, “This [lipoic acid] was prepared for Dr. Tan, it wasn’t prepared specifically for the plaintiff?” Appellants’ counsel answered, “That is true.” Later, counsel was asked, “The record, it sounds like at least, does not contain a written prescription, but there was a telephonic order from the doctor’s office to the pharmacy.” And she responded, “Absolutely.” She was asked, “And was that telephone order in bulk for his patients or was it specifically stated that it was addressed for these plaintiffs or this plaintiff?” She answered, “No, it was for office use. They had provided it in the past. He administers it to a number of patients.”

Occ. Code Ann. § 551.003(16), (43); see also 21 C.F.R. § 1306.04(b) (2005) (specifically prohibiting a pharmacist from filling a bulk order for a controlled substance for office use by the doctor by providing that “[a] prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients”); Tex. Health & Safety Code Ann. § 481.002(41) (West 2010) (defining “prescription” as “an order by a practitioner to a pharmacist for a controlled substance *for a particular patient*”) (emphasis added). Appellants did not compound the lipoic acid pursuant to a prescription for Stacey or for delivery to Stacey—the ultimate user. See Tex. Occ. Code Ann. § 551.003(16), (43). Because the lipoic acid was ordered in bulk, not prescribed for any particular person, Appellants could not be compounding the lipoic acid for any particular person, and Dr. Tan cannot be the “agent” of some yet to be determined user. See *id.* § 551.003(16), (43). Appellants fail to meet the TMLA’s definition of pharmacist either because (if lipoic acid is a prescription drug) they were not dispensing lipoic acid pursuant to a practitioner’s lawful order of the drug for any specific person or because (if lipoic acid is not a prescription drug) only pharmacists who, for the purposes of the TMLA are performing “those activities limited to the dispensing of *prescription* medicines” fall within the TMLA’s definition of “pharmacist.” See Tex. Occ. Code Ann. § 551.003(16), (43); Tex. Civ. Prac. & Rem. Code Ann. § 74.001(a)(22).

The dissenting opinion contains nice policy arguments, a good legislative history of the TMLA, and lots of cases claiming to explain current trends in the interpretation of the TMLA concerning elements of health care liability claims other than the one at issue here—whether Appellants meet the definition of a health care provider. We do not disagree with any of this generic information set forth in the dissenting opinion. But it contributes nothing to the required statutory construction analysis. As set forth above, applying the relevant statutory definitions in this case—as we must—under these facts Appellants do not meet the TMLA’s definition of pharmacist. See *TGS-NOPEC*, 340 S.W.3d at 439; *Needham*, 82 S.W.3d at 318.

VI. CONCLUSION

Having overruled Appellants’ sole issue, we affirm the trial court’s order denying Appellants’ motion to dismiss.

SUE WALKER
JUSTICE

PANEL: LIVINGSTON, C.J.; GARDNER and WALKER, JJ.

LIVINGSTON, C.J. filed a dissenting opinion.

DELIVERED: September 19, 2013