# TEXAS COURT OF APPEALS, THIRD DISTRICT, AT AUSTIN

NO. 03-14-00277-CV

Verticor, Ltd., Appellant

v.

### Michael Wood, Appellee

FROM THE DISTRICT COURT OF TRAVIS COUNTY, 419TH JUDICIAL DISTRICT NO. D-1-GN-13-002432, HONORABLE AMY CLARK MEACHUM, JUDGE PRESIDING

## **OPINION**

The pivotal issue in this appeal—one of first impression for this Court—is whether personal-injury claims asserted against the manufacturer of a medical device are "health care liability claims" within the meaning of the Texas Medical Liability Act (TMLA). At least on this record, we hold they are not.

#### **BACKGROUND**

The underlying dispute arises from surgery performed on appellee Michael Wood by James Hansen, M.D., to treat a herniated disc in Wood's lumbar region. As part of the procedure, Dr. Hansen inserted into Wood's spine a device known as the "Eclipse Sphere" that was manufactured by Verticor, Ltd., the appellant here. Complications subsequently developed, and Wood eventually sued both Dr. Hansen and Verticor for money damages.

Wood's liability theories center primarily on a contention that Dr. Hansen used the Eclipse Sphere in a "motion-sparing, non-fusion" surgical procedure even though the federal Food and Drug Administration had cleared the device solely for use in "lumbar intervertebral fusion procedures" and required that a warning be placed on all product packaging and surgical manuals stating that "the safety and effectiveness of this device for use in motion-sparing non-fusion procedures has not been established." Wood alleges in part that Dr. Hansen acted with professional negligence and gross negligence in performing this "off-label" and "experimental" procedure and in failing to obtain Wood's informed consent to it. Wood further complains that Verticor solicited Dr. Hansen's "off-label" use of the Eclipse Sphere and failed to disclose the FDA warning adequately, seeking recovery based on theories of strict product liability for "marketing defect," negligent marketing of the device, and breach of the implied warranty of merchantability. Wood additionally claims that both defendants engaged in a "fraudulent" scheme whereby Verticor made "secret payments" or "kickbacks" to Dr. Hansen to induce his "off-label" uses of the device.

The merits of Wood's allegations are not yet before us—instead, we are called upon only to consider the extent to which his claims implicate the requirements and limitations of the TMLA. The TMLA imposes several substantive and procedural constraints on the prosecution of "health care liability claims" (HCLCs), including damage caps² and the now-familiar (and often-litigated) requirement that a plaintiff must serve one or more "expert reports" as to "each physician

Wood elaborates that the FDA, which regulates the market entry of new medical devices, cleared the Eclipse Sphere for sale through its "510(k)" premarket notification process, an exception to the agency's more rigorous premarket approval requirements that is tied to the device's "substantial equivalence" to a pre-existing device. *See generally Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476–80 (1996) (summarizing the regulatory regime).

<sup>&</sup>lt;sup>2</sup> See Tex. Civ. Prac. & Rem. Code §§ 74.301–.303.

or health care provider against whom a liability claim is asserted" early in the suit or else face dismissal of that claim, with fee shifting, upon motion of that defendant.<sup>3</sup> 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 or death of a claimant, whether the claimant's claim or cause of action sounds in tort or contract.<sup>4</sup>

One implication of this definition, important for this case, is that "only claims brought against physicians and health care providers may qualify as health care liability claims."<sup>5</sup>

Wood has acknowledged that he asserted one or more HCLCs against Dr. Hansen, a physician, and has, accordingly, served what is intended to be a TMLA-compliant "expert report" regarding that defendant. As to Verticor, however, Wood has insisted that his claims each fall

<sup>&</sup>lt;sup>3</sup> *Id.* § 74.351(a), (b); *see Randol Mill Pharmacy v. Miller*, 465 S.W.3d 612, 615–16 (Tex. 2015). To be precise, the expert-report requirement applies to a "claimant" who asserts an HCLC, but "claimant" for present purposes is merely synonymous with a plaintiff who asserts such a claim. *See* Tex. Civ. Prac. & Rem. Code § 74.001(a)(2) (defining "claimant" as "a person, including a decedent's estate, seeking or who has sought recovery of damages in a health care liability claim"). Consequently, there is no dispute here that Wood would be a "claimant" for purposes of the TMLA's expert-report requirement to the extent his claims qualify as HCLCs.

<sup>&</sup>lt;sup>4</sup> Tex. Civ. Prac. & Rem. Code § 74.001(a)(13).

<sup>&</sup>lt;sup>5</sup> Randol Mill Pharmacy, 465 S.W.3d at 616 (quoting Tex. Civ. Prac. & Rem. Code § 74.001(a)(13)); see also Texas West Oaks Hosp., LP v. Williams, 371 S.W.3d 171, 179–80 (Tex. 2012) ("An HCLC contains three basic elements: (1) a physician or health care provider must be a defendant; (2) the claim or claims at issue must concern treatment, lack of treatment, or a departure from accepted standards of medical care, or health care, or safety or professional or administrative services directly related to health care; and (3) the defendant's act or omission complained of must proximately cause the injury to the claimant.").

outside the TMLA's definition of an HCLC and, in turn, are not subject to the Act's procedures and limitations. That issue was initially raised by Verticor in its answer, in which it pleaded, as an affirmative defense, that "Verticor is a healthcare provider as defined by statute and case law" and that "[Wood's] claims are, in reality, healthcare liability claims as that term is defined by [the TMLA]." Verticor's pleading prompted Wood to move for partial summary judgment that Verticor is not a "health care provider" as defined by the TMLA (a conclusion that, again, would also mean that his claims against Verticor could not be HCLCs).

In his summary-judgment motion, Wood asserted no-evidence grounds challenging whether Verticor could present evidence that it met any component of the TMLA's definition of "health care provider." That definition states as follows:

- (A) "Health care provider" means 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:
  - (i) a registered nurse;
  - (ii) a dentist;
  - (iii) a podiatrist;
  - (iv) a pharmacist;
  - (v) a chiropractor;
  - (vi) an optometrist;

<sup>&</sup>lt;sup>6</sup> See Randol Mill Pharmacy, 465 S.W.3d at 616 (quoting Tex. Civ. Prac. & Rem. Code § 74.001(a)(13)). There has been no contention that Verticor is a physician, so Wood's claims against it could be HCLCs only if (1) Verticor is a "health care provider" and (2) the other elements of an HCLC definition are also satisfied.

- (vii) a health care institution; or
- (viii) a health care collaborative certified under Chapter 848, Insurance Code.

#### (B) The term includes:

- (i) an officer, director, shareholder, member, partner, manager, owner, or affiliate of a health care provider or physician; and
- (ii) an employee, independent contractor, or agent of a health care provider or physician acting in the course and scope of the employment or contractual relationship.<sup>7</sup>

Wood also asserted "traditional" grounds seeking to negate certain of the definition's components with evidence that consisted of Verticor's responses to requests for admissions. In them, Verticor had admitted that, *inter alia*, none of its principals or employees is a registered nurse, dentist, podiatrist, pharmacist, chiropractor, or optometrist; that neither "Verticor nor any of its employees performed any act or furnished any treatment to [Wood]; and that "Verticor is not licensed to perform healthcare."

In response to Wood's no-evidence grounds, Verticor joined issue only with respect to the portion of the definition's paragraph (A) that refers generally to a "person, partnership, professional association, corporation, facility, or institution duly licensed, certified, registered, or chartered by the State of Texas to provide health care." As evidence that it met that requirement, Verticor relied solely on proof that it had operated at relevant times under a "device manufacturer"

 $<sup>^7\,</sup>$  Tex. Civ. Prac. & Rem. Code § 74.001(a)(12).

<sup>&</sup>lt;sup>8</sup> Verticor similarly admitted that none of its principals or employees holds "any advanced degree in the medical or healthcare field."

license issued by the Texas Department of State Health Services. Verticor likewise denied that it had conceded the issue through its admissions that it "is not licensed to *perform* health care" or that neither it nor any employee had "performed any act or furnished any treatment to [Wood]." What the TMLA's definition of "health care provider" actually required, Verticor urged, was that it be "licensed . . . to *provide* health care," not that it be licensed to perform any procedure or treatment directly on Wood. It was "licensed . . . to provide health care," Verticor insisted, because it was licensed to manufacture a medical device that is used in and integral to medical procedures that physicians like Dr. Hansen perform on patients like Wood.

The district court granted Wood's motion for partial summary judgment without specifying the grounds on which it relied. Subsequently, Verticor moved for reconsideration of that order. Contemporaneously with this motion, Verticor filed—in its first request for affirmative relief based on its arguments seeking to invoke the TMLA—a motion to dismiss Wood's claims against it on the basis that Wood, consistent with his position that the Act was inapplicable, had not timely served the "expert report" that the Act would require. In support of these motions, Verticor presented no new evidence to demonstrate that it is a "health care provider" or that the claims against it are "health care liability claims."

<sup>&</sup>lt;sup>9</sup> Verticor also urged that it had not been afforded adequate opportunity for discovery, *see* Tex. R. Civ. P. 166a(i), but has not brought this complaint forward on appeal. Nor has it preserved any other objection regarding Wood's no-evidence motion.

<sup>&</sup>lt;sup>10</sup> See Tex. Civ. Prac. & Rem. Code § 74.351(a), (b).

The district court denied both Verticor's motion to reconsider the prior summary-judgment ruling and the new motion to dismiss. <sup>11</sup> Verticor timely perfected an appeal from the order denying its motion to dismiss. <sup>12</sup> Our statutory grant of jurisdiction over this interlocutory appeal also extends to reviewing the district court's otherwise-unappealable interlocutory summary-judgment order, to the extent that ruling bears upon the validity of the appealable order. <sup>13</sup>

The district court had initially issued a letter indicating that it would deny Verticor's motion for reconsideration but would decline to rule on Verticor's motion to dismiss, in the view that its summary-judgment ruling would "moot" the expert-report issue. After Verticor objected, the district court proceeded also to rule on Verticor's motion to dismiss and denied it, and the court's signed order reflects both this ruling and its denial of reconsideration.

<sup>&</sup>lt;sup>12</sup> See id. § 51.014(a)(9) (authorizing interlocutory appeal from an order that "denies all or part of the relief sought by a motion under Section 74.251(b)); Tex. R. App. P. 26.1(b), 28.1 (twenty-day deadline to perfect this appeal). Although Verticor's motion to dismiss necessarily turned in part on whether it was a "health care provider," an issue already addressed in the district court's earlier summary-judgment ruling, the dismissal motion marked the first occasion in which Verticor, in either form or substance, had sought "the relief sought by a motion under Section 74.241(a)"—dismissal based on Wood's failure to file an expert report. Consequently, this is not a situation in which the earlier summary-judgment ruling would be deemed a "den[ial of] all or part of the relief sought by a motion under Section 74.251(b)" that triggered Verticor's appellate deadlines and rendered untimely its appeal from the later ruling on its dismissal motion. Cf. Texas Cityview Care Ctr. LP v. Foster, No. 02–13–00315–CV, 2015 WL 736559, at \*3 (Tex. App.—Fort Worth Feb. 19, 2015, no pet.) (mem. op.) (where defendant filed TMLA motion to dismiss, was denied, and subsequently "repackaged" motion as a "motion for summary judgment" that was also denied, then attempted to appeal latter ruling under Tex. Civ. Prac. & Rem. Code § 51.014(a)(9), appellate court lacked jurisdiction because ruling substantively was the unappealable denial of a motion to reconsider an order that "denies all or part of the relief sought by a motion under Section 74.251(b)," not an appeal from an order denying the original motion, and came too late to invoke appellate jurisdiction to review the order denying the original motion (citing City of Houston v. Estate of Jones, 388 S.W.3d 663, 667 (Tex. 2012) (analogous holdings regarding attempted interlocutory appeal of order denying a successive duplicative plea to the jurisdiction))). Though he chides Verticor for its multiple "bites at the apple" below, Wood has not asserted that the prior summary-judgment ruling gives rise to any jurisdictional impediment on appeal.

<sup>&</sup>lt;sup>13</sup> See Railroad Comm'n v. Air Prods. & Chems., Inc., 594 S.W.2d 219, 221–22 (Tex. Civ. App.—Austin 1980, writ ref'd n.r.e.) ("Non-appealable interlocutory orders cannot be attacked in an appeal from an appealable interlocutory order, except insofar as the question raised might

#### **ANALYSIS**

In a single issue on appeal, Verticor urges that the district court had no discretion but to grant its TMLA motion to dismiss based on Wood's failure to serve an "expert report" with respect to his claims against the company. Verticor cannot prevail, as it acknowledges, unless it can establish that it is a "health care provider" as defined by the TMLA. In the posture of this case, that issue turns on the meaning of a particular phrase within that definition, "licensed . . . by the State of Texas to provide health care." And, as Verticor has relied solely on evidence that it holds a type of license from the State of Texas, a "device manufacturer" license, the issue distills further to whether this license means Verticor is "licensed . . . by the State of Texas to provide health care," as the definition requires. Further, as framed by the proceedings below, Verticor's argument reduces to the narrow proposition that it is "licensed . . . by the State of Texas to provide health care" because it is licensed to manufacture a medical device that is then used by another person or entity in the care or treatment of a patient. There is no evidence nor contention from Verticor, for example, that it had any involvement whatsoever in Wood's care or treatment, or was licensed to be involved in his care or treatment, beyond merely manufacturing the Eclipse Shield that Dr. Hansen ultimately used in Wood's surgery and placing it in the stream of commerce. In fact, Verticor's admissions negate such direct or additional involvement.

Resolution of these questions turns on construction of the TMLA, a question of law that we review de novo.<sup>14</sup> Our primary objective in construing a statute is "to determine and

affect the validity of the appealable order." (citing *State v. Cook United, Inc.*, 464 S.W.2d 105, 106 (Tex. 1971); *Texas State Bd. of Exam'rs in Optometry v. Carp*, 343 S.W.2d 242, 234 (Tex. 1961))).

<sup>&</sup>lt;sup>14</sup> See Texas West Oaks, 371 S.W.3d at 177 (citing MCI Sales & Serv., Inc. v. Hinton, 329 S.W.3d 475, 500 (Tex. 2010)).

give effect to the Legislature's intent."<sup>15</sup> We rely on the plain meaning of the text as expressing the Legislature's intent unless a different meaning is supplied by legislative definition or is apparent from the context, or the plain meaning leads to "absurd results" that the Legislature could not possibly have intended. Further, the Legislature has specifically instructed that "[a]ny legal term or word of art used in [the TMLA], not otherwise defined [therein], shall have such meaning as is consistent with the common law." We presume the Legislature selected language in a statute with care and acted purposefully in including or excluding particular words and phrases. <sup>18</sup>

Whether Verticor is "licensed . . . by the State of Texas to provide health care" turns in part on the meaning of "health care," which is itself a defined term within the TMLA. "Health care" means "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." The crux of Verticor's position is that it "provide[s] health care" under its "device manufacturer" license, and is thus a "health care provider," because it provides the Eclipse Shield "for, to, or on behalf of a patient during the patient's medical care, treatment, or confinement." Verticor's reasoning is belied by a close examination of the statutory text.

Verticor's argument might find stronger support if the TMLA's "health care provider" definition had referred to a person "licensed . . . by the State of Texas to provide

<sup>&</sup>lt;sup>15</sup> Texas Lottery Comm'n v. First State Bank of DeQueen, 325 S.W.3d 628, 635 (Tex. 2010).

<sup>&</sup>lt;sup>16</sup> *Id*.

<sup>&</sup>lt;sup>17</sup> Tex. Civ. Prac. & Rem. Code § 74.001(b).

<sup>&</sup>lt;sup>18</sup> *DeQueen*, 325 S.W.3d at 635.

<sup>&</sup>lt;sup>19</sup> Tex. Civ. Prac. & Rem. Code § 74.001(10).

products or services used in health care" or that "have some relationship to health care." But the Legislature did not write the statute that way—instead, it required that a "health care provider" be "licensed... by the State of Texas to provide health care." That phrasing indicates that Verticor's license must authorize it "to provide" something that is in itself "health care."

As the issue is framed here, Verticor's license authorizes it "to provide" (at least in the sense of manufacturing and selling) the Eclipse Sphere—and nothing more. Consequently, Verticor can be "licensed... by the State of Texas to provide health care" only if the Eclipse Sphere is, in itself, "health care" as the TMLA defines that term. That definition defies such an application. Under it, "health care" is distinguished by either of two nouns—"act" or "treatment"—that is "performed or furnished," or should have been, "for, to, or on behalf of a patient during the patient's medical care, treatment, or confinement." The first alternative, an "act," denotes some sort of deed or activity. As an inanimate object, the Eclipse Shield, in itself, could not be an "act," although it might be utilized in acts that qualify as "health care," such as surgery. Similarly, the other alternative, "treatment" also denotes some form of activity that is performed or furnished for or to a patient. Consequently, the Eclipse Shield would not, in itself, be a "treatment," although it might be utilized in a "treatment." Indeed, Verticor effectively concedes these same conclusions

See The Compact Edition of the Oxford English Dictionary 14 (2d ed. 1994) (defining noun "act" as a "thing done; a deed, a performance (of an intelligent being)"); American Heritage Dictionary of the English Language 16 (5th ed. 2011) (defining noun "act" as the "process of doing or performing something" and "[s]omething done or performed; a deed").

<sup>&</sup>lt;sup>21</sup> See Black's Law Dictionary 1731, 1732 (10th ed. 2014) (defining "treat" as "care for (a medical patient); to try to cure the illness or injury of (a person) by using medicine, hospital care, surgery, etc." and "subject (a disease, debility, etc.) to a regimen of medicine, exercise, etc."); see also Covenant Health Sys. v. Barnett, 342 S.W.3d 226, 230–31 (Tex. App.—Amarillo 2011, no pet.) (concluding that heart screening is within TMLA's definition of "treatment" by referring to Black's Law Dictionary and medical dictionary and citing TMLA section 74.001(b)).

through its admission that neither it nor any of its employees "performed any act or furnished any treatment to Wood."

These conclusions find further support when taking account of the broader statutory and jurisprudential context in which this language appears.<sup>22</sup> Historically, Texas common law has distinguished between the tort duties owed by health-care practitioners, which focus on specialized "standards of care" that define the parameters of reasonableness in providing their services to patients, versus the duties owed by the manufacturers and sellers of the products utilized by health-care practitioners, which focus on the condition of the product itself or the manner in which it was made or sold.<sup>23</sup> One corollary of this basic distinction, in fact, is that the "learned intermediary" doctrine may limit the duty of a manufacturer or seller of prescription drugs or medical devices to warn end users of the product's dangerous propensities, in the view that a physician or health care provider who receives an adequate warning should be relied upon to convey such information to the end user as is appropriate under the circumstances.<sup>24</sup> The distinction is also reflected in important

See, e.g., In re Office of Attorney Gen., 422 S.W.3d 623, 629 (Tex. 2013) ("We must endeavor to read the statute contextually, giving effect to every word, clause, and sentence."); TGS-NOPEC Geophysical Co. v. Combs, 340 S.W.3d 432, 441 (Tex. 2011) ("Language cannot be interpreted apart from context. The meaning of a word that appears ambiguous when viewed in isolation may become clear when the word is analyzed in light of the terms that surround it."); see also Texas Bd. of Chiropractic Exam'rs v. Texas Med. Ass'n, 375 S.W.3d 464, 474 (Tex. App.—Austin 2012, pet. filed) ("We also presume that the legislature was aware of the background law and acted with reference to it." (citing Acker v. Texas Water Comm'n, 790 S.W.2d 299, 301 (Tex. 1990)).

<sup>&</sup>lt;sup>23</sup> See, e.g., Ethicon, Inc. v. Parten, 520 S.W.2d 527, 532–34 (Tex. Civ. App.—Houston [14th Dist.] 1975, no writ) (in case involving broken surgical needle left in patient, appellate court resolved issues as to needle manufacturer under products-liability law and issues as to physician under medical-malpractice law).

<sup>&</sup>lt;sup>24</sup> See Centocor Inc. v. Hamilton, 372 S.W.3d 140, 153–70 (Tex. 2012) (extensively analyzing the "learned intermediary" doctrine and its underlying rationales and applying it to hold

differences between the TMLA and the statutory scheme the Legislature has addressed to claims arising from the allegedly defective condition of products.

In 1993, the Legislature enacted Chapter 82 of the Civil Practice and Remedies Code to impose certain limitations upon "products liability actions," defined as those asserted against a "manufacturer" or "seller" for recovery of personal injuries or property damage "allegedly caused by a defective product whether that action is based on strict tort liability, strict products liability, negligence, misrepresentation, breach of express or implied warranty, or any other theory or combination of theories." A "manufacturer" is defined as "a designer, formulator, constructor, rebuilder, fabricator, producer, compounder, processor, or assembler of any product or any component part thereof and who places [it] in the stream of commerce," while a "seller" is "a person engaged in the business of distributing or otherwise placing, for any commercial purpose, in the stream of commerce for use or consumption a product or any component part thereof. In contrast to Chapter 82's concern with liability arising from the allegedly deficient condition of products, the TMLA is focused on liability arising from the allegedly deficient quality of services provided to a patient. Among other examples, the TMLA requires that any expert who gives

that drug manufacturer satisfied duty to warn end users of product's dangerous propensities by providing warnings to prescribing physician); *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 663 (Tex. App.—Houston [14th Dist.] 1998, no pet.) (applying doctrine to benefit of breast-implant manufacturer where entity provided warnings to physicians).

<sup>&</sup>lt;sup>25</sup> See Act of Feb. 24, 1993, 73d Leg., R.S., ch. 5, §§ 1–5, 1993 Tex. Gen. Laws 13 (codified at Tex. Civ. Prac. & Rem. Code §§ 82.001–.008).

<sup>&</sup>lt;sup>26</sup> Tex. Civ. Prac. & Rem. Code § 82.001(2).

<sup>&</sup>lt;sup>27</sup> *Id.* § 82.001(4).

<sup>&</sup>lt;sup>28</sup> *Id.* § 82.001(3).

testimony regarding the standard of care must have knowledge of "accepted standards" of "medical care" or "health care" "for the diagnosis, care, or treatment of the illness, injury, or condition involved in the claim." Against this backdrop, it would hardly be surprising that the Legislature would define "health care" under the TMLA in terms of "acts" and "treatments," as opposed to products or things.<sup>30</sup>

This understanding of "health care" also comports with the common usage of that term. While statutory definitions in theory trump the ordinary meaning of the terms being defined, the Texas Supreme Court has also instructed us to "presume that the definition of a common word accords with and does not conflict with the ordinary meaning unless the language clearly indicates otherwise." In common usage, one associates "health care" with medical intervention, assistance, or other acts—e.g., one's family doctor performing an annual physical or a nurse administering a flu shot—as opposed to the mere making or selling of a product used in providing such services.<sup>32</sup> Focusing as it does on acts and treatment provided to patients, the TMLA's definition of "health care" does not clearly depart from this basic notion.

Nor does the Act's definition of "health care provider" clearly depart from that meaning. The TMLA's definition, again, refers to persons or entities who are "duly licensed,

<sup>&</sup>lt;sup>29</sup> *Id.* §§ 74.401(a)(2), .402(b)(2).

<sup>&</sup>lt;sup>30</sup> *Id.* § 74.001(10).

<sup>&</sup>lt;sup>31</sup> *In re Ford Motor Co.*, 442 S.W.3d 265, 271 & n.20 (Tex. 2014) (citing Antonin Scalia & Bryan A. Garner, *Reading Law* 232 (2012)).

<sup>&</sup>lt;sup>32</sup> See, e.g., American Heritage Dictionary at 810 (defining "health care" as "prevention, treatment, and management of illness and the preservation of mental and physical well-being through the services offered by the medical and allied health professions").

certified, registered, or chartered by the State of Texas to provide health care," and goes on to cite several specific examples.<sup>33</sup> While these exemplars are non-exclusive, <sup>34</sup> they nonetheless tend to confirm that the Legislature had in mind the sorts of trained professionals that provide or perform the sorts of acts that one ordinarily associates with "health care"—e.g., registered nurses, dentists, podiatrists, chiropractors, optometrists, and "health care institutions," <sup>35</sup> a term that includes the likes of hospitals, ambulatory surgical centers, hospice, and nursing homes. <sup>36</sup> This is not the sort of text the Legislature would use if it intended to transform ordinary notions of "health care" or "health care provider" to include persons or entities whose only involvement in patient care is to provide some product or device used in that process.

That is not to say, however, that the acts or treatments distinguishing "health care" or "health care providers" under the TMLA cannot ever encompass some element of product manufacture or sale that would implicate Chapter 82, or vice versa. In Chapter 82, for example, the Legislature contemplated that the defendants in a "products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to pharmaceutical

<sup>&</sup>lt;sup>33</sup> See Tex. Civ. Prac. & Rem. Code § 74.001(a)(12).

<sup>&</sup>lt;sup>34</sup> See id. (preceding list of examples with "including"); Tex. Gov't Code § 311.005(13) (Code Construction Act provision stating that "[i]ncludes' and 'including' are terms of enlargement and not of limitation or exclusive enumeration, and use of the terms does not create a presumption that components not expressed are excluded"). Accord, e.g., San Antonio Extended Med. Care, Inc. v. Vasquez, 327 S.W.3d 193, 197–98 (Tex. App.—San Antonio 2010, no pet.) (reaching the same conclusion); see also Texas West Oaks, 371 S.W.3d at 179 (stating that use of "including" in TMLA's definition of "claimant" "renders any components of the definition nonexclusive" (citing Tex. Gov't Code § 311.005(13); In re Allcat Claims Serv., L.P., 356 S.W.3d 455, 468 (Tex. 2011); Entergy Gulf States, Inc. v. Summers, 282 S.W.3d 433, 440–41 (Tex. 2009)).

<sup>&</sup>lt;sup>35</sup> See Tex. Civ. Prac. & Rem. Code § 74.001(a)(12).

<sup>&</sup>lt;sup>36</sup> See id. § 74.001(a)(11).

products" may potentially include "a health care provider," although the statute does not purport to adopt the TMLA's definition of that term.<sup>37</sup> Similarly, within the TMLA, the Legislature saw fit to craft a specific definition of "pharmacist" (one of the exemplars cited in the Act's "health care provider" definition)<sup>38</sup> that serves to distinguish between HCLCs arising from pharmacists' "dispensing of prescription medicines" under their licenses, which are made subject to the Act, versus claims arising from their "manufacture" of medications or "other cause of action that may exist at common law against them, including but not limited to [those] for the sale of mishandled or defective products," which are excluded.<sup>39</sup> And some of our sister courts have held that persons or entities operating under licenses similar to Verticor's can, in some circumstances, fall within "health care providers" under the TMLA.<sup>40</sup>

From the latter group of cases, Verticor distills the broad proposition that "medical device manufacturers—like Verticor—are health care providers under the TMLA." In response, Wood urges that the opposite is true, referring us to cases that have appeared to assume that product-liability claims against medical-device manufacturers are governed by Chapter 82 to the exclusion

<sup>&</sup>lt;sup>37</sup> See id. § 82.007(a).

<sup>&</sup>lt;sup>38</sup> See id. § 74.001(a)(12)(A)(iv).

<sup>&</sup>lt;sup>39</sup> *Id.* § 74.001(a)(22); *see Randol Mill Pharmacy*, 465 S.W.3d at 617–23 (analyzing application of definition to compounding pharmacies and concluding that claims arising from compounding of pharmaceuticals were HCLCs).

<sup>&</sup>lt;sup>40</sup> See Strobel v. Marlow, 341 S.W.3d 470 (Tex. App.—Dallas 2011, no pet.); Vasquez, 327 S.W.3d at 198–99; Perkins v. Apria Healthcare, Inc., 3:10-CV-2295-D, 2012 WL 4928895, at \*3–4 (N.D. Tex. Oct. 17, 2012).

of the TMLA.<sup>41</sup> The true picture, as we have already suggested, is more complicated than either of these diametrically opposing views.

In the alternative, Wood urges that the cases on which Verticor relies are distinguishable. Those cases, Wood maintains, involve instances in which the scope of the medical-device manufacturer's licensed authority was shown to extend to the provision of acts or treatment that would plainly be "health care" under the TMLA's definition, as contrasted with the situation here, where a defendant relies on the authority to manufacture or sell a medical product. We agree with Wood. In *Strobel*, for example, the manufacturer in question was a prosthetist licensed under the Orthotics and Prosthetics Act<sup>42</sup> to custom fabricate or fit medical devices to replace the missing limbs of specific patients. Further, there was evidence that the license extended to providing direct patient care, Plainly acts or treatment that would characterize "health care" under the TMLA. Similarly, in *Vasquez*, the San Antonio Court of Appeals emphasized proof that the licensee was authorized by the Department of State Health Services to manufacture and distribute oxygen, a regulated drug requiring a prescription, and that its authority extended to supplying doctor-prescribed

In re Temple, 239 S.W.3d 885, 889 (Tex. App.—Texarkana 2007, no pet.) ("Claims regarding products liability or negligent manufacture—even when those items are medical devices—are not expressly or impliedly covered by Chapter 74."); accord Meredith v. NuVasive, Inc., No. A-13-CA-208-SS, slip op. at 7 (W.D. Tex. Dec. 9, 2013) (citing Temple, 239 S.W.3d at 889, to support its conclusion that, in Texas, products liability claims are distinguishable from health care liability claims, even where negligence theories are involved).

<sup>42</sup> See Strobel, 341 S.W.3d at 474; see also Tex. Occ. Code §§ 605.001-.411 (Act).

<sup>&</sup>lt;sup>43</sup> See Tex. Occ. Code § 605.002(8) (defining "Licensed prosthetist"), (17) (defining "Prosthesis"), (18) (defining "Prosthetics").

<sup>&</sup>lt;sup>44</sup> See id. § 605.002(16) ("Orthotic and prosthetic services include direct patient care, including consultation, evaluation, treatment, education, and advice to maximize the rehabilitation potential of disabled individuals."); *Strobel*, 341 S.W.3d at 475–76.

"oxygen therapy" to a patient in his home, including setting the flow rate for the oxygen tanks. 45 At

most, these authorities would refute the categorical notion that medical-device manufacturers can

never be "health care providers." They fall far short of demonstrating that the mere manufacture

and sale of a medical device ipso facto constitutes the provision of "health care" under the TMLA,

as Verticor argues.

Without more, Verticor has not raised a fact issue, let alone demonstrated

conclusively, that it is a "health care provider" under the TMLA. Consequently, Wood's claims

against it cannot be HCLCs, and the district court did not err in denying Verticor's motion to

dismiss. We overrule Verticor's issue on appeal.

**CONCLUSION** 

We affirm the district court's order denying Verticor's motion to dismiss Wood's

claims against it.

Bob Pemberton, Justice

Before Justices Puryear, Pemberton, and Field

Affirmed

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<sup>45</sup> Vasquez, 327 S.W.3d at 198–99. As for the remaining case cited by Verticor, *Perkins*, it is factually similar to Vasquez and, as such, relies on its holding. See Perkins, 2012 WL 4928895,

at \*5.

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