NUMBER 13-07-00090-CV

COURT OF APPEALS

THIRTEENTH DISTRICT OF TEXAS

CORPUS CHRISTI - EDINBURG

ALZA CORPORATION, **Appellant,**

v.

**DORIS THOMPSON, INDIVIDUALLY,
AND TOWNSI FOULKROD
AS LEGAL REPRESENTATIVE OF
KENZEY THOMPSON, MINOR,
INDIVIDUALLY AND ON BEHALF
OF THE ESTATE OF MICHAELYNN THOMPSON,** **Appellees.**

**On appeal from the 113th District Court
of Harris County, Texas.**[1]

MEMORANDUM OPINION

**Before Justices Yañez, Benavides, and Vela
Memorandum Opinion by Justice Yañez**

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[1] This appeal was transferred to this Court from the First Court of Appeals by order of the Texas Supreme Court. *See* TEX. GOV'T CODE ANN. § 22.220 (Vernon 2004) (delineating the jurisdiction of appellate courts); TEX. GOV'T CODE ANN. § 73.001 (Vernon 2005) (granting the supreme court the authority to transfer cases from one court of appeals to another at any time that there is "good cause" for the transfer).

Alza Corp. ("Alza") appeals a judgment on a jury verdict rendered against it in a wrongful death case involving allegations of negligence, strict products liability manufacturing defects,[2] and gross negligence regarding its manufacture of the Duragesic patch. The manufacturing defect asserted is a flaw in the seal of the Duragesic patch which allowed decedent, Michaelynn Thompson, to receive a fatal overdose of fentanyl, a potent narcotic.[3] The negligence and gross negligence claims include complaints that Alza continued to employ a visual inspection process, intended to spot manufacturing defects in the Duragesic patches as they passed on a conveyor belt, even after Alza knew that such a process was inadequate to detect the flawed patches in order to remove them from distribution to patients.[4]

The plaintiffs-appellees ("the Thompson family")[5] tried their claims arising from the death of Michaelynn Thompson against Alza before a jury in the 113th Judicial District Court in Harris County, Texas, with the Honorable Patricia Hancock presiding. The jury found that there was a manufacturing defect in the Duragesic patch worn by Thompson which was a cause of her death, and further found that Alza was negligent, but declined to find Alza grossly negligent. The trial court rendered judgment on the jury's verdict. Alza

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[2] "While strict liability focuses on the condition of the product, '[n]egligence looks at the acts of the manufacturer and determines if it exercised ordinary care in design and production.'" *Am. Tobacco Co., Inc. v. Grinnell*, 951 S.W.2d 420, 437 (Tex. 1997) (quoting *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995)).

[3] Alza's brief describes fentanyl as "a powerful narcotic painkiller" administered by a "Duragesic patch that releases doses of the medicine into the patient's bloodstream via the skin."

[4] We note that the trial court was not the first court to address punitive damage claims against Alza based on allegedly defective Duragesic fentanyl patches. *See*, *e.g.*, *Lake-Allen v. Johnson & Johnson, L.P.*, No. 2:08CV00930DAK, 2009 U.S. Dist. LEXIS 64860, at *9-10 (D. Utah July 27, 2009) (denying defendants' motion for summary judgment on punitive damage claims).

[5] Plaintiffs below and appellees herein include Doris Thompson, individually, and Townsi Foulkrod as legal representative of Kenzey Thompson, minor, individually and on behalf of the estate of Michaelynn Thompson.

appeals by five issues and multiple sub-issues, generally challenging the sufficiency of the evidence and two evidentiary rulings. We affirm.

I. BACKGROUND

The Duragesic patch is a prescription pain patch utilized to treat moderate to severe chronic pain. It is a transdermal system that adheres to a patient's skin and is designed to provide the patient with a continuous, systematic delivery of fentanyl, a potent opioid analgesic, for a period of seventy-two hours. This patch is comprised of four layers: an external backing of polyester film, a drug reservoir containing fentanyl and alcohol in a gel solution, a membrane that controls the rate of fentanyl delivery to the skin surface, and an adhesive worn next to the skin. The Duragesic patches come in several strengths.

The Duragesic 75 mcg/hr patch worn by Thompson at the time of her death[6] was manufactured on Alza's Bodolay machine. The patches at issue were made at a rate of about four per second, and the quality control process for the patches entailed a visual assessment by two inspectors as the patches went by on a high-speed conveyor belt. From 2001 through 2004, Alza documented many instances where patients had received Duragesic patches manufactured on its Bodolay machine with flawed seals[7] that were not detected by Alza's visual inspection process. The number of patient complaints regarding defective 75 mcg/hr patches escalated sharply in 2003 and early 2004, ultimately involving an inspection by the United States Food and Drug Administration ("FDA") and the recalls of four lots of 75 mcg/hr Duragesic patches.

Rudolph Holland, a senior technician on the Bodolay running the Duragesic line for

[6] The evidence showing that Thompson was wearing this patch will be discussed later in this opinion.

[7] The FDA ultimately identified eight different kinds of defects, which ranged in severity from, e.g., "stringer leakers," where a strand of gel kept the seal on the patch from complete closure, to the defect at issue herein, a "fold-over" defect, which left an entire side of the Duragesic patch unsealed.

Alza, testified about the specific manufacturing process and product components that constitute the Duragesic patch. At trial, Holland testified that he was not mechanically inclined, and that no one ever asked him what could have contributed to the number of leaking patches.

Holland testified that he was aware that Alza had been notified of a fold-over defect in a Duragesic patch in 2001. Holland's sworn testimony established that in 2001, after learning that a fold-over occurred, and after realizing how the defect occurred during its manufacturing process, the company made no changes to its quality control procedures; however, Alza did instruct its employees to look for fold-over defects during the visual inspection process. Holland testified that Alza's visual inspection process entailed watching 120 lines of product go by per minute. Holland testified that he has never seen a fold-over defect. Alza's visual inspections detected no problems with the two-and-a-half million Duragesic patches that were ultimately recalled by Alza in 2004 because of the prevalence of fold-over defects.

In 2003, Holland "thought everything was fine" regarding the company's manufacturing process, and thought that the visual inspection process was sufficient, but conceded in retrospect that "we could have made some changes," and concluded in his testimony before the jury that asking the employees to look harder for defects was not sufficient to prevent product defects. Holland testified that Alza improved and modified some of its inspection procedures after the Duragesic recall in 2004, so that the Duragesic patches now go through a weight check, a pressure check, a visual inspection, and quali-pack testing with a vacuum. He further testified that quality assurance employees also hold "line audits" every eight hours.

Holland did not know how many leaking patches Alza produced; however, based on

patient complaints to the company, 35 out of 40 lots of 75 mcg patches manufactured between January 1, 2003 and June 8, 2004 contained leaking patches. According to documents he reviewed at trial, Holland testified before the jury that reports of leaking patches were lower in two of the five recalled batches than in other batches that Alza chose not to recall. Holland expressly admitted in testimony to the jury that he would have notified the FDA of the escalating number of fold-over defects earlier than Alza did.

As mentioned above, when complaints from the public about the Duragesic patch escalated sharply in late 2003 and 2004, the FDA investigated this problem. According to the FDA's inspection report,[8] Alza characterized the initial problem as an isolated incident, and Alza's approach to the problem was to re-train the operators:

> The firm first came across a fold over defect from a field sample return back in 10/01 . . . and assigned a probable cause as the polyester/EVA film being folded over during a roll change or start up. The firm's corrective action was to train operators to "heightened awareness" and that the fold over was an "isolated incident." This corrective action did not prevent the fold over defect from reoccurring . . . .

The FDA's inspection report found Alza's remedial actions inadequate:

- Corrective actions implemented on 10/01 for Pouched Lot #0101663 were inadequate to prevent the fold over defect from reoccurring as demonstrated in Pouched Lot #'s 0327192 and 0327294 on 02/04.
- Lack of increased acceptance criteria should an inspection fail a level one inspection.
- Firm did not follow SOP 05-020-045 to discard product after a defect was found.
- After awareness of fold over defect and Voluntary Class 1 Recall, firm released Pouched Lot # 0330362 into commercial distribution without further inspection.
- Pouched Lot # 0327711 was released into commercial distribution

[8] For another court's discussion of the FDA's Establishment Inspection Report and its Inspectional Observations, please see *Miller v. Janssen Pharmaceutical Products, L.P.*, No. 05-CV-4076-DRH , 2007 U.S. Dist. LEXIS 31863, at *8-9 (S.D. Ill. May 1, 2007) (not designated for publication).

even though it failed release specifications.

- In-process and QC checks were inadequate to prevent the release of the fold over defect as demonstrated in Pouched Lot #'s 0327192 and 0327294.

- Firm did not follow Sop 0-109 to justify continuation of production.

The FDA's inspection report also specifically addressed Alza's training of the operators:

> [T]his approach of reactionary training of operators from field complaints did not appear to alleviate these types of product defects due to this corrective action being seen in one Exception Report after another. I expressed the possibility of the firm to institute a preventative training program for the operators in addition to their routine GMP training on a regular basis through the year. All parties agreed that this was a positive approach and provided a memo reflecting this preventative training program . . . .

The FDA inspection report also noted that the "defect would be incorporated into the patch and could go undetected with current QA checks in place." Similarly, the FDA proposed ways "to prevent this defect from reoccurring," and Alza agreed that "equipment changes and controls are the best remedies for preventing this defect in the future." In this context, the FDA report documented numerous changes in Alza's Bodolay machine, which was at the end of its usefulness and scheduled for replacement, in order to reduce the incidence of manufacturing defects. The report includes an evaluation of this process with Alza's management:

> On 6/08/04, [the FDA representative] held a discussion with [Alza representatives] regarding the Bodolay I FFS and [its] ability to produce quality product or should the machine be retired. All three expressed their desire to improve operations and that the implementation of the HH FFS is on top priority to be validated and put into production to be the main manufacturing line for Duragesic and therefore reserve the Bodolay I FFS as a backup machine. They continued to express that the changes made to the Bodolay I FFS and the implementation of the vision system on the Bodolay I should and will improve the quality of product produced.

As a result of this defect, Alza recalled about 2,500,000 of its Duragesic patches in 2004.[9]

Also during 2004, Dr. Elias Benhamou, a pain management specialist who is board-certified in anesthesiology, prescribed Duragesic patches for Michaelynn Thompson, who was suffering chronic back pain after a car crash.[10] Dr. Benhamou prescribed these Duragesic patches during the time period after Alza began its defect investigation but before Alza initiated the recall.[11] At trial, Dr. Benhamou testified that an overdose of fentanyl results in symptoms including discomfort, difficulty breathing, sweating, dizziness,

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[9] The FDA has stated that:

> Recall is an effective method of removing or correcting consumer products that are in violation of laws administered by the Food and Drug Administration. Recall is a voluntary action that takes place because manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.

21 C.F.R.§ 7.40(a) (2009). A recall is an "alternative" to a FDA-initiated court action, and the agency, by setting forth specific procedures, can "monitor recalls and assess the adequacy of a firm's efforts in recall." *Id.* The FDA evaluates the health hazard presented by a product being recalled or considered for recall and assigns the recall a classification, i.e., Class I, Class II, or Class III, to indicate the relative degree of health hazard of the product being recalled or considered for recall:

> (1) Class I is a situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
>
> (2) Class II is a situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
>
> (3) Class III is a situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

21 C.F.R. § 7.41 (2009); 21 C.F.R.§ 7.3(m)(1)-(3) (2009). The recall of Alza's Duragesic patches was originally classified as a Class I recall and ultimately reclassified as a Class II recall.

[10] We note that some of the cases involving claims against Alza based on flaws in its Duragesic fentanyl patches have also included claims against the prescribing doctor. *See, e.g., Borowicz v. Alza Corp*., No. 1:09-CV-00785, 2009 U.S. Dist. LEXIS 53589, at *1-3 (N.D. Ohio June 24, 2009); *Browning v. Alza Corp*., No. 1:09-04402009, 2009 U.S. Dist. LEXIS 42755, at *2 (S.D. W. Va. May 20, 2009). *But see Middlebrooks v. Johnson & Johnson Co.*, No. 4:08-CV-54 (CDL), 2008 U.S. Dist. LEXIS 75420, at *1-2 M.D. Ga. Aug. 26, 2008) (not designated for publication)(no claims raised against prescribing physician in context of suit against Alza and other makers of allegedly defective Duragesic fentanyl patches); *Workman v. Johnson & Johnson,*, No. 06-2523 (DMC), 2007 U.S. Dist. LEXIS 46214, at * 1-2 (D. N.J. June 26, 2007) (not designated for publication) (same). In this case, neither party raised any allegation against the prescribing physician.

[11] Less than a month passed from Dr. Benhamou's prescription of the Duragesic patches and Thompson's death. During that same general time period, Alza logged 21 complaints about leaking Duragesic patches from one particular lot in circulation within the health care supply system.

and nausea, and that a Duragesic patch leaking an uncontrolled amount of fentanyl could result in the death of the patient.

During the early morning hours of February 13, 2004, Thompson began vomiting and complaining of dizziness and back pain. The vomiting continued on an hourly basis until morning. Thompson's thirteen-year old daughter, Kenzey Marie Thompson, ultimately called an ambulance for her at approximately 9:00 a.m. While transporting Thompson to the emergency room, the emergency technicians performed an electrocardiogram ("EKG")[12] on Thompson showing normal results.

Thompson's medical records from Fort Bend Methodist Hospital state that Thompson was wearing a "Duragesic patch" upon admission to the emergency room. These records indicate that Thompson's complaints included dizziness, nausea, vomiting, abdominal pain, and left flank pain. Nurse Camille Green testified that Thompson complained of abdominal pain and dizziness. Kenzey testified that her mother was acting "weird" at the hospital.

Dr. Donnie Evans, the emergency room physician, treated Thompson. He ordered numerous tests, including a chest pain evaluation, an electrocardiogram, and cardiac enzyme tests. The tests showed no arrhythmia or heart damage. After Thompson's complaints of pain subsided, Fort Bend began preparations to release her. Kenzey telephoned members of their church to come pick them up from the hospital, and Thompson and Kenzey waited to be released. Kenzey testified that her mother told her that she was really tired and that she was going to take a nap. Kenzey slept also. Upon

[12] An electrocardiogram, or EKG, graphically records the electrical activity of the heart. *See Columbia Med. Ctr. of Las Colinas, Inc. v. Hogue*, 271 S.W.3d 238, 244 (Tex. 2008) (citing CECIL ESSENTIALS OF MEDICINE 47, 55 (Thomas E. Andreoli, M.D. *et al.* eds., 6th ed. 2004)).

waking, Kenzey attempted to wake her mother but was unable to do so. She informed a nurse, who told her that her mother would have to be awake to be discharged. Kenzey saw her mother, apparently asleep, lying on her stomach. Kenzey noted that her mother's legs were bluish-purple with goose bumps, and she was lying face-down in her pillow with her hands up by her face, and her fingernails were purple. Kenzey attempted to rouse her mother because the nurse had said they could leave if she could wake her, but Kenzey was unable to do so.

Kenzey testified that she had seen a patch on her mother's abdomen the night before, and she said her mother was really good about going to her doctor and changing out her patches.

During this period, Nurse Karen Marie Cothran testified that Kenzey approached her sometime before 3:50 p.m., and told her that her mother was sleeping a lot. Cothran told Kenzey that her mother would have to wake up before she could be discharged. Cothran entered the room at 3:50 p.m. and found Thompson, who was not breathing, laying on her stomach with her face in the pillow. She moved Thompson and sounded an emergency code.

Dr. Evans testified that when he entered the room, Thompson's back was noticeably blue. He and a team began resuscitation efforts to no avail. He saw the patch on Thompson's back and ripped it off because it was "an unknown," and threw it away. On the same day that Thompson died, Alza initiated the initial phase of the recall, and several days later, Dr. Evans received notice of the recall. He promptly contacted Thompson's family so that they could look into whether the patch had any causal relationship to her death. Dr. Evans testified that he had no concerns about drug toxicity, nor did he see signs thereof when he was treating her, but at the same time, he did not realize she had the

patch on. In this regard, we note that testimony at trial established that symptoms of an overdose of fentanyl include, inter alia, nausea, vomiting, sleepiness, dizziness, and respiratory depression.

As a result of the contact between Dr. Evans and the Thompson family, the family repeatedly requested the medical examiner to test the level of fentanyl in Michaelynn's blood. Despite these requests, the medical examiner performed a routine medical drug screen, with negative results, but did not test Thompson's blood for fentanyl. Evidence at trial confirmed that it is not possible to determine whether someone has a toxic level of fentanyl in their blood without testing for it. The medical examiner did save a femoral blood sample and sent it to an outside laboratory, Accu-Chem, for testing at the Thompson family's request. This test showed that Thompson had a blood fentanyl quantitation of 11.4 ng/ml. A therapeutic range for fentanyl is 1.0 to 2.0 ng/ml, and a toxic range is 3.0 to 5.0 ng/ml. Stated otherwise, the test confirmed that Thompson's blood showed a toxic level of fentanyl that was over ten times the low end of the expected range based on her fentanyl prescription, and over five times the uppermost end of that range.[13]

Having not performed a test for fentanyl, the Harris County Medical Examiner's report showed Thompson's cause of death as "cardiomegaly with biventricular hypertrophy associated with obesity," which, according to the testimony at trial, simply means that Thompson had an enlarged heart. According to the autopsy report, Thompson was forty-two years old, six feet tall, and weighed 367 pounds.

At the trial arising from Thompson's death, Mika Greenfield, Alza's corporate representative and quality assurance manager, testified regarding Alza's knowledge of product defects and its manufacturing process. She conceded that fold-over defects exist

[13] The expected range of fentanyl in Thompson's blood, based on the strength of her Duragesic patch prescription, was between 1.0 to 2.0 ng/ml, but the actual level in her blood was 11.4 ng/ml.

where an entire side of the patch is leaking, and she agreed that fold-over defects and stringer leakers tend to release fentanyl in an uncontrolled way. Despite the fact that she was Alza's corporate representative, her testimony was conflicting regarding her knowledge of whether fentanyl was a dangerous drug, and she was unaware whether morphine was more potent than fentanyl.

Greenfield testified Alza began receiving increasing numbers of public reports of leaking patches as early as January 7, 2004. She testified that, for instance, Alza confirmed forty-two fold-over defects in one of its lots of Duragesic patches. She admitted that these defects were originally found by the public, and not by Alza or its employees. She was unable to describe the safety process utilized by Alza to find product defects in 2003, and conceded that Alza's technicians found no fold-over defects in any of the Duragesic patches produced during the last six months of 2003.

Greenfield confirmed that Alza was notified of more than one fold-over defect in Duragesic patches in 2001. At that time, the company's response was to heighten visual inspection of the patches in a two-foot space on a conveyer belt as the product was traveling through the Bodolay system.

Greenfield testified that she did not know what changes were made on the Bodolay after the product recall to ensure that it was not producing defective products even though, as part of the company's quality assurance team, her responsibility was to ensure that the manufacturing process is completed without defects. She did offer sworn testimony, however, admitting that all changes that were put in place after the product recall, including a mechanical visual system, different evaluating methods, equipment modifications, and equipment cleaning, would have been available for use in 2001.

Greenfield testified that Alza did not examine the recalled patches to determine how

many of the recalled patches actually had defective seals or fold-over defects. She conceded that after determining that there was a fold-over defect problem, Alza released additional patches for public distribution without any additional inspection of the patches. Greenfield further testified that internal correspondence at Alza acknowledged the fact that it was keeping the Duragesic patches on the market, despite the defects, because of product shortages. Finally, she admitted that the FDA's inspection processes resulted in Alza's making changes to improve its processes and equipment.

Juanita Hawkins, the worldwide vice president of Quality Assurance and Technical Operations for Cordis Corporation, which is a subsidiary of Johnson & Johnson,[14] also provided testimony on behalf of Alza. In 1995, Hawkins worked for Janssen as the vice president of quality assurance. Hawkins testified that Alza would not and should not knowingly release a lot that contained defective products; nevertheless, she admitted that the FDA concluded that, and internal documents confirmed that, the company continued to release products for commercial distribution despite knowing of product defects therein.

Dr. David Upmalis also testified on behalf of Alza. He is a general practice physician who joined the pharmaceutical industry, and now works with Pharmaceutical Research and Development ("PRD"), a research group that "supports Alza, among other companies." He does clinical research in painkillers, "providing medical support for Duragesic and a couple of other pain killers that are in the marketplace." He handles correspondence with regulatory agencies, including the FDA, regarding product issues and works to obtain approval for drugs. He worked with pediatric clinical trials for the Duragesic patch and helped derive labeling for the patch.

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[14] Evidence at trial, including testimony from William Parks, the director of trade relations for Janssen, established that Alza manufactures the Duragesic patch and Janssen sells and markets the Duragesic patch. Alza and Janssen are both subsidiaries of Johnson & Johnson.

Dr. Upmalis testified about two general types of leaks that a Duragesic patch could exhibit. A stringer leaker is a patch that has a piece of gel stuck in the seal. According to Dr. Upmalis, Alza's assessments concluded that there was no significant health risk posed by stringer leakers. Dr. Upmalis also testified about fold-over defects, where the seal breach covers an entire side of the patch.

Dr. Upmalis testified that, in response to the escalating number of public complaints about product defects, Alza formed a health hazard assessment committee which was asked to look at fold-over defects on President's Day weekend, February 14-15, 2004. According to Dr. Upmalis, the health risk involved in fold-over defects was higher than for stringer leakers because more fentanyl gel could leak from a fold-over defect. Dr. Upmalis testified that each lot of Duragesic patches contained around 400,000 units, and Alza ultimately estimated that approximately 3,600 patches would be affected by fold-over defects in each lot. Dr. Upmalis testified that Alza utilized Medline searches and three studies, which were not peer reviewed, in its determination regarding the health risks incident to leaking Duragesic patches. In its research, Alza found many incidents of adverse events related to the rapid release of fentanyl.

Dr. Upmalis was involved in writing the Physician's Desk Reference ("PDR") materials on the Duragesic patch. The warning in the PDR states: "Duragesic patches are intended for transdermal use on intact skin only. Using damaged or cut Duragesic patches can lead to the rapid release of the contents of the Duragesic patch and absorption of a potentially fatal dose of Fentanyl." Dr. Upmalis testified that this warning resulted from people's "abuse" of, or damage to, the patches. Despite the explicit text of the PDR warning, Dr. Upmalis testified that the warning of adverse health consequences therein concerns the absorption of fentanyl through mucous membranes rather than skin.

Dr. Upmalis explained that the adverse drug reporting system requires doctors to report to the company and to the FDA if there is an adverse drug event. He admitted that under-reporting is a known problem, and he has heard that only one to ten percent of adverse reactions are reported. He agreed that the FDA thought that under-reporting is particularly high with the Duragesic patch because of the nature of the patient population utilizing the patch. Dr. Upmalis examined Duragesic adverse event reports, which included, in 2002, for instance, 53 cases of hypoventilation, 270 cases of dyspnea (shortness of breath), 15 cases of respiratory arrest, 33 cases of respiratory depression, 8 cases of respiratory disorder not otherwise specified, 8 case of respiratory distress, and 14 cases of respiratory failure. The 2003 adverse event report numbers were similar. According to Dr. Upmalis, given the incidence of under-reporting, these adverse reactions were just "the tip of the iceberg."[15]

Dr. Leslie Benet, a pharmacologist who is a professor at the University of California, provided further testimony on Alza's behalf. Dr. Benet testified that he works for almost all drug companies. While Alza does not pay him directly for his work, Alza pays the university for which he works, which in turn funds his laboratory. Dr. Benet conceded that the FDA did not concur with the pharmaceutical-industry funded tests which downplayed the health risks from Duragesic patch defects, and that the FDA had determined that the justification presented to support the safety of leaking patches was inadequate.[16]

Dr. Benet admitted that Alza's Duragesic labels do not corroborate his trial testimony

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[15] We note that the jury was instructed that evidence regarding adverse events was relevant on the issue of notice to Alza, but not on causation or for any other purpose.

[16] Testimony at trial indicated that the absorption of fentanyl from a damaged patch may be increased, even without the patch system in place, where, for example, clothes cover the patch and act as an occlusive layer, or the patient is laying on the patch, thus causing less evaporation of the vehicle medium and a greater absorption of fentanyl. Dr. Benet further testified that temperature increases the rate of fentanyl absorption.

regarding adverse health risks associated with damaged patches. He attempted to explain this discrepancy as a result of the fact that all labeling is supposed to include all potential toxic eventualities whether they occur or not: "And today, because of litigation such as this, every company lists everything that could potentially lead to a litigious situation." Dr. Benet conceded that Alza knew about a number of leaking patches before 2005, and at that time, Alza did not place a warning on the Duragesic packaging. According to Dr. Benet, the warning that Alza ultimately included on the Duragesic labels is directed to patient caregivers, and not to the patch-users themselves, because the caregivers are more likely to have a toxic reaction to exposure. Upon cross-examination, Dr. Benet admitted that the Duragesic label states that it is for use only in opioid tolerant patients, and that because serious or life-threatening hypoventilation could occur, the Duragesic transdermal system is contraindicated in patients who are not opioid-tolerant. The label further states that damaged or cut patches can lead to rapid release of the contents and absorption of a fatal dose.

Dr. Benet ultimately concluded that Alza and Janssen both knew that fentanyl was a toxic substance and the exposure of fentanyl at an uncontrolled rate might be dangerous; however, Dr. Benet testified that in this case, given that Thompson had been on pain medication for a number of years and had been wearing a patch for more than a month, he did not believe that fentanyl gel leaking out on her skin would pose a health risk to a reasonable degree of scientific certainty.

As mentioned above, the Thompson family's case was tried before Judge Hancock in Harris County, Texas, and the jury returned affirmative findings concerning the manufacturing defect and Alza's negligence, but did not find Alza grossly negligent. Alza challenges Judge Hancock's judgment on the verdict by five issues. Alza's first three

issues concern the sufficiency of the evidence supporting the verdict.

II. Sufficiency of the Evidence

A. Standard of Review

In reviewing the legal sufficiency of the evidence, we view the evidence in the light most favorable to the jury's findings, giving full credit to all favorable evidence if any reasonable person could, and disregarding contrary evidence unless reasonable persons could not. *City of Keller v. Wilson*, 168 S.W.3d 802, 807 (Tex. 2005). In Texas, the jury is the sole judge of the witnesses' credibility, and that time-honored principle is a part of our standard of review:

> Jurors are the sole judges of the credibility of the witnesses and the weight to give their testimony. They may choose to believe one witness and disbelieve another. Reviewing courts cannot impose their own opinions to the contrary. Most credibility questions are implicit rather than explicit in a jury's verdict. Thus, reviewing courts must assume jurors decided all of them in favor of the verdict if reasonable human beings could do so. Courts reviewing all the evidence in a light favorable to the verdict thus assume that jurors credited testimony favorable to the verdict and disbelieved testimony contrary to it.

Id. at 819 (footnotes and paragraph break omitted). Accordingly, we must deny a legal sufficiency challenge unless: (1) there is a complete absence of evidence of a vital fact; (2) all the evidence offered to prove a vital fact amounts to only a mere scintilla and no more; (3) the rules of law or evidence completely forbid any consideration of the only evidence offered to prove a vital fact; or (4) the evidence which the jury was compelled to consider and believe conclusively establishes the opposite of the vital fact. *See id.* at 810 & n.15-16. These vital facts may be proved by direct or circumstantial evidence. *See Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 601 (Tex. 2004); *Russell v. Russell*, 865 S.W.2d 929, 933 (Tex. 1993).

In reviewing the factual sufficiency of the evidence, we must consider and weigh all

the evidence, and we should set aside the judgment only if it is so contrary to the overwhelming weight of the evidence as to be clearly wrong and manifestly unjust. *Pool v. Ford Motor Co.*, 715 S.W.2d 629, 635 (Tex. 1986); *Cain v. Bain*, 709 S.W.2d 175, 176 (Tex. 1986).

B. Evidence of a Manufacturing Defect and Causation

By its first and third issues, Alza challenges the legal and factual sufficiency of the evidence supporting the jury's finding of a manufacturing defect which was a producing cause of Thompson's death. In the instant case, the jury found that "there was a manufacturing defect in a Duragesic patch worn by Michaelynn Thompson at the time the patch left the possession of Alza that was a producing cause of Michaelynn Thompson's death."

In its first issue, Alza contends that there is legally and factually insufficient evidence to support the jury finding that a manufacturing defect, existing at the time of manufacture, caused Thompson's death. In connection with this issue, Alza argues: (1) there was no proof of proper use of any Duragesic patch in question, and specifically, no proof regarding a 75 mcg/h patch; (2) there was no evidence to support a finding of malfunction; and (3) the evidence conclusively established that Thompson could not have been wearing a 75 mcg/h patch from a recalled lot when she died.

1. Manufacturing Defect

"A manufacturing defect exists when a product deviates, in its construction or quality, from the specifications or planned output in a manner that renders it unreasonably dangerous." *Cooper Tire & Rubber Co. v. Mendez*, 204 S.W.3d 797, 800 (Tex. 2006); *see Bic Pen Corp. v. Carter*, 251 S.W.3d 500, 509 (Tex. 2008). A plaintiff must prove that the product was defective when it left the hands of the manufacturer and that the defect was

a producing cause of the plaintiff's injuries. *Ridgway*, 135 S.W.3d at 600; *Torrington Co. v. Stutzman*, 46 S.W.3d 829, 844 (Tex. 2000). A specific defect "must be identified by competent evidence and other possible causes must be ruled out." *Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 42 (Tex. 2007) (quoting *Nissan Motor Co. v. Armstrong*, 145 S.W.3d 131, 137 (Tex. 2004)).

Both direct and circumstantial evidence may be used to establish any material fact. *Lozano v. Lozano*, 52 S.W.3d 141, 149 (Tex. 2001); *Browning-Ferris, Inc. v. Reyna*, 865 S.W.2d 925, 928 (Tex. 1993). To raise a genuine issue of material fact, however, the evidence must transcend mere suspicion. *Ridgway*, 135 S.W.3d at 601. Evidence that is so slight as to make any inference a guess is in legal effect no evidence. *Id.*; *Lozano*, 52 S.W.3d at 148.

2. Proper Use

Alza contends that appellees' claims are dependent on "proof of proper use of the patch," citing *Parsons v. Ford Motor Co.*, 85 S.W.3d 323, 329-30 (Tex. App.–Austin 2003, pet. denied) (citing *Plas-Tex, Inc. v. U.S. Steel Corp.*, 772 S.W.2d 442, 444-45 (Tex. 1989)). Alza contends that appellees presented no evidence of how any Duragesic patch was handled by Thompson on the occasion in question. According to Alza, "[t]he patch that was removed by Dr. Evans from [Thompson's] back was reportedly unremarkable. The strength of the patch found on her body at the time of her death was never established. The decedent's daughter claimed that Thompson had a patch on her stomach on the day she died."

Manufacturers face liability only for products which are defective when used in the intended manner or when used in a reasonably foreseeable way. *See Houston Lighting & Power v. Reynolds*, 765 S.W.2d 784, 786-87 (Tex. 1998) (liability is "limited to uses that

are objectively reasonable to expect . . . it does not encompass uses . . . which represent wholly unexpected product misuse.") (citations omitted).[17] In this regard, a manufacturing defect exists if a product does not conform to the design standards and blueprints of the manufacturer, and the flaw makes the product more dangerous and therefore unfit for its intended or reasonably foreseeable uses. *See Benavides v. Cushman, Inc.*, 189 S.W.3d 875, 881 (Tex. App.–Houston [1st Dist.] 2006, no pet.).

Dr. Benhamou, the physician who treated Thompson for pain management and who prescribed Duragesic for her, reviewed Thompson's medical records and testified regarding her usage of the Duragesic patches. Thompson had worn Duragesic patches ten separate times, from January 13 until February 11, without incident or adverse effect.[18] The timing of her prescription refills for Duragesic patches fit with the prescribed usage of the product, and the timing would also illustrate that Thompson was wearing one of the newly prescribed 75 mcg patches at the time of her death.

Thompson's medical records from the emergency room state that she was admitted with a "Duragesic Patch." Dr. Evans, the emergency room physician, testified that Thompson told him she sometimes used the Duragesic patch. He further testified that he saw the patch on Thompson's back and removed it when attempting to resuscitate her when she coded because he "thought it may have inhibited our resuscitation [efforts] only

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[17] We note that the foreseeable risk of harm due to a misuse of the product, rather than an intended use, is not an absolute bar to liability for that portion of an injury caused by a product's defective design; instead, misuse of a product is a factor that must be considered in allocating responsibility for the injury. *Hernandez v. Tokai Corp*., 2 S.W.3d 251, 258 (Tex. 1999).

[18] Dr. Benhamou testified that the Duragesic prescriptions came with five patches in each box with directions to change the patches every 72 hours. Dr. Benhamou testified that he prescribed a box of five Duragesic 50 mcg patches to Thompson on January 13. On January 26, Dr. Benhamou increased the dosage and prescribed a box of five Duragesic 50 mcg patches and a box of five 25 mcg patches. On February 11, Thompson was given a prescription for a box of five 75 mcg patches. Utilizing a calendar and medical records, Dr. Benhamou testified that the prescription dates indicated proper usage of the product and the timing indicated usage of the 75 mcg patch at the time of Thompson's death.

because it was an unknown factor." In short, the evidence indicates that Thompson was wearing a 75 mcg Duragesic patch at the time of her death.[19]

Dr. Benhamou testified that he never had any indication that Thompson was abusing Duragesic during his course of treating her. He further testified that he never had any indication that she was not following his instructions with regard to the medication. Further, Dr. Benhamou testified that he had required Thompson to enter a "medication contract" with him, entered into evidence at trial, which spelled out Thompson's obligations with regard to the proper usage of Duragesic. Dr. Robert C. Bux, a physician and board-certified forensic pathologist and medical examiner, who was testifying on behalf of the Thompson family, concurred that there was "no evidence" that Thompson had misused her medication. Dr. Vincent DiMaio, a medical examiner testifying on behalf of Alza, conceded that there was "no physical evidence" that Thompson abused the patches.

Based upon the foregoing, we conclude that the jury had before it legally and factually sufficient evidence from which it may have concluded that Thompson was wearing and properly using a Duragesic 75 mcg at the time of her death.

3. Malfunction

Alza next contends that there is no evidence to support the jury's finding that the Duragesic patch malfunctioned. In connection with this issue, Alza argues that the Accu-Chem blood test is unreliable because it was not performed properly, and the 11.4 blood level reading does not establish a malfunction because of postmortem redistribution.[20]

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[19] While Thompson's daughter testified that she was wearing the patch on her stomach, and medical records and testimony indicate that she was wearing the patch on her back, this discrepancy is not material to the issue of whether or not Thompson properly used the product.

[20] As explained at trial, the concept of postmortem drug redistribution is based on data suggesting that there is a post-mortem diffusion of drugs along a concentration gradient, from sites of high concentration in solid organs and central blood vessels, to sites of the lowest concentration in peripheral vessels such as the subclavian and femoral veins. Postmortem redistribution of a drug may be the basis for elevated or toxic drug concentrations after death, and accordingly, in certain cases, postmortem drug concentrations may not

Alza asserts that Accu-Chem deviated from its protocol in performing its testing and further failed to perform the testing correctly. Alza also attacks the blood test in its third issue, contending that: (1) the Accu-Chem test was not performed properly; (2) Accu-Chem did not validate its methodology; (3) Accu-Chem's methodology of relying on "only one" calibrator was not shown to be reliable; (4) Accu-Chem's test on Thompson's blood had technical break-downs; (5) Accu-Chem had insufficient experience testing for fentanyl in human blood for the results to be considered accurate; and (6) the Accu-Chem test is based on an inference not supported by the evidence.

As stated previously, following Thompson's death, the coroner took blood samples from Thompson's femoral artery and sent the samples to Accu-Chem for testing. According to expert testimony at trial, blood from the femoral artery area is not subject to contamination from gastric contents or trauma and will represent the levels and concentration of substances in the blood at the time of death. Accu-Chem, an independent testing agency, analyzed the blood and determined that Thompson had 11.4 ng/ml of fentanyl in her body. This amount is toxic and is well over three times the therapeutic level of fentanyl.

Accu-Chem utilized gas chromatography/mass spectrometry (GC/MS) technology to test Thompson's blood. We may consider prior judicial opinions allowing the admission of evidence in determining whether the underlying theory of scientific evidence is valid. *See Emerson v. State*, 880 S.W.2d 759, 767-68 (Tex. Crim. App. 1994); *Combs v. State*, 6 S.W.3d 319, 322 (Tex. App.–Houston [14th Dist.] 1999, no pet.); *Jones v. State*, 716 S.W.2d 142, 147 (Tex. App.–Austin 1986, pet. ref'd). Such evidence may be considered for the first time on appeal. *Emerson*, 880 S.W.2d at 765. Texas and federal courts have

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accurately reflect antemortem drug levels.

found the gas chromatography test to be a reliable method for identifying compounds, and it has been generally accepted in the scientific community. *See Combs*, 6 S.W.3d at 322; *Wright v. State*, 853 S.W.2d 154, 155 (Tex. App.–Corpus Christi 1993, pet. ref'd); *Jones*, 716 S.W.2d at 145-52; *see also United States v. Bynum*, 3 F.3d 769, 772 (4th Cir. 1993); *Bolieu v. State*, 779 S.W.2d 489, 490 (Tex. App.–Austin 1989, no pet.) (discussing the GC/MS testing as "the Golden Rule" in the field of toxicology). The scientific theory and principles underlying GC/MS testing have been proven to be reliable. The experts in the instant case appeared to agree that the GC/MS procedure has been properly validated and is considered the most accurate method of identifying and quantifying drug levels.

We next turn our attention to whether the methodology of GC/MS was reliably applied in this specific case. *Guadalupe-Blanco River Auth. v. Kraft*, 77 S.W.3d 805, 808 (Tex. 2002); *Merrell Dow Pharms. v. Havner*, 953 S.W.2d 706, 712 (Tex. 1997); *In re S.E.W.*, 168 S.W.3d 875, 884 (Tex. App.–Dallas 2005, no pet.). In this regard, we note that the law does not require a "court to admit opinion evidence which is connected to existing data only by the ipse dixit of the expert." *Kerr-McGee Corp. v. Helton*, 133 S.W.3d 245, 258 (Tex. 2004) (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

Dr. Gary Harold Wimbish, a board-certified forensic toxicologist, testified on behalf of the Thompson family. He has performed more than a thousand GC/MS tests. He testified that the GC/MS test can be used to determine the level of fentanyl in someone's body, and it is an "excellent instrument" that is "commonly used" to determine the level of fentanyl in a sample of human blood. He has used GC/MS on several occasions for that purpose. He testified that whether a drug level in a person's body is at a fatal level is part of his field of study.

Dr. Wimbish testified that he is familiar with Accu-Chem and its operations. He

testified that Accu-Chem is certified by the American Society of Laboratory Chiefs of Police, the College of American Pathology, and the Clinical Society for Drug Testing. Analytical laboratories such as Accu-Chem are accredited by various organizations and, as part of their accreditation, are regularly inspected and participate in "proficiency studies," in which identical portions of the same sample are analyzed by many labs at the same time in order to check the accuracy of each procedure as it is performed in the individual participating labs. Accu-Chem participates in proficiency testing by the College of American Pathology and it is certified by organizations for performing drug testing on parolees and probationers. Dr. Wimbish testified that he is personally experienced with Accu-Chem and that it is his "laboratory of choice" for a forensic laboratory.

Accu-Chem had specifically passed the College of American Pathology's proficiency test for fentanyl, although Dr. John Arthur Tarver, the director of Accu-Chem, testified that Accu-Chem does not frequently perform tests for fentanyl. Dr. Tarver further testified that an outside organization, the American Society of Crime Laboratory Directors, reviewed and approved Accu-Chem's testing procedures. Further, the particular procedure used to test fentanyl was validated externally with a proficiency sample from the College of American Pathologists. Accu-Chem sent the College a proficiency sample, and with those standards and control standards, Accu-Chem was within five-tenths standard deviations of the mean of all the laboratories that performed the test.

Dr. Graham Richard Jones, a forensic toxicologist, testifying on behalf of Alza, acknowledged that Accu-Chem had passed the proficiency test administered by the College of American Pathologists in March 2004, before Accu-Chem did the test at issue in this case, and had done "well" on the proficiency test.

Accu-Chem's report of October 18, 2004 shows a concentration of fentanyl in

Thompson's blood of 11.4 nanograms per milliliter.[21] The therapeutic range for fentanyl, that is, the amount found in the blood related to the relief of pain, is from one to two nanograms per milliliter. The toxic range for fentanyl, that is, the range that would have toxicity or adverse and deleterious effects, is three to five nanograms per milliliter. Dr. Wimbish testified that 11.4 nanograms was a little more than two times the upper limit of the toxic range for fentanyl, and was toxic enough to be lethal. Specifically, Dr. Wimbish testified that while Thompson may have developed some tolerance to fentanyl, the tested level of fentanyl found in her blood was nevertheless three to four times larger than an amount which she could have tolerated.

Based on testimony at trial, the GC/MS test is performed by analyzing and comparing the unknown blood sample, in this case, Thompson's femoral blood specimen drawn by the Harris County coroner, with other blood samples where the amount of the target substance is known. The results for the unknown sample are then compared to the results for the known samples in order to calculate the amount of the target substance present in the blood sample. The testimony in this case is complicated by the various names and descriptions the experts used with regard to these "known samples," of which we have been able to delineate three basic categories.

The first category of known samples discussed by the experts is a set of "calibrators," which are samples prepared in a matrix of blood, ethanol, or some other

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[21] Accu-Chem initially tested a sample of Thompson's blood for fentanyl in April; however, that test failed. Dr. Tarver and Dr. Wimbish, both testified that this initial test was not valid and the results were not reliable because the sample of blood provided for testing was insufficient and Accu-Chem did not have the "amount of specimen that our protocol requires." Accu-Chem received six-tenths of a milliliter of blood, whereas the standard operating procedure called for four milliliters, and the resulting analytical data did not allow for forensic results. Dr. Jones, testifying on behalf of Alza, stated that Accu-Chem's first test failed because the entire calibration failed "miserably" and the failure had "absolutely nothing" to do with the amount of the sample. We need not further consider this issue because the results of this initial test are not at issue in this case. We do note that Dr. Tarver stated that the testing methodology utilized by Accu-Chem did not change between the two tests.

solvent, each of which contains a known amount of the target compound, in this case, fentanyl. A set of calibration standards includes several samples that contain various known amounts of the target compound within a specific and broad range. The second set of known samples involves "ion ratios." The ion ratio is the ratio between the abundance of two different ions within the same chemical, or two ions representing different chemicals, such as fentanyl, and the internal standard form of fentanyl. Ion ratios can be used either qualitatively or quantitatively; in other words, they are employed in either identifying the substance or in measuring the amount of the substance. The third category of known samples are quality control samples, which are used to check the reproducibility of results. A quality control sample is a sample which is prepared in the same type of matrix as the unknown sample, but which has a known concentration of the target compound that is near the expected concentration of the unknown sample. Samples from proficiency studies, if they are sufficiently stable, may be used as external quality controls.

In the instant case, Accu-Chem utilized four calibrators and ion ratio tests in its analysis of the fentanyl quantitation in Thompson's blood. The .5 calibrator failed both the quantitative error test and the ion ratio test. The 2.0 calibrator passed the quantitative error test and failed the ion ratio test. The 5.0 calibrator failed the quantitative error test and passed the ion ratio test. The 20.0 calibrator passed both tests. Utilizing this data, Accu-Chem calculated that Thompson's blood contained 11.4 ng/ml of fentanyl. The result of these calculations was validated by comparison to the quality control samples, which had been validated by separate protocols before Thompson's test. Using the quality control samples, Accu-Chem's analysis of Thompson's blood showed a quantitation of 10.48 ng/ml.

Dr. Tarver, the director of Accu-Chem, testified by deposition regarding the test

protocols and results. Dr. Tarver has degrees in biology and chemistry and a master's degree in biomedical science. He is a diplomat of the American Board of Forensic Toxicology and a toxicological chemist for the National Registry of Certified Chemists. Dr. Tarver testified that there are no methodology standards that require a certain number of calibrators to work to produce a valid test result. While Accu-Chem's standard procedure required the use of four calibrators, Dr. Tarver rejected two of those calibrators. Dr. Tarver testified that the rejected controls had no effect on his ultimate conclusions because Accu-Chem validated, through external sources, the actual lot number of the standard calibration material and the quality control material.

Dr. Wimbish reviewed and explained Accu-Chem's written protocols for postmortem testing for controlled substances. Accu-Chem's standard operating procedures allow Dr. Tarver, the lab director, to review the analytical protocol and provide that Dr. Tarver has the final authority on any analytical protocol in the laboratory, particularly with regard to forensic specimens because of their limited and unique quality. With limited samples, the laboratory director has to make a decision about reporting results, and often, as per his instructions in the standard operating procedures, he can modify those within scientific limits as to the acceptability or reportability of a result under unique circumstances. In other words, Accu-Chem's standard operating procedures allow Dr. Tarver to deviate from those procedures. Dr. Wimbish testified that it is not unusual for a laboratory director to have that kind of discretion with regard to forensic samples.

Dr. Wimbish testified that Accu-Chem's test rendered a reliable quantitation within reasonable scientific certainty. He explained that Accu-Chem derived its results by utilizing and comparing two separate sample sets, then explained his own calculations verifying Accu-Chem's results. Accu-Chem used two of the four calibrators to derive its results. Dr.

Wimbish verified Accu-Chem's mathematical analysis utilizing those two calibrators, then re-examined the veracity of Accu-Chem's results utilizing zero as an additional calibration point. Dr. Wimbish testified that ideally, all four of the calibrators in Accu-Chem's test would have been functional; however, changing the number of calibrators affects the test's precision, but not its accuracy. In contrast, if all four calibrators fail, then the result is not valid because there is no data with which to undertake any quantitative analysis. In short, Dr. Wimbish testified that Accu-Chem's test rendered test results with reasonable scientific certainty.

Dr. Graham Richard Jones, a forensic toxicologist, testified on behalf of Alza. According to Dr. Jones, the GC/MS is very powerful, but "it is basically a dumb instrument unless you . . . calibrate it." Calibrators are blood samples containing known amounts of fentanyl so that the machine can relate a signal to a concentration of fentanyl. According to Dr. Jones, it is "critical" that the calibrators are working. Dr. Jones testified that multiple calibrators are utilized in order to obtain multiple data points because the response across a concentration range is not always consistent, and different calibrators are used to establish the reliability of the test. According to Dr. Jones, the GC/MS machine may "behave" differently at higher or lower concentrations; therefore, the calibrators should be run at a range of concentrations within which the blood samples are expected to fall. In his lab, Dr. Jones requires five out of six calibrators to be working to produce a quantitative result for fentanyl. In other testimony, Dr. Jones stated that he might allow one or two calibrators to fail; however, the calibrators must be dropped at the "extreme," or at a place distant from where the actual quantitation was. In Dr. Jones's opinion, the Accu-Chem test failed.

Dr. Jones conceded that Dr. Wimbish disagreed with this analysis, and

acknowledged that Dr. Wimbish is a reputable forensic toxicologist and that Dr. Jones had invited Wimbish to speak at a seminar on the subject of postmortem redistribution. Dr. Jones further agreed that, in the instant case, the 10 quality control sample read close to the target value, and further conceded that a limited sample of blood affects whether it is appropriate to drop a calibrator. As lab director, he acknowledged that he has approved a test where a distant calibrator was dropped because of a limited quantity of blood.

Alza further contends that Accu-Chem's test was not properly performed because Accu-Chem obtained its quality control material from the same source that it obtained its calibrators. Dr. Wimbish addressed the "same source issue" with regard to Accu-Chem's testing. Dr. Wimbish testified that it is generally recommended that a laboratory obtain its quality control material from a source separate from the source used to obtain the calibrators, but it is not required. Alza does not further explain or show how this adversely affected the quality of the test or the test results itself.

Finally, we note that Dr. Wimbish testified that Accu-Chem also tested Thompson's blood for the metabolite of fentanyl and found less than 2 nanograms per milliliter. Based on the amount of fentanyl in Thompson's system, Dr. Wimbish would have expected 8 or 10 nanograms per milliliter, and the discrepancy means that the fentanyl in Thompson's system came in acutely, or over a short period of time. According to Dr. Wimbish, the "only way" to explain the discrepancy between the amount of fentanyl and the amount of fentanyl metabolites is that within a day's period, fentanyl came into Thompson's system in a "fairly rapid" fashion in a "bolus amount," which is a "large amount . . . flooding into something at the same — at the same time."

The trial court's gatekeeping function under Rule 702 does not supplant cross-examination as "the traditional and appropriate means of attacking shaky but

admissible evidence." *Gammill v. Jack Williams Chevrolet*, 972 S.W.2d 713, 728 (Tex. 1998) (citing *Daubert v. Merrell Dow Pharms.*, 509 U.S. 579, 596 (1993)); *see* TEX. R. EVID. 702. The reasons given by Alza as to why it thought the Accu-Chem test was unreliable affect the weight and credibility of the test, but not its admissibility. *See Mo.-Kan.Tex. R.R. Co. v. May*, 600 S.W.2d 755, 756 (Tex. 1980). Alza and its expert witnesses had the opportunity to explore the consequences of these alleged defects in the testing procedures and did so at great length.

Once the trial court found that the scientific principles and procedures underlying the test were generally accepted in the relevant scientific community, and the application of this theory was reliable, the threshold determination of admissibility of the test was met, and the judge was allowed, if not required, to allow the experts to render opinions on the presence of fentanyl in Thompson's blood, leaving for the jury to determine the credibility of those expert opinions. *See Ledesma*, 242 S.W.3d at 42. The issue of whether the particular analysis of Thompson's blood by Accu-Chem was performed in the proper manner, including whether sufficient quality control procedures were used to ensure the accuracy of the test results, was a question of credibility and probative value for the jury to determine, after hearing the testimony of all the experts.

4. Postmortem Redistribution

Alza contends that even if Accu-Chem's blood test was accurate, the level of fentanyl in Thompson's blood was the result of postmortem redistribution rather than an overdose. Dr. Wimbish testified that postmortem redistribution occurs after death when body tissue and organs break down and drug concentrations in one organ may leak into, or contaminate, other organs. In other words, for instance, if a drug is known to concentrate in certain tissues, such as the lung, after death, the drug concentration may

migrate or leak from the lung tissue into the heart and cause an artificially elevated level of the drug to be found in a blood sample taken from the heart. Dr. Wimbish testified that all pathologists have been trained that the best place to collect a blood specimen to prevent contamination is the femoral specimen, and it is scientifically reliable to form an opinion about levels of fentanyl in someone's blood at the time of death based on levels taken postmortem from a femoral draw. According to Dr. Wimbish, "[t]hat's been studied on many occasions, and the femoral specimen is by far the best." Dr. Wimbish testified that drugs that are highly protein bound and drugs that have high volumes of distribution are those that are most susceptible to postmortem redistribution. If postmortem redistribution were to occur, it would be significantly reduced by the refrigeration prior to autopsy.

Dr. Wimbish testified regarding an article entitled "Postmortem Redistribution of Morphine and its Metabolites," published in the Journal of Forensic Sciences. Dr. Wimbish testified that fentanyl and morphine are very similar compounds and are both considered to be drugs that have reasonably high volumes of distribution, and accordingly, a study regarding the postmortem redistribution of morphine would render results that could be used to analyze whether fentanyl was susceptible to postmortem redistribution. According to Dr. Wimbish, the morphine study analyzed blood samples taken from the femoral artery and from heart blood to determine whether morphine is susceptible to postmortem redistribution and determined that there was no significant difference in the results; thus, postmortem redistribution of morphine from a human femoral draw was unlikely. This study, like all others published in the Journal of Forensic Sciences, was subjected to peer review, a critique by other scientists to evaluate and determine if the scientific integrity and the protocol as designed in the study would allow a conclusion on a scientific basis.

Dr. Wimbish testified that there are no peer reviewed, published articles concerning postmortem redistribution of fentanyl from a human femoral draw; accordingly, theories that postmortem fentanyl redistribution in humans regarding femoral and heart blood specimens are speculation.

Dr. Wimbish also testified about a study performed by Janssen Research Foundation, which involved the application of Duragesic patches to six rabbits. This study was not published or subject to peer review and was instead a "confidential" study by Janssen, a private company and a subsidiary of the manufacturer of the Duragesic patch. Janssen administered fentanyl to these rabbits through Duragesic transdermal patches and collected blood specimens from the rabbits at different time intervals, both prior to and after the death of the rabbits, to try to determine if postmortem redistribution occurred in the rabbits. Although Janssen concluded that the study indicated that some postmortem redistribution occurred with fentanyl, Dr. Wimbish disagreed.

Dr. Wimbish testified that it was not scientifically reliable to derive an opinion about the postmortem redistribution of fentanyl in human femoral blood from a test involving the postmortem distribution of fentanyl in six four-and-a-half-pound rabbits and there was not "any equivalence" to allow that correlation. Dr. Wimbish offered some scathing and detailed criticisms of Janssen's study, which may be summarized as follows. This study utilized a human patch on the body of a 4.5 pound rabbit. The "rabbit" sample was too limited, and the concentrations in the blood and plasma ranged from therapeutic to toxic in three of the six rabbits. The dosages of fentanyl were not administered on a milligram per killigram basis, whereby the amount of drug administered to the rabbits could be compared to the amount of drug typically prescribed to a human. The surface area of the patch proportionally covered a much larger portion of the rabbits than it does humans.

Utilizing the study data, Dr. Wimbish testified that it shows no real difference in the initial blood concentrations and the allegedly increased blood concentrations. While there are some increases in concentrations, the Duragesic patches were left on the rabbits after their deaths and the continued infusion of fentanyl could cause a rise in fentanyl levels throughout the body after death. Dr. Wimbish stated that this process could not be differentiated from what Alza's experts identified as postmortem redistribution. In short, Dr. Wimbish testified that this study gives no support to the theory that postmortem redistribution of fentanyl occurs in human femoral blood.

Dr. Wimbish further testified about an article entitled "Duragesic Transdermal Patch: Postmortem Tissue Distribution of Fentanyl in 25 Cases," published in the Journal of Analytical Toxicology by Anderson and Muto. This peer-reviewed study analyzed twenty-five cases involving humans wearing fentanyl patches where death occurred. According to Dr. Wimbish, this study did not show that there was any postmortem redistribution. The authors referenced five cases indicating that the postmortem level of fentanyl in the femoral blood was higher than in the central blood. However, according to Dr. Wimbish, the paper was not designed to test whether postmortem redistribution occurred, and it does not support a scientifically reliable theory that it occurs. On cross-examination, Dr. Wimbish agreed that the study states that: "As with other drugs, the amount of postmortem redistribution appears to increase as the Fentanyl concentration increases."

Dr. Jones testified that in his opinion, the Accu-Chem test was not valid, and even if the 11.4 level was accurate, that the blood level shown 18 hours after death did not accurately reflect the level of fentanyl in Thompson's system at the time of death. Dr. Jones testified that fentanyl is susceptible to postmortem redistribution, and the Anderson and Muto study stands for the proposition that the amount of postmortem redistribution

appears to increase as the fentanyl concentration increases. According to Dr. Jones, postmortem redistribution occurs most strongly around the lungs and heart and less so peripherally in locations like the femoral artery. However, draws from the femoral artery can still be affected unless it is a "closed" draw. According to Dr. Jones, the Anderson and Muto study shows that postmortem redistribution occurs with fentanyl but "maybe in not every case." He agreed that the scientific community had not reached a conclusion as to whether postmortem redistribution artificially elevates fentanyl concentrations in human femoral blood. Dr. Jones further testified that resuscitation efforts can increase the degree of postmortem redistribution, and noted that testimony from nurse Kathryn Nu Bourn indicated that CPR was performed on Thompson for approximately twenty minutes prior to death.

Dr. Jones testified that the "rabbit" study performed by Janssen indicates that fentanyl concentrations increase after death, and "the most likely cause or contributor would be postmortem redistribution." Dr. Jones first became aware of the Janssen rabbit study when he was provided that study by Janssen's counsel. He conceded that it was unpublished and was not peer-reviewed, and that it was performed "confidentially" by the defendant that has been sued in this case. He acknowledged that the four-to-five pound rabbits were subjected to more than twenty-two times the level of fentanyl that is used in humans, and that the Duragesic patches remained on the rabbits after death and continued to distribute fentanyl into the rabbits.

Dr. Jones was retained by Janssen as an expert in at least sixteen cases. He expects that in "certainly most cases" he will testify that the fentanyl levels are too high because postmortem redistribution "could have occurred." He cannot say how much Thompson's fentanyl blood level would have been affected by postmortem redistribution

to calculate what the fentanyl level would have been at the time of death.

Based on the foregoing testimony, we cannot conclude that Alza's evidence conclusively established that the level of fentanyl in Thompson's blood was the result of postmortem redistribution. At most, the evidence presented in support of this theory was speculative in nature. Alza's own expert, Dr. Jones, stated that postmortem redistribution of fentanyl in humans "could have occurred," but "maybe in not every case," and he conceded that the scientific community had not yet determined if postmortem redistribution artificially elevates fentanyl concentrations in human femoral blood. The studies utilized by Alza to support its theory were either not directed at determining whether postmortem redistribution occurs with fentanyl, such as the Anderson and Muto study, or were "confidential" studies, which were not peer reviewed, which were performed by Alza or its own subsidiaries or employees. The study that Alza primarily relies on to support its theory of postmortem redistribution relied solely on fentanyl testing on six rabbits. Animal studies, standing alone, are generally held to be inadequate to prove causation in humans absent other confirming epidemiological data. *See, e.g., Havner*, 953 S.W.2d at 729 (collecting authorities). Accordingly, we reject Alza's contention that Thompson's fentanyl blood level of 11.4 ng/ml was conclusively caused by postmortem redistribution.

5. Use of a Recalled Patch

Alza contends that the evidence conclusively establishes that Thompson could not have been wearing a 75 mcg/h patch from a recalled lot when she died.[22] First, Alza argues that the Thompson family cannot prove that Michaelynn Thompson's Duragesic patch was among the 2,500,000 patches recalled either during the initial recall or the

[22] William Parks, the director of trade relations for Janssen and the liaison between retail and wholesale customers and the company, was unable to determine which lot that the patch Thompson was wearing came from.

subsequent expanded recalls that Alza had to perform when it became apparent that its initial recall was not nearly broad enough. However, proof that Thompson's Duragesic patch was itself recalled is not an element of the Thompson family's claims and is, therefore, immaterial.

Under the Texas Rules of Evidence, "written notification by a manufacturer of any defect in a product produced by such manufacturer to purchasers thereof is admissible against the manufacturer on the issue of existence of the defect to the extent that it is relevant." TEX. R. EVID. 407(b); *Parsons*, 85 S.W.3d at 331 n.2; *Wright v. General Motors Corp.*, 717 S.W.2d 153, 155 (Tex. App. Houston 1st Dist. 1986, no writ). While evidence that a product fell within a recall is evidence of a defect, the converse is not true: evidence that a manufacturer did *not* recall a product or evidence that the product at issue fell outside the recall is no evidence that the product is not defective. If the Thompson family had brought claims that focused on an allegation that Alza had negligently executed a recall which it undertook to perform,[23] evidence that Michaelynn Thompson's Duragesic patch was among the 2,500,000 patches recalled might possibly be of some relevance, but Alza's argument is wholly irrelevant to the Thompson family's strict product liability manufacturing defect claims (and also irrelevant to the family's general negligence claims, which focused on Alza's careless quality assurance processes).

Although the emergency room doctor removed and discarded Thompson's

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[23] *See Torrington Co. v. Stutzman*, 46 S.W.3d 829, 838-39 (Tex.2000) (discussing circumstances when a defendant's post-sale defect investigation gives rise to a duty to perform that undertaking with ordinary care). As we recognized years ago, Texas law is generally not the source of any duty to warn of product defects uncovered after sale, but there is such a duty when the manufacturer has regained control of a product after the defect was learned and the manufacturer failed to remedy a defect before reselling the product. *See Bell Helicopter Co. v. Bradshaw*, 594 S.W.2d 519, 531-32 (Tex. Civ. App.–Corpus Christi 1979, writ ref'd n.r.e.). Although Texas law is not the source of a more general post-sale duty, there are other potential sources of such a duty which might be enforced under Texas law. *See, e.g., Lowe v. Gen. Motors Corp.*, 624 F.2d 1373, 1379-1380 (5th Cir. 1980) (violation of Federal Motor Vehicle Safety Standards can serve as basis for negligence per se claim).

Duragesic patch before it could be analyzed, it has been a well accepted principle of Texas law for at least forty years that, in products liability cases, the claimant need not offer direct evidence to prove a defect because such proof "usually can only be made by circumstantial evidence." *Turner v. Gen. Motors Corp.*, 584 S.W.2d 844, 848 (Tex. 1979) (citing *Darryl v. Ford Motor Co.*, 440 S.W.2d 630, 632 (Tex. 1969)); *see Ridgway*, 135 S.W.3d at 602 (Hecht, J., concurring) (stating that Texas law allows proof of product liability by circumstantial evidence in certain cases); *see also Shaun T. Mian Corp. v. Hewlett-Packard Co.*, 237 S.W.3d 851, 858 (Tex. App.–Dallas 2007, pet. denied) (providing a thorough examination of the principles underlying the use of circumstantial evidence in product liability cases). Accordingly, when "the plaintiff has no evidence of a specific design defect or manufacturing defect, he may offer evidence of the product's malfunction as circumstantial proof of the defect." *Sipes v. Gen. Motors Corp.*, 946 S.W.2d 143, 155 (Tex. App.–Texarkana 1997, writ denied).

In this case, it is undisputed that Alza's Bodolay machine was the machine which would have made Thompson's Duragesic patch as well as the many patches which had documented defects in their seals.[24] This Bodolay machine was already scheduled for replacement, but before it could be replaced, it had to undergo several modifications to try to reduce the number of manufacturing defects it was producing. It is undisputed that these modifications were not implemented until after the time period when Thompson's Duragesic patch would have been manufactured on Alza's Bodolay machine. Moreover, the documentary evidence and Alza's own witnesses confirmed that public reports of leaking patches were higher in some lots of Duragesic patches that were not recalled than

[24] Likewise, Thompson's Duragesic patch was made according to the same control processes as those defective patches which escaped detection and were shipped to the public with flawed seals despite Alza's visual inspection of the patches as they passed along a conveyor belt.

in some of the lots that Alza recalled. Finally, Duragesic patches with defective seals are a known cause of patients receiving an overdose of fentanyl, and as stated in Alza's own second recall notice, it is undisputed that such fentanyl exposure can be fatal:

> Exposure to the leaked medication could result in . . . an increased transdermal absorption of the opiate component fentanyl, leading to potentially life-threatening complications.

Based on the foregoing, and other evidence discussed herein, the jury had before it legally and factually sufficient evidence from which it may have concluded that a manufacturing defect in the Duragesic patch worn by Thompson caused her death. Accordingly, we overrule Alza's first issue and those subissues therein.

C. CAUSATION

In its third issue, Alza contends that there was legally and factually insufficient evidence to support the jury's causation findings. Alza also challenges the reliability of the expert testimony supporting the causation finding. *See Volkswagen of Am., Inc. v. Ramirez*, 159 S.W.3d 897, 903 (Tex. 2004)("A party may raise a properly preserved complaint on appeal that scientific evidence is unreliable and thus no evidence to support a judgment."). First, we address the reliability of the expert testimony, and then we will separately address the sufficiency of the evidence. *See Whirlpool Corp. v. Camacho*, 298 S.W.3d 631, 639 (Tex. 2009); *Volkswagen of Am., Inc.*, 159 S.W.3d at 904.

1. The Reliability of Thompson's Expert Testimony on Causation

Alza argues that the testimony offered by Thompson's experts, Dr. Robert C. Bux and Dr. Sayed Feghali, was legally and factually insufficient and it varied materially from the actual "undisputed" facts. Alza contends that, because of these deficiencies, Thompson failed to produce expert testimony that any defect in a Duragesic patch worn by Thompson was a producing or proximate cause of her death. Alza further argues that

the causation opinions of Thompson's experts are no evidence because they are based solely on the Accu-Chem test. In this context, Alza argues that Thompson's expert opinion testimony fails the *Robinson* test and is unreliable. *See E.I. du Pont de Nemours & Co. v. Robinson*, 923 S.W.2d 549, 557 (Tex. 1995).

A two-part test governs whether expert testimony is admissible: (1) the expert must be qualified; and (2) the testimony must be relevant and based on a reliable foundation. *Helena Chem. Co. v. Wilkins*, 47 S.W.3d 486, 499 (Tex. 2001). Whether the trial court properly admitted expert testimony is subject to an abuse of discretion standard of review. *Id.*; *Robinson*, 923 S.W.2d at 549, 558. The test for abuse of discretion is whether the trial court acted without reference to any guiding rules or principles. *Id.*; *Downer v. Aquamarine Op., Inc.*, 701 S.W.2d 238, 241-42 (Tex. 1985). The test is not whether "in the opinion of the reviewing court, the facts present an appropriate case for the trial court's action." *Robinson*, 932 S.W.2d at 558. A reviewing court cannot conclude that a trial court abused its discretion merely because it would have ruled differently. *Id*. The trial court has "broad" discretion to determine the admissibility of expert evidence. *Exxon Pipeline Co. v. Zwahr*, 88 S.W.3d 623, 629 (Tex. 2002); *Sanchez*, 997 S.W.2d at 590; *Robinson*, 923 S.W.2d at 558. We must uphold the trial court's evidentiary ruling if there is any legitimate basis for it. *Owens-Corning Fiberglas Corp. v. Malone*, 972 S.W.2d 35, 43 (Tex. 1998); *Norstrud v. Trinity Universal Ins. Co.*, 97 S.W.3d 749, 752 (Tex. App.–Fort Worth 2003, no pet.).

For an expert's testimony to be admissible, it must possess a reliable foundation. *Cooper Tire & Rubber Co.*, 204 S.W.3d at 800. "Admission of expert testimony that does not meet the reliability requirement is an abuse of discretion." *Id.* Expert testimony is unreliable if it is based on unreliable data, or if the expert draws conclusions from his underlying data "based on flawed methodology." *Havner*, 953 S.W.2d at 714. Expert

testimony is also unreliable if "there is simply too great an analytical gap between the data and the opinion proffered." *Gammill*, 972 S.W.2d at 726 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)).

In *E.I. du Pont de Nemours & Co. v. Robinson*, the supreme court set out six factors courts may consider in deciding whether expert testimony is reliable:

1. the extent to which the theory has been or can be tested;
2. the extent to which the technique relies on the subjective interpretation of the expert;
3. whether the theory has been subjected to peer review and/or publication;
4. the technique's potential rate of error;
5. whether the underlying theory or technique generally has been accepted as valid by the relevant scientific community; and
6. the nonjudicial uses which have been made of the theory or technique.

923 S.W.2d at 557. These *Robinson* factors are nonexclusive, *Cooper Tire & Rubber Co.*, 204 S.W.3d at 801, and "are not always useful in evaluating expert testimony." *Id.* at 802. When the *Robinson* factors do not readily lend themselves to a review of the expert testimony, "there must be some basis for the opinion offered to show its reliability." *Gammill*, 972 S.W.2d at 726. An expert's "bare opinion" will not suffice and is unreliable if "based solely upon his subjective interpretation of the facts." *Volkswagen of Am., Inc.*, 159 S.W.3d at 906.

Dr. Bux, a physician and board certified forensic pathologist who practices as a medical examiner and the coroner for El Paso County, Colorado, provided testimony for the Thompson family. Based on his review and analysis of Thompson's medical records from the day of her death, her autopsy report and microscopic pathology slides, and the

Accu-Chem data, Dr. Bux testified that Thompson died from a fentanyl overdose and not heart disease. Thompson presented to the emergency room with symptoms of nausea, vomiting, and back pain, and later complained of dizziness, but she was alert and oriented. She was on an EKG monitor during her transportation to the hospital by the emergency medical personnel, and also while she was in the emergency room, and "those monitors do not reveal any kind of cardiac abnormality or rhythm disturbance" but instead show "her regular normal heartbeat." Thompson's medical records from the day of her death do not show that she reported any symptoms that would suggest that she was experiencing a cardiology-related problem, such as chest pain or shortness of breath.

Dr. Bux further testified that a "cardiac panel" test was performed on Thompson's blood. This panel included an array of tests, which, inter alia, checked for high levels of certain enzymes indicating damage to muscles, including cardiac muscle, and troponin, which is specific for cardiac muscle. The results of the cardiac panel were "all either negative or within normal limits, which tells me that at the time she came in, it did not appear from an enzyme standpoint that she had anything going on with her heart." Finally, examining the autopsy data, Dr. Bux testified that, microscopically, Thompson's heart muscle looked normal except for the hypertrophy. He concluded there was no forensic evidence in the records on the day that Thompson died that supports a determination that Thompson died from sudden cardiac arrest and that sudden cardiac arrest was not a plausible cause of Thompson's death. According to Dr. Bux, a large heart is not an actual cause of death.

Dr. Bux considered the other drugs that were administered to Thompson at the hospital, including Antivert, Zofran, and Dilaudid, and excluded them as factors in Thompson's demise based on the dosages given, the methods of infusion, and the timing

of their administration. He found it significant that the emergency room physician removed the Duragesic patch from Thompson during his efforts to resuscitate her and also administered Narcan, which is an antidote for a narcotic overdose.

Dr. Bux testified that Accu-Chem's toxicological report showed a quantitation of fentanyl at 11.4 ng/ml, which is a "lethal" level. He further testified that respiratory depression due to a drug overdose occurs in the last minutes or hour before death, that it is very difficult to "pick up," and that it is completely foreseeable for Thompson to not show signs of respiratory depression at 3:15 p.m., but die from it thirty-five minutes later.

Dr. Sayed Feghali, a cardiologist who works at the Texas Heart Institute and teaches at Baylor School of Medicine, also testified on behalf of the Thompsons regarding whether or not Thompson could have died from cardiac problems.[25] He is board certified in cardiology and interventional cardiology. This was his first time to provide expert testimony in a lawsuit.

According to Dr. Feghali, fentanyl has a narrow therapeutic margin. He has used it intravenously in thousands of patients. After reviewing all of Thompson's medical records, including EKGs from a sleep study that Thompson had participated in, the EKG taken by emergency workers on the day Thompson died, and the EKGs taken during attempts to resuscitate her, Dr. Feghali testified that Thompson died from an overdose of fentanyl, and Thompson's morbid obesity and sleep apnea played a minor part, if any, in her death. Dr. Feghali testified that other medications that she was given could not have caused respiratory depression because she was given appropriate doses.

Dr. Feghali concluded that Thompson could not have died from a cardiac event

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[25] As part of the Thompson family's burden on specific causation, they were required to offer evidence excluding other causes of Michaelynn's death with reasonable certainty. *Merrell Dow Pharms. v. Havner*, 953 S.W.2d 706, 720 (Tex. 1997).

because her autopsy showed no damaged heart tissue and the pathology report referenced no damage to Thompson's heart muscle or any blockage of her arteries. According to Dr. Feghali, a sudden malignant arrhythmia does not come from nowhere and there should be a cause for it somewhere in the heart, like heart damage, heart scarring, a blockage, or a viral infection. In other words, the heart muscle will show prior damage of some kind. Dr. Feghali further based his conclusion that Thompson did not die from a sudden cardiac event because electric discrepancies did not appear on the EKGs performed either while en route to the emergency room, or saliently, while the emergency team was trying to resuscitate her. Dr. Feghali testified that while Thompson's heart was large, it was normally sized for her body.

On appeal, Alza does not challenge Dr. Bux or Dr. Feghali's credentials. Their testimony analytically linked the data they observed to their theory of how Thompson died. They based their testimony on witness testimony, medical records, autopsy records, blood samples taken at the autopsy, the blood testing, and Alza's own literature and drug warnings. The testing was based on generally acceptable scientific principles. The jury was free to examine this evidence. The experts' testimony does not present a case where "there is simply too great an analytical gap between the data and the opinion proffered," *Gammill*, 972 S.W.2d at 726, or where the expert's testimony amounted to nothing more than a recitation of his credentials and a subjective opinion. *See Cooper Tire*, 204 S.W.3d at 801. The Thompson family met its burden to prove Dr. Bux and Dr. Feghali's testimony was relevant and reliable. *See Whirlpool Corp.*, 298 S.W.3d at 638. We conclude that Alza's complaints about the experts' testimony go to its weight, not its admissibility. The trial court therefore did not abuse its discretion in admitting the testimony of either Dr. Bux or Dr. Feghali.

2. Sufficiency of the Causation Evidence

We next examine the legal and factual sufficiency of the evidence of causation supporting the jury's finding. *See id.* In addition to the evidence and testimony previously recounted herein, we will examine the testimony of Alza's retained expert witnesses: Dr. Vincent DiMaio, the medical examiner in Bexar County; Dr. Joseph Varon, who specializes in internal medicine, intensive care, pulmonary and chest diseases, sleep disorders, geriatrics, and emergency medicine; and Dr. Aaron Kenneth Calodney, a medical doctor and pain management specialist.

Dr. DiMaio testified that Thompson died from a fatal cardiac arrhythmia, an irregular beating of the heart, produced by the massive enlargement of her heart. According to Dr. DiMaio, it was essentially a "coincidence" that Thompson went to the hospital and died of an arrhythmia. Dr. DiMaio testified that thirteen percent of people who die suddenly and unexpectedly have a large heart as the cause of death. Yet he conceded before the jury that one cannot perform a test for cardiomyopathy and he is not a cardiologist. While Dr. DiMaio agreed that Thompson's medical records and testimony evidence sleepiness, and sleepiness is a sign of fentanyl toxicity, he stated that if Thompson had received a fatal dose of fentanyl, she would have become sleepy and then gone into a coma for two to three hours prior to death, in contrast to the evidence herein which indicates that Thompson was found dead thirty to thirty-five minutes after being seen by a nurse. Dr. DiMaio testified that the only way a fentanyl overdose kills immediately is if it is infused intravenously. Finally, Dr. DiMaio testified that, in retrospect, the medical examiner for Harris County should have tested Thompson for fentanyl.

Dr. Varon testified in counterpoint to Dr. Feghali. While Dr. Varon conceded that he is not board-certified in cardiology, he claimed that he is the "number one guy" on

sudden cardiac death. He works at the medical center in Houston and teaches at the University of Texas Health Science Center and other places. According to Dr. Varon, signs to look for in diagnosing a fentanyl or narcotic overdose include: constricted pupils, sweating, drowsiness or lethargy, and the cessation of breathing. Dr. Varon testified that these symptoms appear fast with intravenous transfusions of fentanyl or more slowly when the drug is introduced orally or through a skin patch. With a fentanyl overdose, he would have expected Thompson to be lethargic, sleepy, drowsy, and have depressed respirations, yet he did gave sworn testimony that he did not recall any of these symptoms in her medical records which expressly document some of these symptoms.

According to Dr. Varon, it takes sixteen hours to achieve the full blood level effects of a fentanyl patch. However, when questioned about proper fentanyl dosages, he testified that he does not follow the therapeutic ranges on narcotics in the PDR, and in response to a question regarding whether his dosages regarding fentanyl were "catch as catch can," replied, "exactly right."

Dr. Varon testified that he is familiar with sudden cardiac arrest, and that 500 to 1,000 cases of sudden cardiac arrest occur every day in the United States and that one episode of cardiac arrhythmia can cause death. The underlying arrhythmia can be caused by the heart not getting enough oxygen or potassium. According to Dr. Varon, there are several risk factors for a sudden cardiac arrhythmia, including blockages in the heart, sleep apnea, medications, problems with electrolytes, trauma, or an enlarged heart.

Dr. Varon examined the autopsy report, which stated that Thompson was six feet tall and weighed 367 pounds, and testified that obesity also carries a higher risk for health problems like apnea and sudden cardiac death. Thompson's heart weighed 600 grams and had enlarged chambers, whereas a normal heart weighs between 350 to 500 grams.

According to Dr. Varon, the more dilated the heart is, the higher the chances of cardiac arrhythmia. Dr. Varon testified that in his opinion, Thompson did not have a healthy heart, and he opined that she expired from a sudden cardiac death, which was the result of arrhythmia or a defibrillate. He also testified that it was just a coincidence that Thompson was in the hospital when she died of arrhythmia. In this regard, he stated that Thompson had participated in a sleep study which showed she had sleep apnea, although he conceded that the records from that study showed that she had 144 instances of apnea without any corresponding arrhythmia. Dr. Varon testified that Thompson's medical records from 2001 and 2002 show potential heart problems in two instances where she complained of chest pains and tightness, difficulty breathing, nausea, and general weakness, although the records fail to show any such diagnosis.

According to Dr. Varon, an individual can experience a regular heart rate which progresses to full arrhythmia in minutes. However, Dr. Varon admitted that the EKGs which were performed on Thompson on the date of her death showed no abnormalities with regard to Thompson's heart valves, and her autopsy showed no atherosclerosis or other heart damage. He further agreed that big people can have big, healthy hearts.

Dr. Aaron Kenneth Calodney, a medical doctor and pain management specialist, provided further testimony on behalf of Alza. Dr. Calodney has written thousands of prescriptions for Duragesic patches. He testified that Duragesic patches fall within a "class II" system of narcotics, and a class II narcotic is something that is "[d]efinitely" dangerous if misused. Dr. Calodney testified that he would not start an opioid naive patient on a 50 milligram patch because it could potentially be fatal. He testified that fentanyl is an opioid like morphine, but is approximately 100 times more potent than morphine.

Dr. Calodney testified that the PDR is a common reference for professionals to use

to ascertain the particular qualities and properties of drugs, and further testified regarding the PDR's section on the Duragesic patch. The PDR states that "since the peak fentanyl levels occur between 24 and 72 hours of treatment, prescribers should be aware that serious or life-threatening hypoventilation may occur, even in opiate tolerant patients during the initial application period." It further states that "[o]verestimating the Duragesic dose when converting patients from another opiate medication can result in fatal overdose with the first dose." The 2005 PDR states that using damaged or cut patches can lead to the rapid release of the contents of the patch and absorption of a potentially fatal dose of fentanyl.

Dr. Calodney has never seen a damaged patch, but he agreed that if the patch was damaged and the drug were to escape, then that could lead to a rapid release of fentanyl. He refused to testify regarding whether a rapid release could lead to a fatal overdose, "not knowing whether the stuff inside the patch can actually be absorbed through the skin" without the patch system itself.

According to Dr. Calodney, Thompson was an appropriate candidate for use of a Duragesic patch. Dr. Calodney stated that complications from an overdose of fentanyl include itching, nausea and vomiting, difficulty urinating, and respiratory depression; he reviewed Thompson's medical records and nevertheless stated that he saw no signs in her medical records that indicated the appearance of fentanyl toxicity. He further testified that if someone is receiving too much fentanyl, a change in their level of consciousness is observable over a period of time; the patient will begin to get drowsy and develop changes in respiration after that. According to Dr. Calodney, these changes happen slowly and gradually as the medication is infused, presumably through a rate-controlled membrane. We note at this juncture that, in contrast, Dr. Wimbish testified that the respiratory center

adapts to drug tolerance and a patient may not experience respiratory depression until the threshold for tolerance is exceeded, and it may be close to the fatal event in a tolerant individual. In other words, respiratory depression is not necessarily observable in a tolerant individual. According to Dr. Wimbish, it could be "part of the terminal event rather than a harbinger of something to come."

To a significant extent, deciding whether Thompson died from an enlarged heart or a sudden arrhythmia, as alleged by Alza, or an overdose of fentanyl, as alleged by the Thompson family, turned on the jury's examination of the evidence and its assessment of the credibility of the various witnesses. We note that the jury was, of course, entitled to weigh the credibility of these witnesses. *Ledesma*, 242 S.W.3d at 41 (holding that the jury was entitled to take into account that an expert had worked for the manufacturer and had never found a defect in a product).[26]

Causation may be established by circumstantial evidence. *Ridgway*, 135 S.W.3d at 601; *Ford Motor Co. v. Cammack*, 999 S.W.2d 1, 7 (Tex. App.–Houston [14th Dist.] 1998, pet. denied); *J.K. and Susie L. Wadley Research Inst. & Blood Bank v. Beeson*, 835 S.W.2d 689, 698 (Tex. App.–Dallas 1992, writ denied). This principle of Texas law has been well recognized for decades. *Gladewater v. Pike*, 727 S.W.2d 514, 518 (Tex. 1987) ("Circumstantial evidence and inferences therefrom are a sufficient basis for a finding of causation."); *Farley v. M M Cattle Co.*, 529 S.W.2d 751, 755 (Tex. 1975) ("Proximate cause, like any other ultimate fact, may be established by circumstantial evidence."); *Lynch v. Ricketts*, 158 Tex. 487, 314 S.W.2d 273, 275-76 (Tex. 1958) ("It is well settled . . . that

[26] We note that we are not the first court to review Alza's claim that its own experts' dismissive testimony about the flaws in its Duragesic fentanyl patches is authoritative or Alza's arguments that the claimant's experts' contrary opinions should be wholly disregarded. *See, e.g., Kunnemann v. Janssen Pharmaceutica Products, L.P.*, No. 05 C 3211, 2008 U.S. Dist. LEXIS 101724, at *8-32 (N.D. Ill. Dec. 2, 2008) (not designated for publication). Likewise, we are not the first court to conclude "[t]hese issues must be resolved by a jury." *See id.* at *32.

negligence and causation, like any other ultimate fact, may be established by circumstantial as well as direct evidence."); *Peveto v. Smith*, 134 Tex. 308, 133 S.W.2d 572, 576 (1939) (relying on circumstantial evidence to prove negligence and causation); *see also Tex. Elec. Coop. v. Dillard*, 171 S.W.3d 201, 206 (Tex. App.–Tyler 2005, no pet.) ("Cause in fact . . . may be proven by circumstantial evidence . . . ."). The question of causation is a fact question for the jury, and the jury has broad latitude to infer causation from the circumstances surrounding an accident, especially when it is not possible to produce direct proof of causation. *J.K. and Susie L. Wadley*, 835 S.W.2d at 698; *Farley*, 529 S.W.2d at 756. The plaintiff need not exclude all possibility that the accident occurred other than as he alleges. *Farley*, 529 S.W.2d at 756. Rather, the plaintiff is only required to convince the jury by a preponderance of the evidence that the accident occurred as alleged. *Renfro Drug Co. v. Lewis*, 235 S.W.2d 609, 621 (1950); *Gulf States Util. Co. v. Dryden*, 735 S.W.2d 263, 267 (Tex. App.- Beaumont 1987, no writ). In the specific context of a strict product liability case, the claimants can support their theory of how the incident occurred with circumstantial evidence. *See, e.g., Ridgway*, 135 S.W.3d at 601; *Gen. Motors Corp. v. Sanchez*, 997 S.W.2d 584, 587 (Tex. 1999); *Kindred v. Con/Chem, Inc.*, 650 S.W.2d 61, 63 (Tex.1983).

As stated previously, under the Texas Supreme Court's articulation of the standard of review in *City of Keller*, in reviewing the legal sufficiency of the evidence, we view the evidence in the light most favorable to the jury's findings, giving full credit to all favorable evidence if any reasonable person could, and disregarding contrary evidence unless all reasonable persons could not. *City of Keller*, 168 S.W.3d at 807. The evidence supporting the jury's finding on causation was not completely lacking, nor was it beyond the court's authority to admit it, nor was it a mere scintilla, nor was it conclusively disproved by

contrary evidence. *See Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 334 (Tex. 1998); *see also Whirlpool Corp.*, 298 S.W.3d at 638. Moreover, considering and weighing all of the evidence in the case, the verdict was not so against the great weight and preponderance of the evidence as to be manifestly unjust, shock the conscience, or clearly demonstrate bias. *See Golden Eagle Archery, Inc. v. Jackson*, 116 S.W.3d 757, 761-62 (Tex. 2003).

Based on the foregoing, we overrule Alza's third issue.

III. Evidence of Negligence

In its second issue, Alza contends that there is legally insufficient evidence to support the submission or jury finding that Alza was negligent because there was no expert evidence on the standard of care.

As an initial matter, we note that a party may pursue claims and seek damages on alternative theories of liability. Tex. R. Civ. P. 48; *Waite Hill Servs., Inc. v. World Class Metal Works, Inc.*, 959 S.W.2d 182, 184 (Tex. 1998). When we have held that the evidence is legally and factually sufficient to support the trial court's judgment on one of multiple alternative causes of action, "it is unnecessary to address" the issues that concern alternative theories that might have also served as a basis to affirm the judgment. *Adams v. H & H Meat Prods., Inc.*, 41 S.W.3d 762, 771 (Tex. App.–Corpus Christi 2001, no pet.) (citing Tex. R. App. P. 47.1); *see Nw. Mortgage, Inc. v. Salinas*, 999 S.W.2d 846, 865 (Tex. App.–Corpus Christi 1999, pet. denied) (stating that when "the trial court's judgment can be supported on the basis of" one of multiple theories of recovery, "we need not address these remaining points" which address alternative theories of recovery). Accordingly, we need not address Alza's second issue, which challenges the legal sufficiency of the evidence supporting the jury's finding of negligence as an alternative basis for affirming the

judgment. *See* TEX. R. APP. P. 47.1.

Nevertheless, even if we were to find it necessary to address this issue, we note that the jury was instructed that:

> "Negligence" means failure to use ordinary care, that is, failing to do that which a pharmaceutical manufacturer of ordinary prudence would have done under the same or similar circumstances or doing that which a pharmaceutical manufacturer of ordinary prudence would not have done under the same or similar circumstances.

Where an issue involves only general knowledge and experience rather than expertise, it is a matter entrusted to the jury to decide. *See GTE Sw., Inc. v. Bruce*, 998 S.W.2d 605, 620 (Tex. 1999). In contrast, "[e]xpert testimony is necessary when the alleged negligence is of such a nature as not to be within the experience of the layman." *FFE Transp. Servs. v. Fulgham*, 154 S.W.3d 84, 91 (Tex. 2004) (quoting *Roark v. Allen*, 633 S.W.2d 804, 809 (Tex. 1982) (holding that diagnosis of skull fractures is not within the experience of the layman)); *see also Turbines, Inc. v. Dardis*, 1 S.W.3d 726, 738 (Tex. App.–Amarillo 1999, pet. denied) (holding that inspection and repair of an aircraft engine are not within the experience of the layman); *Hager v. Romines*, 913 S.W.2d 733, 734-35 (Tex. App.–Fort Worth 1995, no writ) (holding that operation of an aircraft and aerial application of herbicide are not within the experience of the layman). In determining whether expert testimony is necessary to establish negligence, Texas courts have considered whether the conduct at issue involves the use of specialized equipment and techniques unfamiliar to the ordinary person. *Fulgham*, 154 S.W.3d at 91.

In light of the testimony and admissions by Alza's employees and representatives regarding its manufacturing and quality inspection process for the Duragesic patch, the determination regarding whether Alza breached the standard of care applicable to a reasonable pharmaceutical manufacturer does not entail specialized knowledge or skill

unique to a scientific discipline and beyond the knowledge and experience of the average jury. *See, e.g, Worsham v. A.H. Robins Co.*, 734 F.2d 676, 685 (11th Cir. Fla. 1984) (affirming a judgment against the manufacturer of the Dalkon Shield IUD on claims of negligence despite the absence of expert testimony on the duty of care); *Palmer v. A.H. Robins Co.*, 684 P.2d 187, 209-10 (Colo. 1984) (same); *cf. McNeil Pharm. v. Hawkins*, 686 A.2d 567, 585 (D.C. 1996) (requiring competent expert testimony regarding the violation of the statutes and regulations submitted to the jury in warnings case). On the contrary, resolution of the negligence issue turns on an assessment of evidence relating to Alza's decision to manufacture the Duragesic patch on a machine known to produce defective patches and to test its products with a method known to be insufficient to ascertain the absence of defect. The ultimate determination of whether Alza's conduct comported with that degree of care which a reasonably prudent drug manufacturer would use under the same or similar circumstances was well within the experience of persons of ordinary intelligence. Thus, expert opinion evidence was not essential to the Thompson family's claim in negligence.[27]

However, even if we were to determine otherwise, and conclude that expert testimony was necessary, this requirement would have been met by the testimony proffered by Alza's own representatives and employees. While the Thompson family might not have presented a retained expert on pharmaceutical manufacturing to establish their claim that Alza was negligent in its manufacturing process, Alza's own representatives and employees, including a senior technician, the company representative, and its quality assurance specialist, offered expert opinion testimony regarding Alza's acts and omissions

[27] In this context, the determination whether expert testimony is necessary is reviewed under a de novo standard of review. *See FFE Transp. Servs. v. Fulgham*, 154 S.W.3d 84, 90 (Tex. 2004).

with regard to the Duragesic patch, from which credible and expert evidence the jury may have concluded that Alza was negligent. These witnesses testified that Alza released leaking patches to the public and only learned that its patches were defective because of consumer complaints; that Alza wrongly determined that the 2001 fold-over incidents were isolated events and accordingly, did not take corrective action that would have prevented distribution of the 2004 recalled lots; that Alza's inspection plan for the product lots was deficient; that Alza did not follow its own deficient plan and allowed distribution of trays of patches that it knew contained defects; that Alza continued to release patches after both learning of the leaks and determining the manufacturing flaw that resulted in the leaks; and that Alza continued to implement a visual inspection process despite knowing that it was ineffective to discover product defects.

Ultimately, in the instant case, the primary facts were accurately presented to the jury, and the jurors were as capable of understanding and drawing correct conclusions from the facts as an expert witness. While there are cases that would fail without expert testimony because the technical and scientific aspects of the case would result in a jury's inability to comprehend the issues, Alza has not shown that the standard of care issue is, by definition, a matter beyond the jurors or that this is "one of the rare causes of action in which the law predicates recovery upon expert testimony." *Salem v. U.S. Lines Co.*, 370 U.S. 31, 35 (1962).

For the foregoing reasons, we overrule Alza's second issue.

IV. Evidentiary Rulings

Alza's fourth and fifth issues attack the trial court's admission of evidence regarding Accu-Chem's test and its recall of the Duragesic 75 mcg patch.

A. Standard of Review

We review the admission or exclusion of evidence under an abuse of discretion standard. *See In re J.P.B.*, 180 S.W.3d 570, 575 (Tex. 2005). Thus, evidentiary rulings admitting or excluding evidence are committed to the trial court's "sound" discretion. *See Tex. Dep't of Transp. v. Able*, 35 S.W.3d 608, 617 (Tex. 2000); *City of Brownsville v. Alvarado*, 897 S.W.2d 750, 753 (Tex. 1995); *Gee v. Liberty Mut. Fire Ins. Co.*, 765 S.W.2d 394, 396 (Tex. 1989). A trial court abuses its discretion if it acts without reference to any guiding rules and principles or if the act complained of is arbitrary and unreasonable. *City of Brownsville*, 897 S.W.2d at 754; *see also Carpenter v. Cimarron Hydrocarbons Corp*., 98 S.W.3d 682, 687 (Tex. 2002). We must uphold a trial court's evidentiary ruling if there is any legitimate basis in the record to support it. *Owens-Corning Fiberglas Corp.*, 972 S.W.2d at 43.

For the exclusion of evidence to constitute reversible error, the complaining party must show that (1) the trial court committed error, and (2) the error probably caused the rendition of an improper judgment. *State v. Cent. Expressway Sign Assocs*., No. 08-061, 53 Tex. Sup. Ct. J. 134, 2009 Tex. LEXIS 967, at **5-6 (Tex. Nov. 30, 2009); *McCraw v. Maris*, 828 S.W.2d 756, 757 (Tex. 1992); *see* TEX. R. APP. P. 44.1; *Nissan Motor Co. v. Armstrong*, 145 S.W.3d 131, 144 (Tex. 2004). A person seeking to reverse a judgment based on evidentiary error need not prove that "but for" the error a different judgment would necessarily have been rendered, but only that the error probably resulted in an improper judgment. *State*, 2009 Tex. LEXIS 967, at *6; *City of Brownsville*, 897 S.W.2d at 754; *McCraw*, 828 S.W.2d at 758. A successful challenge to evidentiary rulings usually requires the complaining party to show that the judgment turns on the particular evidence excluded or admitted. *Bay Area Healthcare Group, Ltd. v. McShane*, 239 S.W.3d 231, 234 (Tex. 2007); *Nissan Motor Co.*, 145 S.W.3d at 144. In making this determination, we review the

entire record. *Reliance Steel & Aluminum Co. v. Sevcik*, 267 S.W.3d 867, 871 (Tex. 2008); *Nissan Motor Co.*, 145 S.W.3d at 144.

The supreme court has recognized the impossibility of prescribing a specific test for harmless error review and has characterized the standard as "more a matter of judgment than precise measurement." *Reliance Steel*, 267 S.W.3d at 871 (quoting *Nissan Motor Co.*, 145 S.W.3d at 144). Accordingly, as stated by Justice O'Neill, that determination is entrusted "to the sound discretion of the reviewing court." *State*, 2009 Tex. LEXIS 967, at *5 (citing *McCraw*, 828 S.W.2d at 757-58; *Lorusso v. Members Mut. Ins. Co.*, 603 S.W.2d 818, 821 (Tex. 1980)).

We consider several factors in conducting a harmless error review for the erroneous admission of evidence: the state of the evidence, the strength and weakness of the case, and the verdict. *Reliance Steel*, 267 S.W.3d at 871. Stated otherwise, we consider the effect of the admission of the evidence; the role the evidence played in the context of trial; efforts by counsel to emphasize the erroneous evidence; and whether the admission of the improper evidence was calculated or inadvertent. *See id.* at 871-75. Thus, "the exclusion or admission is likely harmless if the evidence was cumulative, or the rest of the evidence was so one-sided that the error likely made no difference in the judgment." *State*, 2009 Tex. LEXIS 967, at *6; *see Reliance Steel*, 267 S.W.3d at 873. But if erroneously admitted or excluded evidence was "crucial" to a "key issue," the error is likely to be found harmful. *State*, 2009 Tex. LEXIS 967, at *6. We further consider whether there was contrary evidence that the improperly admitted evidence was calculated to overcome. *Id*; *Armstrong*, 145 S.W.3d at 144.

B. Admission of Evidence Regarding Fentanyl Levels in Thompson's Blood

In its fourth issue, Alza contends that the trial court committed harmful error resulting

in an improper judgment by admitting the results of the Accu-Chem postmortem blood test that was improperly performed and by permitting Thompson's experts to opine on the cause of death based solely on unreliable test results. We have previously addressed this matter with regard to Alza's other issues and need not further address it herein. *See* TEX. R. APP. P. 47.1. This issue is overruled.

C. ADMISSION OF EVIDENCE REGARDING ALZA'S RECALL OF FENTANYL PATCHES

In its fifth issue, Alza contends that the trial court's admission of evidence that Alza recalled several lots of Duragesic patches constituted an abuse of discretion that was reasonably calculated to and probably caused the rendition of an improper judgment. In several sub-issues, Alza argues that: (1) there is no evidence independent of the recall that Thompson was wearing a patch with the same defect; (2) the evidence of recall does not tend to make a fact that is of consequence to the suit any more or less probable; (3) the evidence of recall was outweighed by prejudice and caused a confusion of the issues; and (4) the admission of the recall evidence was reasonably calculated to and probably caused the rendition of an improper judgment. Thompson counters that this evidence was both admissible and relevant.

On February 17, 2004, Alza recalled one lot of 75 mcg Duragesic patches through an "Urgent Class 1 Drug Recall Notification." This recall notice stated that a "potential seal breach on one edge may allow drug to leak from the patch." The notice further stated that:

> Exposure to the Duragesic hydrogel contents could result in an increased absorption of the opioid component, fentanyl, leading to increased drug effect, including nausea, sedation, drowsiness, or potentially life threatening complications.

On April 7, 2004, Alza recalled four additional lots of 75 mcg Duragesic patches in an "Urgent Expanded Drug Recall Notification." This recall warned that:

> Exposure to the leaked medication could result in inadvertent ingestion or an

> increased transdermal absorption of the opiate component, fentanyl, leading to potentially life-threatening complications.

Texas Rule of Evidence 407 provides:

> A written notification by a manufacturer of any defect in a product produced by such manufacturer to purchasers thereof is admissible against the manufacturer on the issue of existence of the defect to the extent it is relevant.

TEX. R. EVID. 407(b). This Court addressed the admissibility of recall evidence in *Ford Motor Co. v. Durrill*, 714 S.W.2d 329 (Tex. App.–Corpus Christi 1986), *judgm't vacated by agreement*, 754 S.W.2d 646 (Tex. 1988):

> In appellant's twentieth point of error, Ford urges that the trial court erred in admitting the Pinto recall letter and testimony relating to the Pinto recall. The Durrills argue that the evidence was relevant to show Ford's conscious disregard for the public safety. Rule 407(b) allows a written ratification by a manufacturer of a product defect to be admitted against the manufacturer on the issue of existence of the defect to the extent that it is relevant. The fact that recall letters are admissible is settled by the existence of TEX. R. EVID. 407(b). The circumstances for admission in this case are somewhat unusual in that the letter was admitted to show both Ford's failure to warn of an alleged similar defect in the Mustang II and to show that a defect existed in the Mustang II by showing its similarities to the recalled Pinto.
>
> Dr. Robert Brenner testified that the Ford Motor Company should have sent a recall letter like the "Pinto" letter to Mustang owners as well. He testified that the safety related defect which precipitated the Pinto -Bobcat recall was very similar, if not identical to the safety related defect that Ford knew existed in the Pinto-Bobcat and Mustang.
>
> The evidence of the Pinto recall was relevant both to the defect issue and the failure to warn. It was incumbent upon the Durrills to show by independent evidence that the Mustang II was defective at the time of injury in order for the letter to be admissible to show the existence of a defect. *See* Blakely, *Article IV: Relevancy and Its Limits*, 20 HOUS. L. REV. 151, 220 (1983). The Durrills established, by independent evidence, that the Mustang II was defective in the same manner as the Pinto. Additionally, we find that the evidence was admissible to illustrate Ford's failure to warn.

See id. at 340.

Rule 407(b) clearly states that the evidence of the recalls is admissible in evidence on the issue of the existence of the defect to the extent that it is relevant. Specifically, the

issue of recall is, in the words of Texas Rule of Evidence 407, "admissible against [Alza] on the issue of existence of the defect to the extent it is relevant." The defect referenced in the recall is the same defect as alleged in the instant case, that is, an alleged breach in the seal of the patch causing an uncontrolled release of fentanyl, and thus, the recall is relevant.

Alza contends that there is no evidence independent of the recall that Thompson was wearing a patch with the same defect as referenced in the recall. Assuming without deciding that Thompson was required to show some independent proof that the particular product in question suffered from the same defect, the record contained such evidence. Thompson was prescribed the same patch that was the subject of Alza's recall, and her patch was manufactured during the same period of time and on the same machine as the recalled patches. Prior to and upon admission to the hospital, she displayed symptoms of overdose including nausea, vomiting, sleepiness, and dizziness. Thompson's blood test showed an overdose of fentanyl. Accordingly, there is independent evidence of the alleged defect in the involved product.

Alza contends that the evidence of recall does not tend to make a fact that is of consequence to the suit any more or less probable. However, recall letters are admissible as some evidence that the defect existed when the product left the manufacturer. This is an element that Thompson was required to prove. *Ridgeway*, 135 S.W.3d at 600 (holding that the plaintiff must prove that the product was defective when it left the hands of the manufacturer and that the defect was a producing cause of the plaintiff's injuries).

Finally, Alza contends that the evidence of recall was outweighed by prejudice and caused a confusion of the issues, and the admission of the recall evidence was reasonably calculated to and probably caused the rendition of an improper judgment. Because

Thompson was required to prove that the defect existed not only at the time of her death but also at the time when the Duragesic patch left Alza's hands, the relevancy of the recall letters outweighs any possible prejudice in their admission into evidence. In this regard, we note that "testimony is not inadmissible on the sole ground that it is 'prejudicial' because in our adversarial system, much of a proponent's evidence is legitimately intended to wound the opponent." *Bay Area Healthcare Group*, 239 S.W.3d at 234. A jury is entitled to know that the existence of the defect in a particular kind of Duragesic patch was likely and that such likelihood was greater as to the 75 mcg patches as to other patches manufactured by Alza. Accordingly, the prejudicial impact of the recall letters is outweighed by its relevance on the issue whether the product was defective when it left the hands of the manufacturer. We note that the recall does not by itself make a prima facie case, shift the burden of proof, or prove that the defect existed at the time of the incident. *See, e.g., Fields v. Volkswagen of Am., Inc*., 555 P. 2d 48, 58 (Okla. 1976),

We conclude that, under the circumstances of this case, the recalls were properly admissible in evidence for the purpose of determining whether the defect identified by Thompson's expert witnesses existed when Alza put the patch into Thompson's hands. We note that to sustain a verdict for a plaintiff based upon an existing defect, such recall evidence, standing alone, would be insufficient. Here, however, we have the credible testimony of Thompson's experts, albeit contradicted by that of Alza's expert witnesses, which justified the jury's conclusion that the Duragesic patch worn by Thompson was defective and the defect caused her death. Accordingly, we hold that, in the circumstances of this case, the recall evidence was properly admissible in evidence for the limited purpose of determining whether the defect identified by plaintiff's expert witnesses arose while the product was in Alza's control. We overrule Alza's fifth issue.

V. Conclusion

Having overruled each of Alza's issues, we affirm the judgment of the trial court.

_____
Linda R. Yañez
Justice

Delivered and filed
the 1st day of April, 2010.