# TADC
# PRODUCTS LIABILITY NEWSLETTER

***Selected Case Summaries***
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## I. SUMMARY

**1. In a case of first impression, the Austin Court of Appeals held that, under the Texas Medical Liability Act (TMLA), a medical device was not itself "health care" and that products liability claims against the manufacturer of the device were therefore not subject to the additional procedural requirements and limitations of the TMLA.** *Verticor, Ltd. v. Wood*, No. 03-14-00277-CV, 2015 WL 7166024 (Tex. App.—Austin Nov. 13, 2015, pet. filed Dec. 23, 2015).

**2. For a plaintiff challenging defendant's assertion of the trade secret privilege to protect product specifications and financial information during discovery, (1) the bare assertion that defendant's affidavit in support of its privilege was not based on personal knowledge was not sufficient to invalidate the affidavit and (2) plaintiff's failure to articulate its need for the requested discovery in order to prove a safer alternative design defeated plaintiffs' request.** *In re Michelin North America, Inc.*, No. 05-15-01480-cv, 2016 WL 890970 (Tex. App.—Dallas Mar. 9, 2016, no pet. h.).

**3. An airplane insurer who sold salvaged aircraft could be reasonably found not to fall under the laws governing sellers of unreasonably dangerous products where the particular products at issue were the engine and vacuum pump of a salvaged aircraft, and the airplane insurer only sold whole salvaged aircraft.** Clay v. AIG Aerospace Insurance Services, Inc., No. 06-15-00024-cv, 2016 WL 1252628 (Tex.App.—Texarkana Mar. 31, 2016, no. pet. h.).

**4. Testimony in a products liability case regarding a witness's inability to form an opinion on, or the lack of evidence sufficient to make a conclusion as to, whether a product caused the plaintiff's injury is expert testimony, subject to *Daubert*.** *Carlson v. Bioremedi Therapeutic Systems, Inc.*, No. 14-20691, 2016 WL 2865256 (5th Cir. May 16, 2016).

**5. The United States District Court for the Southern District of Texas held that the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act expressly preempted claims for design defect, manufacturing defect, failure to warn, negligence and breach of warranty against the manufacturer of a surgically implanted medicine delivery pump.** *Morgan v. Medtronic, Inc.*, No. 3:15-cv-32, 2016 WL 1162400 (S.D. Tex. March 22, 2016).

## II. DISCUSSION

### 1. *Verticor, Ltd. v. Wood*, No. 03-14-00277-CV, 2015 WL 7166024 (Tex. App.—Austin Nov. 13, 2015, pet. filed Dec. 23, 2015).

In a case of first impression, the Austin Court of Appeals held that, under the Texas Medical Liability Act (TMLA), a medical device was not itself "health care" and that products liability claims against the manufacturer of the device were therefore not subject to the additional procedural requirements and limitations of the TMLA.

Plaintiff Wood underwent surgery to treat a herniated disc in his lumbar region. During the surgery, Wood's surgeon inserted an "Eclipse Sphere" device into Wood's spine. Wood alleged that the use of the device in his surgery was "off-label" and "experimental" and caused complications after his surgery. Wood sued both his surgeon, for negligence and fraud, and the manufacturer of the Eclipse Sphere device, Verticor—for certain products liability claims.

The TMLA established several procedural and substantive limitations on the litigation of health care liability claims, including damage caps and special expert discovery rules. 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 . . . which proximately results in injury or death of a claimant, whether the claimant's claim or cause of action sounds in tort or contract

(emphasis added).

In his suit, Wood acknowledged that one or more of his claims against his surgeon fell under the TMLA. Verticor, in its answer to Wood's complaint, attempted to bring its lawsuit under the TMLA umbrella as well, by alleging that it was a "health care provider" under the TMLA and that the products liability claims against Verticor were also health care liability claims. In response, Wood filed a partial motion for summary judgment that Verticor is not a health care provider under the TMLA.

Verticor contended that it fell under the definition as "person, partnership, professional association, corporation, facility, or institution duly licensed, certified, registered, or chartered by the State of Texas *to provide health care*," supporting this with evidence of Verticor's "device manufacturer" license issued by the Texas Department of State Health Services (emphasis added). Although by Verticor's own admission, it did not "*perform* health care," according to Verticor, it was licensed by the state to "*provide* health care" in the form of medical devices that were subsequently used in medical procedures by physicians on patients.

Without specifying the grounds on which it relied, the district court granted Wood's motion for partial summary judgment. Verticor simultaneously moved the court to reconsider that order and filed a motion to dismiss based on Wood's failure to comply with the expert report requirements of the TMLA. When the district court denied both motions, Verticor appealed the denial of its motion to dismiss.

On appeal, the Court considered Verticor's argument that it fell within the bounds of the TMLA's "health care provider" definition because it is "licensed ... by the State of Texas to provide health care " by virtue of the "device manufacturer" license. The Court first turned to the plain language of the statute and its definition of "health care," noting that this definition does not reference the provision of "products or services used in health care," but limits its scope to the provision of a specific act or treatment. Although the Eclipse Sphere device may be *used* in a treatment, the Court explained, the device is not a treatment itself, and is therefore not included in the TMLA definition of "health care."

The Court supported this conclusion through the examination of Texas common law distinction between duties of health care practitioners, which address the reasonableness of patient treatment, and duties of manufacturers and sellers, which address the condition of the product and its manufacture and sale. The Court additionally illustrated this distinction through reference to the separate statutory schemes of the TMLA and Chapter 82 of the Texas Civil Practice and Remedies Code's provisions regarding products liability actions.

Ultimately, the Court rejected Verticor's argument. In its analysis, the Court acknowledged that the TMLA's treatment of medical device manufacturers is not always categorically black and white. The Court noted a handful of decisions from other courts finding medical device manufacturer to be health care providers where the relevant state license allowed license-holders to provide some form of direct patient care. For Verticor, however, the evidence presented did not create an issue of fact, let alone conclusively demonstrate, that it was a health care provider under the TMLA. As such, Wood's products liability claims against Verticor were not subject to the TMLA's procedural requirements or damages caps.

**2. *In re Michelin North America, Inc.*, No. 05-15-01480-cv, 2016 WL 890970 (Tex. App.—Dallas Mar. 9, 2016, no pet. h.).**

The Dallas Court of Appeals applied the trade secrets privilege to limit the scope of a trial court discovery order that required the defendant to produce certain manufacturing specifications and financial data.

On September 3, 2012, the Plaintiffs, the Medina family were injured in a single-car accident after one of their vehicle's tires failed. The tire that failed was produced by Michelin and manufactured at Michelin's plant in Dothan Alabama in 2001. The Medinas sued Michelin for strict products liability, among other claims, and alleged that the tire was defective for a number of reasons related to its production.

During discovery, Michelin produced documents related to the tire model that failed on the Medina's car for its entire six-year production period, as well as documents related to three similar tires produced at the Dothan facility. However, Michelin objected to a majority of the Medina's further discovery requests, asserting that the requests were both overbroad and that they sought disclosure of Michelin's trade secrets.

The Medinas moved to compel production of Michelin's tire aspect specifications, *i.e.* the plant-specific quality assurance documents used during post-manufacturing inspection. The Medinas contended that these documents were necessary to "show that the defects/conditions/components alleged" in the lawsuit were present when the tire left the factor.

Michelin's production included the Dothan plant's aspect specifications related to the particular tire model that failed, but the trial court ordered further production of aspect specifications for different sized tires produced in different plants. Upon the Medinas' request, the trial court also ordered Michelin to produce a corporate representative to give deposition testimony regarding Michelin's financial condition from two years prior to the incident to the current time. Michelin filed an emergency motion for mandamus relief, requesting that the trial court withdraw these portions of the discovery orders because the discovery sought protected trade secrets.

Michelin supported its trade secret assertion by an affidavit of a Michelin senior technical advisor. The advisor attested, among other things, that the company's aspect specification documents are marked with Michelin's designation for confidential documents and that no two Michelin plants have the same equipment, leading each plant to develop its own specifications. Michelin also offered an affidavit of its controller, who testified that Michelin's financial statements are consolidated with its corporate parent's financial statements and not publicly available and that Michelin considers its financial information "highly confidential" and "vitally sensitive."

The Medinas challenged both affidavits. As for the tire specifications affidavit, the Medinas argued that it did not satisfy Michelin's burden of asserting the trade secret privilege because the affiant lacked personal knowledge. In essence, the Medinas alleged that the affidavit was "made up" by the Michelin legal team. Regarding the financial affidavit, the Medinas argued that Michelin had waived its trade secret privilege by failing to produce the affidavit until after the relevant hearing and trial court order.

The Dallas Court of Appeals rejected both arguments. The Court determined that the record sufficiently established the senior technical advisor's personal knowledge of Michelin's tire manufacturing and inspection processes, despite the fact that the advisor had never personally worked in those capacities. As the Court noted, the advisor was a "trained chemical engineer" and had previously worked as a tire designer.

Based on the "length of [the advisor's] employment and the nature of his positions," the Court found a basis for his personal knowledge of Michelin's trade secret policies.

The Court found that the Medinas had not only failed to effectively challenge the basis of the affidavit, but further failed to meet their own burden to show how the lack of the requested information would impair their case and cause an unjust result. While the Medinas asserted that the information was needed to prove the existence of a safer alternative design, the Court identified "no effort" by the Medinas to demonstrate that the trade secret information was the only means of proving this. Based on the Medinas' failure to articulate a need for the aspect specifications of the tires of different sizes and manufacturing locales ordered by the trial court, the Court also found that the order was overly broad. As stated by the Court, parties alleging a safer alternative design are not permitted to "go fishing" among documents describing a defendant's products to "attempt to stumble upon some element of another product . . . that might prove to be safer."

With respect to the financial affidavit, the Court determined that although Michelin's failure to timely produce the affidavit waived its trade secret argument, the trial court's order regarding discovery of financial information was overly broad. Under Texas law, the Medinas were entitled only to documents showing the current net worth of Michelin. Because the Medinas had made no showing that Michelin's current balance sheet was insufficient to provide an accurate representation of Michelin's current net worth, they were not entitled to the years of financial statements ordered by the trial court.

Therefore, the Court granted Michelin's writ of mandamus and limited the scope of the trial court's discovery order as to both Michelin's tire aspect specifications and financial statements.

**3. *Clay v. AIG Aerospace Insurance Services, Inc.*, No. 06-15-00024-cv, 2016 WL 1252628 (Tex.App.—Texarkana Mar. 31, 2016, no. pet. h.).**

The Texarkana Court of Appeals affirmed a jury verdict that relieved AIG, an airplane insurer, from liability for the deaths of a pilot, Phillips, and his passenger in a private airplane crash caused by the failure of a engine that had been resold by AIG as part of a salvaged aircraft. The Court found that evidence was sufficient to support the jury's findings that AIG was not engaged in the business of selling aircraft engines and that any negligence by AIG in selling the salvaged aircraft did not proximately cause the deaths.

In 2005, AIG resold an aircraft that had been severely damaged in a hurricane to offset the company's cost of paying the insurance claim. AIG posted the listing on the company's salvage sales website, and noting that the aircraft was a "hurricane loss," describing damage to "both wings, all control surfaces, tail section, prop, fuselage, [and] cowling," and displaying photographs of the interior and exterior damage. The listing also stated that the aircraft was being sold "AS IS/WHERE IS."

The original buyer of the aircraft received the aircraft's maintenance records, photographs of the damage, and logbooks. The logbooks did not include any record of the hurricane damage. Six years later, the original buyer resold the salvaged aircraft's engine to a business that bought and sold aircraft engines. The original buyer and secondary reseller disputed whether the original buyer informed the secondary reseller about the hurricane damage. However, the secondary reseller received the engine's logbooks, which indicated that the engine had not been inspected during the previous six years and that its vacuum pump had been in service for at least twelve years.

Without inspecting the interior of the engine, the secondary engine reseller sold the salvaged engine to Phillips, who had it installed in his private aircraft. Thirteen minutes after takeoff on its initial flight, the engine's vacuum pump failed, and the aircraft crashed, killing both Phillips and his passenger.

The estates and families of Phillips and the passenger (the "Plaintiffs") sued AIG, alleging that the company was strictly liable and negligent because it failed to provide adequate warnings regarding its sale of a salvaged aircraft engine. At trial, the jury found that (1) AIG was not in the business of selling engines and vacuum pumps and (2) Phillip's negligence was the sole proximate cause of the crash. The Plaintiffs appealed the verdict, contending that the evidence was factually insufficient to support these findings.

Section 402A of the Restatement (Second) of Torts, as applied by Texas courts, holds strictly liable sellers who are engaged in the business of selling unreasonably dangerous defective products to consumers. However, the Court accepted the jury's apparent distinction between categories of unreasonably dangerous products, finding that the jury could have reasonably determined that AIG was not "engaged in the business of selling aircraft engines and vacuum pumps" where the evidence was undisputed that AIG had sold only whole aircraft, and had never sold aircraft engines or vacuum pumps separately.

The Court found that Plaintiffs' further argument regarding AIG's admission in its pleadings that it is a "nonmanufacturing seller" had been waived by Plaintiffs' failure to object to the introduction of evidence to the contrary and the submission of a jury question on the issue.

The Court additionally upheld the jury's finding that Phillip's negligence, and not any negligence on the parts of AIG or the other defendants, was the sole proximate cause of the deaths of Phillips and his passenger. Although the Plaintiffs argued that the duty of care required that AIG provide a proper warning of the hurricane damage in the logbook, the Court found "conflicting evidence" on the issue. Furthermore, AIG, who was neither the registered owner of the aircraft nor intending to return the aircraft to service, was exempt from record-keeping and inspection duties under the FAA and other aviation regulations. Therefore, the Court determined that the jury could have reasonably concluded that AIG was either not negligent in its actions or that any negligence on AIG's part did not proximately cause the deaths.

**4. *Carlson v. Bioremedi Therapeutic Systems, Inc.*, No. 14-20691, 2016 WL 2865256 (5th Cir. May 16, 2016).**

Plaintiff David Carlson received treatment with a ProNeuroLight device for his peripheral neuropathy, a loss of nerve sensation in his feet caused by diabetes. The ProNeuroLight uses infrared light to increase circulation in the area of application. Within 48 hours of treatment, Carlson noticed ulcers on the bottom of his heels, which, according to Carlson's podiatrist, led to a bone infection that ultimately required a below-the-knee amputation of one of Carlson's legs and a heel amputation on his opposite foot.

Carlson and his wife (the Plaintiffs) sued both the manufacturer and the distributor of the ProNeuroLight, alleging that the device caused his injury, and claiming three counts of alleged products liability—defects in design, manufacturing, and marketing. At trial, defendants called a single witness: Dr. Lance Durrett, a "chiropractor and alternative medicine specialist" who initially examined Carlson and recommended the ProNeuroLight treatment. The trial court denied Plaintiffs' pre-trial motion to exclude Dr. Durrett's testimony, and the jury returned a unanimous verdict in favor of the defendants. Plaintiffs appealed the verdict, challenging the court's admission of Dr. Durrett's testimony.

Plaintiffs argued that the trial court abused its discretion by allowing Dr. Durrett to opine on matters outside his expertise, including "wound care, podiatry, neurology, nephrology, and diabetic medicine" as well as "the temperature necessary to cause a burn injury." In response, the defendants contended that Dr. Durrett's testimony did not contain any expert opinion, but rather Dr. Durrett testified that he "couldn't conclude the device did [cause the burns] or did not" cause the burns. Evaluating the opinion of a witness offered by the Plaintiffs who concluded that the device caused Carlson's burns, Dr. Durrett testified that there was "not enough data to make that decision."

The Fifth Circuit rejected the defendants' argument that Dr. Durrett's "no conclusion" and "not enough data" statements did not constitute opinion testimony. On the contrary, the Fifth Circuit recognized these "ostensibly equivocal opinion[s]" were in fact opinion testimony that supported the defendants' case by challenging the Plaintiffs' evidence that the product caused the alleged injury. Further, Dr. Durrett's testimony that "the placement of the [product's] pads couldn't have" caused Carlson's injuries was clearly a medical opinion. As explained by the Fifth Circuit, Dr. Durrett's chiropractic and alternative medicine background did not align with the medical causation testimony he offered, and there was no evidence to suggest that he was otherwise qualified to testimony about other fields of medicine.

Beyond the substantive questions regarding Dr. Durrett's qualifications, the Fifth Circuit determined that the trial court's failure to hold any *Daubert* inquiry before admitting Dr. Durrett's testimony was an abuse of discretion. Given that Dr. Durrett was the defendants' sole witness and the defendants relied on Dr. Durrett's medical testimony in closing arguments, the Fifth Circuit found that the trial court's failure could not be considered harmless error.

**5. *Morgan v. Medtronic, Inc.*, No. 3:15-cv-32, 2016 WL 1162400 (S.D. Tex. March 22, 2016).**

In *Morgan v. Medtronic, Inc.*, the United States District Court for the Southern District of Texas held that a Plaintiff's claims for design defect, manufacturing defect, failure to warn, negligence, and breach of warranty against the manufacturer of a medicine delivery pump were expressly preempted by the pre-market approval ("PMA") process established by the Medical Device Amendments (MDA) to the Food, Drug, and Cosmetic Act.

Plaintiff Morgan had a SynchroMed II Pump surgically implanted to dispense pain medication. Morgan alleged that the pump malfunctioned and failed to provide a warning that the pump's supply of morphine had been depleted. As a result, Morgan experienced drug withdrawal symptoms, and his pump was removed and replaced. Morgan alleged that he suffered "permanent injuries and damages" as a result of this experience.

Defendant Medtronic filed a motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c), arguing that the pump was subject to the FDA's PMA process and that Morgan's claims were therefore (1) expressly preempted to the extent they were based on state-law, and (2) impliedly preempted to the extent they attempted to enforce federal law regarding the pump.

The Court applied the two-step express preemption test established by the Supreme Court in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008), which requires courts to determine:

(i) whether the federal government established requirements applicable to the medical device; and, if so,

(ii) whether the state-law claim would impose requirements different from, or in addition to, the federal requirements.

As noted by the Court, state law claims may avoid express preemption by imposing duties that parallel federal requirements (thereby sidestepping the second part of the *Riegel* test).

The Court began its analysis by determining that PMA-approved medical devices, such as the SynchroMed II Pump, "automatically satisfy the first step of the express-preemption test" because the PMA process imposes federal requirements.

From there, the Court examined whether Morgan's state law claims were "parallel claims" or whether they in fact imposed requirements that were different from, or in addition to, federal requirements. In its analysis, the Court relied on *Riegel*'s finding that "state common-law and statutory 'duties underlying negligence, strict-liability, and implied-warranty claims' are considered 'requirements . . . with respect to devices.'"

As the Court explained, Morgan's claims were not "parallel claims," and thus failed under the second step of *Riegel*. Morgan did not allege that the design of the pump deviated from the PMA-approved design. Instead, Morgan's state-law design defect claim would have required that Morgan prove Medtronic should have used a safer alternative design, different from that approved in the PMA process. Likewise, Morgan's state-law manufacturing defect claim was not based on any allegation that the pump deviated from PMA-approved specifications. Furthermore, Morgan's failure to warn claim would require that Morgan prove that Medtronic should have provided different or additional warnings from those approved by the FDA. Therefore, as the Court determined, these strict liability state-law claims contemplate different and/or additional requirements beyond what the FDA required through the PMA process. The Court similarly disposed of Morgan's claims for negligence and breach of warranty, finding all claims asserted by Morgan against Medtronic expressly preempted by the MDA, and therefore dismissing the claims with prejudice.

**The Court also considered, and alternatively based its dismissal of Morgan's breach of warranty claims on, Morgan's failure to provide Medtronic with pre-suit notice of the alleged breach "within a reasonable time," as required by Texas state law.