IN THE SUPREME COURT OF TEXAS

NO. 10-0223

CENTOCOR, INC., PETITIONER,

v.

PATRICIA AND THOMAS HAMILTON,
RESPONDENTS AND CROSS-PETITIONERS,

v.

MICHAEL G. BULLEN, M.D.,
CROSS-RESPONDENT

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

Argued December 8, 2011

JUSTICE GREEN delivered the opinion of the Court.

Under the learned intermediary doctrine, the manufacturer of a pharmaceutical product satisfies its duty to warn the end user of its product's potential risks by providing an adequate warning to a "learned intermediary," who then assumes the duty to pass on the necessary warnings to the end user. *See, e.g.*, *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App.—Corpus Christi 1973, writ ref'd n.r.e.). In this case, we consider the applicability of the

learned intermediary doctrine to a patient's claims against a prescription drug manufacturer, whose product allegedly caused a serious injury. We hold that the doctrine generally applies within the context of a physician-patient relationship and allows a prescription drug manufacturer to fulfill its duty to warn end users of its product's potential risks by providing an adequate warning to the prescribing physician. We further hold that the court of appeals erred by creating an exception to the learned intermediary doctrine for direct-to-consumer (DTC) advertising. Although the patient alleged various common law causes of action, all of the patient's claims turn on the prescription drug manufacturer's failure to warn. Therefore, the learned intermediary doctrine applies to all of the patient's claims, and the patient was required to show that an inadequate warning to the prescribing physicians caused the patient's injuries. Because the patient presented no evidence that the allegedly inadequate warning was a producing cause of her physicians' decisions to prescribe the prescription drug, her claims fail as a matter of law. Accordingly, we reverse the court of appeals' judgment in part and render judgment that the plaintiffs take nothing.

I. Background

In March 2003, Patricia and Thomas Hamilton sued Centocor, Inc., a prescription drug manufacturer and subsidiary of Johnson & Johnson, claiming that Centocor provided "inadequate and inappropriate warnings and instruction for use" of its prescription drug Remicade, which made Remicade "defective and unreasonably dangerous," and seeking damages for injuries that Patricia allegedly incurred from using the drug.[1] In August 2006, the Hamiltons amended their claims and

[1] Despite suing Centocor in March 2003, Patricia continued receiving Remicade treatments for approximately six months after filing suit.

added Patricia's prescribing and treating physicians as defendants. They claimed that Centocor was liable for, among other things, (1) "manufacturing, promoting, distributing and/or selling Remicade®," which was "defective and unreasonably dangerous" because of "inadequate and inappropriate warnings and instructions for use"; (2) negligence; (3) gross negligence; (4) fraud; and (5) malice. The Hamiltons claimed that Remicade caused Patricia to suffer a serious drug-induced side effect called lupus-like syndrome. The Hamiltons also alleged that Patricia's medical providers failed to adequately warn Patricia of the risks associated with Remicade and failed to obtain her informed consent to the treatment.

In the course of her prescribed treatments, Patricia's treating physician, Michael Bullen, M.D., showed her an informational video that he received from Centocor. The Hamiltons alleged that Centocor's video over-emphasized the benefits of Remicade and intentionally omitted warnings about the potential side effect of lupus-like syndrome. They argued that the video bypassed the physician-patient relationship and required Centocor to warn Patricia directly of Remicade's potential risks and side effects, thereby making Centocor liable for Patricia's injuries. The jury found in favor of the Hamiltons, and the trial court entered judgment for approximately $4.6 million. The court of appeals reversed the award of future pain and mental anguish damages but affirmed the remainder of the trial court's judgment, adopted a DTC advertising exception to the learned intermediary doctrine, and held that the record contained sufficient expert evidence to prove that Centocor's actions caused Patricia's injuries.

A. Patricia's Medical History Prior to 2001

Patricia Hamilton has a complicated medical history. For more than two decades, she has suffered from Crohn's disease, recurring joint pain, arthritis, and several other ailments. Crohn's disease is a chronic, lifelong inflammatory condition that can affect any part of the digestive system. There is no cure for the disease; however, patients have several treatment options, which seek to control intestinal inflammation. Over the years, Patricia underwent various procedures to treat the disease and mitigate its effects. By 2001, Patricia had part of her small intestine, colon, and rectum removed, and she lived with a colostomy. During a resection surgery—a procedure to reconnect her bowels after removing damaged tissues—Patricia contracted hepatitis C from a blood transfusion. She was also diagnosed with sarcoidosis.[2]

B. Dr. Hauptman Treats Patricia's Crohn's Disease

In September 2001, Patricia experienced a "flare" in her Crohn's disease and sought treatment from Ronald Hauptman, M.D., a gastroenterologist who was practicing in Corpus Christi. To confirm that Patricia's symptoms were caused by her Crohn's disease, Dr. Hauptman tracked Patricia's reported abdominal pains for several weeks and ordered a series of tests, including a CAT scan and an upper GI.[3] By December 2001, Dr. Hauptman confirmed that Patricia was experiencing a moderate flare in her Crohn's disease.

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[2] Sarcoidosis is a disease in which inflammation occurs in the lymph nodes, lungs, liver, eyes, skin, or other tissues.

[3] At trial, Dr. Hauptman explained that a CAT scan or computed axial tomography is a specialized x-ray that takes images of the inside of the human body, while an upper GI series or gastrointestinal tract radiography is another method of viewing the digestive system with x-ray pictures. Dr. Hauptman explained that an upper GI tracks the movement of barium that has been ingested by the patient as it progresses through the patient's digestive tract.

Dr. Hautpman testified that it was important to treat the Crohn's flare quickly to mitigate the risk that Patricia would lose more of her bowels. Based on Patricia's existing medical regimen and her reported allergic reactions to one type of anti-inflammatory medication used to treat Crohn's disease, Dr. Hauptman testified that Patricia's only two options to treat the Crohn's flare were through steroids or Remicade infusions. According to Dr. Hauptman, he consulted with Patricia about the available treatments and explained the risks and benefits of each approach. Based in part on Patricia's desire to avoid steroid treatments, which had previously caused severe adverse effects, Dr. Hauptman prescribed three treatments of Remicade, a relatively new drug that had been developed since Patricia's surgery in 1997, administered at six-week intervals of 400 milligrams each.

C. Remicade

Remicade is a prescription drug, manufactured by Centocor, that is approved by the Food and Drug Administration (FDA) for the treatment of Crohn's disease and rheumatoid arthritis.[4] An immunomodulator medication, Remicade is designed to suppress the immune system's inflammatory response to the affected bowel. Patients receive Remicade treatments through intravenous infusions—the medication is injected through an IV catheter in the patient's arm.

1. The FDA Approval Process

Barbara Matthews, M.D., an FDA administrator from 1994 to 2000, testified as an expert on the FDA approval process. Dr. Matthews was the clinical reviewer of Centocor's application for

[4] Remicade is Centocor's brand name for the drug infliximab.

FDA approval of Remicade and testified about her knowledge of the drug and her review of the safety and clinical data supporting Centocor's application. According to Dr. Matthews, once the FDA approves a drug for prescription use, the drug manufacturer drafts a package insert, which contains the clinical information, warnings, and other information known about the drug. The FDA then reviews the proposed package insert, makes revisions, and ultimately approves the insert for distribution with the drug. According to Dr. Matthews, the purpose of a package insert

> is to describe both the safety and efficacy that were reported to [the] FDA and . . . provide[] information to the physician regarding the types of events, the serious[] nature of some of the events, the incidents of the events and, yes, the physician uses [this information to assess the] risk to the patient when they prescribe the medication.
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> . . . .
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> The degree of risk to the individual patient really depends on the physician's knowledge of the patient and then also the information that's in the label but the label really doesn't link directly that patient to the degree of risk.

Additionally, once a drug has received FDA approval, the manufacturer must submit periodic safety update reports to the FDA. These post-approval reports contain cumulative summaries of the drug's safety information, including updated clinical studies and any other medical findings published about the drug. Depending on the number, nature, and severity of events reported for a given adverse reaction, the FDA may recommend that the manufacturer (1) continue to monitor the events, (2) change the warning label, or (3) conduct additional studies. Because the FDA requires continuing studies of the safety and efficacy of the prescription drug, it is common for the package insert to undergo revisions as new information becomes available.

2. The 2001 Remicade Package Insert

At the time of Patricia's initial Remicade prescription in December 2001, Centocor provided Patricia's doctors with a package insert that warned Remicade's use could lead to certain adverse reactions. The package insert included the following warning information regarding lupus-like syndrome:

> **PRECAUTIONS:**
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> **Autoimmunity**
> Treatment with REMICADE may result in the formation of autoantibodies and, rarely, in the development of a lupus-like syndrome. If a patient develops symptoms suggestive of a lupus-like syndrome following treatment with REMICADE, treatment should be discontinued (see *ADVERSE REACTIONS*, *Autoantibodies/Lupus-like Syndrome*).
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> . . . .
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> **ADVERSE REACTIONS:**
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> A total of 771 patients were treated with REMICADE in clinical studies. In both rheumatoid arthritis and Crohn's disease studies, approximately 6% of patients discontinued REMICADE because of adverse experiences. The most common reasons for discontinuation of treatment were dyspnea, urticaria and headache. Adverse events have been reported in a higher proportion of patients receiving the 10 mg/kg dose than the 3 mg/kg dose.
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> . . . .
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> **Autoantibodies/Lupus-like Syndrome**
> In the ATTRACT rheumatoid arthritis study through week 54, 49% of REMICADE-treated patients developed anti-nuclear antibodies (ANA) between screening and last evaluation, compared to 21% of placebo-treated patients. Anti-dsDNA antibodies developed in approximately 10% of REMICADE-treated patients, compared to none of the placebo-treated patients. No association was seen between REMICADE dose/schedule and development of ANA or anti-dsDNA.
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> . . . .

> In clinical studies, three patients developed clinical symptoms consistent with a lupus-like syndrome, two with rheumatoid arthritis and one with Crohn's disease. All three patients improved following discontinuation of therapy and appropriate medical treatment. No cases of lupus-like reactions have been observed in up to three years of long-term follow-up (see *PRECAUTIONS*, *Autoimmunity*).

The package insert also included a table noting that serious adverse reactions—including systemic lupus erythematosus syndrome—occurred at frequencies of less than 2% "by body system in all patients treated with REMICADE."

D. Lupus-Like Syndrome

According to Mary Olsen, M.D., an expert witness hired by Centocor but called by the Hamiltons, lupus-like syndrome, also called drug-induced lupus, has similar characteristics to the autoimmune disorder systemic lupus erythematosus (SLE), except that lupus-like syndrome is caused by a drug. All of the testifying experts generally agreed that symptoms of both lupus-like syndrome and SLE include joint pain and swelling, weight gain, fatigue, unusual weakness, leukopenia, lymphopenia, rash, oral ulcers, fever, and pericarditis. Patients with Crohn's disease or rheumatoid arthritis, another autoimmune disorder, could also present similar symptoms to lupus-like syndrome, making it sometimes difficult to diagnose SLE or drug-induced lupus.

Physicians can conduct lab tests to check for the presence of anti-nuclear antibodies (ANA), double-stranded DNA antibodies (anti-dsDNA), and antihistone antibodies, which are specific indicators that may help a physician diagnose the presence of an autoimmune condition. Although no antibody is definitive of lupus-like syndrome, positive tests for ANA or anti-dsDNA may indicate the patient has lupus-like syndrome. Physicians also use electrophoresis and immunoelectrophoresis as other immunology blood tests to help diagnose lupus. According to Atilla Ertan, M.D., an expert

witness for Centocor, the anti-dsDNA test is the most important indicator for diagnosing drug-induced lupus. Additionally, Dr. Olsen testified that antihistone antibodies are classically seen in patients with drug-induced lupus and "as a rule, an antihistone antibody often is a flag [that indicates] a drug-induced problem." Because Remicade may produce ANA or anti-dsDNA in patients, however, Dr. Olsen explained that it is often difficult to diagnose lupus-like syndrome. A doctor must look to both the laboratory tests and the clinical presentation of symptoms. If a patient has drug-induced lupus rather than SLE, removing the patient from the drug should improve the patient's lupus-like symptoms.

E. Dr. Bullen and the Remicade Infusions

Dr. Hauptman prescribed three infusions of Remicade over a six-week period from December 2001 to January 2002 and referred Patricia to Dr. Bullen for treatment. Dr. Bullen is an infectious disease specialist and, at that time, operated an infusion clinic in Corpus Christi where Patricia received the Remicade infusions. As the non-prescribing, treating physician, neither Dr. Bullen nor his staff discussed with Patricia the risks inherent in Remicade, but they informed her of the potential risks directly associated with the infusion process. At trial, Dr. Bullen did not recall confirming that Dr. Hauptman had informed Patricia of Remicade's risks. Dr. Bullen stated that he was aware that Remicade could cause lupus-like syndrome, but admitted that he probably did not give Patricia any warnings or instructions concerning the risk of developing lupus-like syndrome.

Polly Swinney, a registered nurse at Bullen's infusion clinic, took Patricia's patient history, advised Patricia on the potential infusion-related side effects,[5] and monitored Patricia during her Remicade treatments at the infusion center. Before Patricia received her first infusion, Dr. Bullen's clinic performed a tuberculin skin test, per Dr. Hauptman's orders, because of the serious risks related to treating tuberculosis-infected patients with Remicade.[6] After confirming that Patricia did not have tuberculosis, Patricia received her first Remicade infusion at Dr. Bullen's infusion clinic on December 19, 2001.

F. Centocor's Informational Video

After Swinney connected Patricia's IV and started the first Remicade infusion, she showed Patricia an informational video about Remicade and the treatment process, which Centocor had provided to Dr. Bullen. Centocor had submitted the video to the FDA, but the FDA neither approved nor disapproved it.

Dr. Bullen, Dr. Matthews, and Swinney generally agreed that the main purpose of the video was to educate patients and make them more comfortable with the infusion process. The video, titled "Patient Guide to Remicade® (infliximab) IV Administration," was viewed by the jury during trial. It depicts the effects of Remicade on several people and includes statements from a doctor, identified as Alan Safdi, M.D., who explains the Remicade infusion process and warns about some

[5] Swinney testified that she warned Patricia of potential side effects like headache, chills, fever, nausea, vomiting, dyspnea, vertigo, upper respiratory infections, hypertension, and hypotension.

[6] Because Remicade can lower the body's ability to fight infections, the 2001 package insert contained a "black box" warning of the potentially fatal risks associated with treating tuberculosis-infected patients with Remicade and instructed doctors to conduct tuberculosis tests prior to treating patients with Remicade.

of the drug's side effects. The video shows several patients receiving Remicade infusions, provides answers to common questions about the treatment process, and shows the patients continuing their daily routines after the treatment while the bottom of the screen states: "RESULTS MAY VARY." Although Dr. Safdi states that "there are very little side effects that people need to watch for" and adverse reactions are "extremely rare," he also instructs patients to contact their medical providers if they have any discomfort and states that there have been some reports of serious, life-threatening side effects.

In addition to Dr. Safdi's verbal warnings, the video provides several written warnings and disclaimers at the end of the production. It instructs patients to contact their healthcare provider if they have any questions and provides a Remicade website address for further information. The video warns of various risks associated with the infusion process, advises that "[p]hysicians should discuss with their patients all potential side effects that may occur during these infusions," and cautions that the "video should not be used as a substitute for talking with your doctor." For the treatment of fistulizing Crohn's disease,[7] the video warning states that "[t]he safety and efficacy of therapy continued beyond three doses have not been studied." After listing a series of potential side effects, the warning instructs patients to "see the accompanying Full Prescribing Information." It is undisputed that the video did not mention lupus-like syndrome as a potential side effect of Remicade.

[7] A fistula is a connection of two body cavities or a connection of a body cavity to the skin, e.g., a connection of the rectum to the skin. It is common for Crohn's disease patients to develop fistulas.

Swinney testified that the infusion clinic received the videotapes from Centocor in cellophane-wrapped boxes that usually contained the video, informational brochures about Remicade, and package inserts that provided more extensive details about the drug. She claimed that after showing Patricia the video, she placed it back in the box with the written materials on top and gave it to Patricia. At trial, Patricia denied receiving any written information about Remicade, but stated that she never looked in the box that Swinney gave her or reviewed any additional written information about Remicade. During one of Patricia's infusions, Swinney gave Patricia a second Centocor video to give to Patricia's sister, who had rheumatoid arthritis. The second video contained the same visual content but was enclosed in different packaging material. The box containing the second video had a plastic sleeve on the inside cover that contained the Remicade package insert and an informational brochure.[8]

Patricia reported an excellent response to her Remicade treatments at Dr. Bullen's infusion clinic, and the treatments helped relieve the symptoms of her Crohn's disease. After her first two Remicade infusions, Dr. Hauptman performed a colonoscopy on Patricia, which revealed that Patricia no longer had abnormalities in her small intestine. Following her third Remicade infusion, Dr. Hauptman believed that Patricia's Crohn's disease was in remission. Dr. Hauptman then planned to continue monitoring Patricia's condition before determining whether Patricia needed a Remicade maintenance dose every eight weeks. Throughout her follow-up appointments with Dr. Hauptman, Patricia reported that she was having no problems with her bowels, leading Dr. Hauptman to

[8] The second video Patricia received was also admitted into evidence at trial. Inside this video's packaging box are three copies of the 2001 package insert.

conclude that the Remicade treatments were successful and that Patricia's Crohn's disease remained in remission. It is undisputed that, since taking Remicade, Patricia's Crohn's disease has been asymptomatic.

G. Dr. Pop-Moody Treats Patricia's Arthritis

In the weeks following her initial treatments with Remicade, Patricia experienced severe arthritis-like pains in her joints. Patricia's family physician referred her to a local rheumatologist, Adriana Pop-Moody, M.D. During her initial visit with Dr. Pop-Moody, Patricia explained her recent treatments with Remicade and told Dr. Pop-Moody that it had dramatically improved her Crohn's condition and that her arthritis pains had markedly improved after her first three doses of Remicade. In April 2002, Dr. Pop-Moody prescribed treatments including additional Remicade infusions at regular intervals to treat Patricia's joint pains. Between April 2002 and September 2003, Patricia received fourteen additional Remicade infusions at the Corpus Christi Medical Center.

Patricia continued to experience severe joint pain. Each treatment provided temporary relief, but the relief periods dwindled. In an attempt to improve Patricia's condition, Dr. Pop-Moody decreased the time between infusions and increased the dosage of Remicade. Dr. Pop-Moody and Patricia remained convinced that Remicade was providing Patricia temporary relief from her joint pains. In her practice, Dr. Pop-Moody routinely diagnosed and treated patients with lupus. Even though Patricia tested positive for SLE in June 2002—a condition similar to drug-induced lupus and a potential side effect of Remicade—because of Patricia's complicated condition, Dr. Pop-Moody did not diagnose Patricia with drug-induced lupus at that time. In April 2003, Dr. Pop-Moody reviewed treatment options with Patricia and discussed that she might need to stop the Remicade

infusions. Dr. Pop-Moody informed Patricia that she may have lupus-like syndrome, but Patricia's medical records indicate that, despite this risk, Patricia desired to continue taking Remicade.

H. The Houston Doctors

Because of Patricia's increasing joint pain and Dr. Pop-Moody's inability to determine the cause of Patricia's continuing ailments, Dr. Pop-Moody referred Patricia to rheumatologists at the University of Texas Health Science Center in Houston, where she saw Maureen D. Mayes, M.D., Noranna B. Warner, M.D., and Leslie Wilson, M.D. (collectively, the Houston Doctors). In response to Dr. Pop-Moody's request, the Houston Doctors examined Patricia's symptoms and Dr. Mayes and Dr. Wilson made the following assessment in September 2003:

> 1. Symmetric polyarthritis involving the hands, elbows, shoulders, knees, and feet that could be consistent with lupus (potentially drug-induced by Remicade), although the literature is limited in supportive evidence of this entity. There have been several studies showing that the presence of double stranded DNA antibodies in patients who receive Remicade is not uncommon; however, there have been limited cases of lupus-like syndrome seen with this medication. The patient, at this time, does appear to have a syndrome that could be classified as systemic lupus erythematosus. The clinical picture is less consistent with ~~sarcoidosis or~~[9] arthritis associated with sarcoidosis. The clinical presentation could be consistent with enteropathic arthritis. This could be arthritis associated with hepatitis C virus.
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> 2. Leukopenia—possibly secondary to lupus-like syndrome or a side effect of Imuran.[10]

[9] The word "sarcoidosis" is marked through with an ink pen on the official trial exhibit. It is unclear who made this change to the document.

[10] Imuran is another immunosuppressant drug that Patricia received for her ailments. Additionally, a third assessment is handwritten on the document, stating: "3. Significant Osteopenia on DEXA—now on chronic prednisone." It is also unclear from the record who made this change to the document.

The Houston Doctors stopped Patricia's Remicade treatments and, instead, prescribed steroids for her joint pains. At her October 2003 follow-up appointment, Patricia reported that she felt much better than she did at her previous visit. Dr. Warner sent Dr. Pop-Moody a status report, which documented Patricia's improvement and stated in pertinent part:

> The patient presented to our clinic for evaluation of possible lupus-like syndrome which may have been induced by Remicade therapy. Upon evaluation by her rheumatologist in Corpus Christi, the patient was found to have a positive ANA and positive double-stranded DNA antibodies. Other significant history included the episode of pericarditis in January of 2003 and the presence of leukopenia (absolute lymphopenia). Upon initial presentation to our clinic a few weeks ago, the patient's physical exam showed significant tenderness on internal and external rotation of both of her shoulders. There was also some swelling of the fingers, particularly in the PIP joints bilaterally. There was decreased hand grip secondary to pain.
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> Today, the patient states that she is much improved since her previous visit. . . .
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> . . . .
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> ASSESSMENT: Symmetric polyarthritis involving hands, shoulders, knees, feet, which is consistent with a lupus-like syndrome (potentially drug-induced by Remicade). The patient has improved on an increased dose of Imuran 150 mg daily, increased from 100 mg daily. The patient also had increased her prednisone dose from 10 mg daily to 15 mg daily.

Within a few months of ceasing the Remicade infusions, Patricia's lupus-like symptoms subsided. Patricia's arthritic symptoms also improved dramatically after she ceased taking Remicade.

II. Procedural Background

A. Trial Court Proceedings

The case proceeded to a multi-week jury trial. At trial, Patricia and her doctors gave conflicting testimony about their conversations concerning the risks and potential adverse effects associated with Remicade. Specifically, Dr. Hauptman and Dr. Pop-Moody testified that they fully

informed Patricia about the risks of developing lupus-like syndrome while Patricia averred that she received no such warning from either doctor when they initially prescribed Remicade treatments. Although Patricia admitted that she was informed by her physicians of certain risks associated with Remicade, including the rare risk of cancer, she testified that her doctors made no mention of the risk of developing lupus-like syndrome. She further stated that the risk of lupus-like syndrome was something that she would have wanted to know, that it "would have impacted [her] decision," and that "[t]he question of lupus would have made [her] stop and ask more questions before [she] made a decision [to take Remicade]." Regardless of the conflicting testimony, it is undisputed that all of Patricia's doctors were aware of the risk of lupus-like syndrome when they chose to prescribe and treat Patricia with Remicade. And according to all of the doctors who testified on the subject, lupus-like syndrome can be difficult to diagnose.

At the charge conference, the Hamiltons abandoned their original failure-to-warn claim and proposed separate jury questions on claims against Centocor for (1) fraud, (2) negligent misbranding, (3) negligent marketing, (4) negligent undertaking, (5) misrepresentation to Patricia's prescribing physicians concerning the risk of lupus-like syndrome, and (6) misrepresentation to Patricia's prescribing physicians concerning the risk of hepatitis C and liver damage. Centocor raised several objections to the Hamiltons' proposed charge, including that it was error for the trial court to submit separately the claims for negligent misbranding, negligent marketing, negligent undertaking, misrepresentation regarding lupus-like syndrome, misrepresentation regarding hepatitis C and liver conditions, and fraud. Centocor argued that each of the Hamiltons' claims were premised on a single failure-to-warn cause of action, the separate questions were duplicative, and the trial court should

only submit one failure-to-warn claim to the jury. The trial court judge overruled each of Centocor's objections and submitted all of the Hamiltons' questions to the jury. Centocor also repeatedly raised the learned intermediary doctrine, contesting its duty to warn Patricia directly. It argued that the record lacked expert testimony to (1) support the Hamiltons' claims that Centocor's warnings to Patricia and her prescribing doctors were inadequate, and (2) prove that the allegedly inadequate product warning was the producing cause of Patricia's injuries. Additionally, Centocor argued that there was no evidence Centocor breached the standard of care.

Before the trial court submitted the charge to the jury, the court granted a directed verdict in favor of Dr. Bullen and his infusion clinic, finding that Dr. Bullen and his staff had no duty to warn Patricia of the risks associated with Remicade because Dr. Bullen was not the prescribing physician.

The jury found Centocor liable for fraud, misrepresentation to Patricia's doctors, negligent misbranding, negligent marketing to Patricia's doctors, and negligent undertaking. The jury awarded Patricia $1.2 million for past pain and mental anguish, $1 million for future pain and mental anguish, $1.1 million for past physical impairment, and $65,908 for past medical expenses. It also awarded Thomas $50,000 for loss of consortium and household services. The jury apportioned liability for the Hamiltons' damages, finding Centocor 85% liable, Dr. Pop-Moody 10% liable, and Dr. Hauptman 5% liable. The jury determined that the Hamiltons established fraud by clear and convincing evidence and awarded Patricia $15 million and Thomas $1 million in exemplary damages based on the fraud claim.

Before the trial court entered judgment on the jury's verdict, Dr. Hauptman and Dr. Pop-Moody settled with the Hamiltons, and the Hamiltons nonsuited those defendants.[11] The trial court denied Centocor's motion for judgment notwithstanding the verdict. On February 13, 2007, the trial court apportioned responsibility, applied settlement credits, applied the exemplary damages caps, and entered judgment against Centocor, awarding a total of $4,687,461.70 to Patricia and $120,833.71 to Thomas in actual damages, punitive damages, and interest. The trial court entered judgment on the Hamiltons' fraud claim only but stated that, in the alternative, the Hamiltons should recover actual damages under the various other theories presented to the jury.

B. Court of Appeals

Centocor timely appealed, arguing first that the learned intermediary doctrine precluded the Hamiltons' recovery because, as a matter of law, Centocor's warnings to Patricia's prescribing physicians were adequate and Centocor had no duty to warn Patricia directly.[12] 310 S.W.3d 476, 499 (Tex. App.—Corpus Christi 2010). The court of appeals disagreed, however, and affirmed the trial

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[11] Dr. Pop-Moody settled for $50,000, and Dr. Hauptman settled for a confidential amount.

[12] In total, Centocor raised twelve issues before the appellate court: (1) under the learned intermediary doctrine, Centocor had no duty to warn Patricia directly and it provided adequate warnings to Patricia's prescribing physicians who had preexisting knowledge of the relevant risks associated with Remicade; (2) the Hamiltons failed to present legally or factually sufficient evidence of causation; (3) Centocor provided adequate warnings, and no expert testified that the warning was inadequate or made Remicade unreasonably dangerous; (4) the Hamiltons failed to present legally or factually sufficient evidence of fraud by omission; (5) the Hamiltons incorrectly asserted claims for implied misrepresentation under Section 402B of the *Restatement (Second) of Torts*, which provides only for claims of express misrepresentation; (6) even if Section 402B of the *Restatement* entitles the Hamiltons to recover for implied misrepresentations, those claims must fail for lack of legally sufficient evidence; (7) the Hamiltons failed to provide expert testimony about the standard of care or evidence that Centocor breached the standard of care; (8) Texas does not recognize a cause of action for negligent misbranding; (9) as a matter of law, distribution of a videotape does not constitute a negligent undertaking; (10) the evidence on future damages was legally and factually insufficient; (11) if Patricia's claims fail, then Thomas's derivative claims must fail; and (12) the judgment should be remitted because the trial court misapplied the punitive damages cap. *See* 310 S.W.3d at 480–81, 521–22.

court's judgment on the Hamiltons' fraud claim but reversed the damages award for future pain and mental anguish. *Id.* at 522.

The court of appeals first examined Centocor's duty under the learned intermediary doctrine, which generally limits a prescription drug manufacturer's duty to warn of its product's risks and potential side effects to prescribing physicians, who then serve as "learned intermediaries" and assume the duty to pass the warnings on to patients. *See id.* at 499–508. Relying on reasoning from the New Jersey Supreme Court's opinion in *Perez v. Wyeth Laboratories*, 734 A.2d 1245, 1246–47 (N.J. 1999), the court of appeals adopted "an exception to the learned intermediary doctrine when a drug manufacturer directly advertises to its consumers in a fraudulent manner." 310 S.W.3d at 480–81. Guided by the *Perez* court's decision, the court of appeals held "that when a pharmaceutical company directly markets to a patient, it must do so without fraudulently misrepresenting the risks associated with its product." *Id.* at 508. The court therefore dismissed Centocor's arguments based on the learned intermediary doctrine and, in a footnote, stated: "[W]e hold today that Centocor cannot rely on its *adequate* warnings to Patricia's physicians when it directly misrepresented its product's dangerous propensities to Patricia." *Id.* at 508 & n.18 (emphasis added).

The court of appeals next considered Centocor's argument that the Hamiltons failed to present legally and factually sufficient evidence of causation and held that the Hamiltons met their burden of proof on causation.[13] *Id.* at 508–12. The court then overruled Centocor's claims that the

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[13] The court of appeals properly noted:

> Centocor did not raise [its claims that the Hamiltons failed to present epidemiological studies or other legally sufficient evidence of general or specific causation] in its motions for directed verdict, objections to the jury charge, or motions for judgment notwithstanding the verdict. Rather, Centocor first raised these challenges to the causation evidence in its motion for new trial. Thus, even if we

trial court erred because (1) no expert testified that the Remicade warnings were inadequate, (2) the side effect of lupus-like syndrome did not make Remicade unreasonably dangerous, and (3) the Hamiltons presented no evidence that a different warning by Centocor would have prevented Patricia's injuries. *Id.* at 512–16. The court of appeals overruled or dismissed as moot Centocor's remaining issues, reversed the trial court's damages award for future pain and mental anguish,[14] and affirmed the trial court's judgment on the Hamiltons' fraud claim. *See id.* at 516–22.

C. Centocor's Petition for Review

Centocor timely petitioned this Court for review, and raises four issues on appeal: (1) the court of appeals erred by creating an advertising exception to the learned intermediary doctrine, and the doctrine applies, thereby limiting Centocor's duty to warn to Patricia's prescribing physicians only and barring the Hamiltons' claims; (2) the Hamiltons failed to present any expert testimony that the warning in Centocor's informational video was inadequate, and the appellate court erred by considering Dr. Matthews's testimony about the FDA approval process and the FDA regulations as sufficient evidence to show that the video's allegedly inadequate warning made Remicade

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> agree with Centocor that there is no legally sufficient evidence of causation on this ground, we may only grant Centocor a new trial.

Id. at 509 (citing *Werner v. Colwell*, 909 S.W.2d 866, 870 n.1 (Tex. 1995)); *see also* TEX. R. APP. P. 43.3; *Horrocks v. Tex. Dep't of Transp.*, 852 S.W.2d 498, 499 (Tex. 1993). Centocor did, however, properly raise and preserve its causation argument regarding its contention that the Hamiltons failed to present any evidence that a different warning would have prevented Patricia's doctors from prescribing the medication or prevented Patricia from taking Remicade.

[14] At trial, the Hamiltons spent considerable time discussing Remicade's potential to damage Patricia's liver or worsen her preexisting hepatitis C. Although the jury found in favor of the Hamiltons on this point, the court of appeals reversed the award of future damages and noted that the Hamiltons "did not present any evidence . . . that [Patricia] actually suffered any injury to her liver as a result of Remicade, that she would likely need a liver transplant, or that she would, in reasonable probability, suffer any injury in the future as a result of Remicade." *Id.* at 520. Neither party disputes the court of appeals' findings on Patricia's damages for the purported risk of liver injury or hepatitis C. Accordingly, the sole issue before us in this appeal is whether the Hamiltons can prevail on their claims for the alleged injury of lupus-like syndrome.

unreasonably dangerous; (3) the Hamiltons failed to show any evidence of causation because they presented no expert testimony of causation or epidemiological studies, but instead relied on the package insert and expert witnesses' unsupported references to clinical trials; and (4) the appellate court erred in affirming the Hamiltons' fraud claim because there was no evidence of any *mens rea* on the part of Centocor, which was isolated from the patient by the intermediary doctors, and that Patricia could not have relied on any alleged misrepresentation because she continued to take Remicade even after suing Centocor. In response to Centocor's first issue, the Hamiltons raise a conditional cross-issue, alleging that if we hold that the learned intermediary doctrine applies, we should reinstate the Hamiltons' claims against Dr. Bullen, the non-prescribing, treating physician, because Centocor deliberately used Dr. Bullen to provide direct marketing materials outside of the context of the prescribing physician's doctor-patient relationship. We granted both petitions. 54 Tex. Sup. Ct. J. 1578 (Aug. 26, 2011).[15] We address the parties' arguments in turn.

III. Learned Intermediary Doctrine

Generally, a manufacturer is required to provide an adequate warning to the end users of its product if it knows or should know of any potential harm that may result from the use of its product. *See, e.g.*, *Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978). In certain contexts,

[15] The following amici curiae submitted briefs in support of Centocor: International Association of Defense Counsel; Pacific Legal Foundation; Pharmaceutical Research and Manufacturers of America; Product Liability Advisory Council, Inc. Also, the Texas Medical Association, Texas Medical Liability Trust, and Texas Alliance for Patient Access (collectively, TMA) jointly submitted an amicus curiae brief in support of the trial court's and court of appeals' judgments, arguing that we should (1) hold that Dr. Bullen, the non-prescribing physician, had no duty to warn, and (2) reject the learned intermediary doctrine and hold that the prescription-drug manufacturer is responsible for warning those whom it should reasonably expect to be endangered by the use of its product. In response to the TMA's arguments, the Washington Legal Foundation submitted an amicus curiae brief, advocating in favor of Centocor and urging the Court to adopt the learned intermediary doctrine in the prescription-drug context.

however, the manufacturer's or supplier's duty to warn end users of the dangerous propensities of its product is limited to providing an adequate warning to an intermediary, who then assumes the duty to pass the necessary warnings on to the end users. *See, e.g.*, *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 590–92 (Tex. 1986); Richard C. Ausness, *Learned Intermediaries and Sophisticated Users: Encouraging the Use of Intermediaries to Transmit Product Safety Information*, 46 SYRACUSE L. REV. 1185, 1195–96 (1996). It is firmly established in Texas that whether a duty exists is ordinarily a legal matter for the court to decide. *See, e.g.*, *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 181 (Tex. 2004). Within the context of prescription drug manufacturers, the underlying premise for the learned intermediary doctrine is that prescription drugs are complex and vary in effect, depending on the unique circumstances of an individual user, and for this reason, patients can obtain them only through a prescribing physician. *See Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974), *cert. denied*, 419 U.S. 1096 (1974).

Centocor argues that the learned intermediary doctrine applies and therefore it had no duty to warn Patricia directly of the risks and potential side effects associated with Remicade. It asserts that it provided warnings of specific side effects and risks associated with Remicade to Patricia's doctors through the FDA-approved package insert, which Patricia did not challenge as inadequate. Centocor further argues that the appellate court erred by adopting a DTC advertising exception. Centocor claims that DTC advertising does not threaten the physician-patient relationship, but helps educate consumers about available medications—sometimes causing patients to seek treatment for ailments they otherwise would not have treated or sometimes even discovered. Additionally, Centocor points out that the FDA and other courts have recognized that over-warning can confuse

the public and, ultimately, can harm treatment efforts by scaring patients from taking the necessary risks associated with some prescription drugs.

In response, the Hamiltons argue that Centocor cannot benefit from the learned intermediary doctrine because it provided an inadequate and misleading warning to the "learned intermediary"—Patricia's prescribing and treating physicians. The Hamiltons contend that Centocor misrepresented the risks and side effects associated with Remicade to Patricia and her doctors by conveying instances of lupus-like syndrome observed only in clinical studies instead of all reported cases, thereby preventing Centocor from relying on the defense of the learned intermediary doctrine. Alternatively, if the learned intermediary doctrine applies, the Hamiltons urge us to adopt the DTC advertising exception and affirm the court of appeals' judgment because when a drug manufacturer directly markets its product to patients, that manufacturer should have a duty, at minimum, to present non-misleading information about the drug and must be liable for its fraudulent or intentionally misleading marketing.

A. The Learned Intermediary Doctrine in Texas Jurisprudence

The learned intermediary doctrine has been part of Texas jurisprudence for many years. *See, e.g.*, *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App.—Corpus Christi 1973, writ ref'd n.r.e.). In *Gravis*, the court of appeals held that it was unreasonable for the law to impose a duty on prescription drug manufacturers to "specifically warn each and every patient that receives drugs prescribed by the physician or other authorized persons" and outlined the underlying rationale for the doctrine:

> The entire system of drug distribution in America is set up so as to place the responsibility of distribution and use upon professional people. The laws and regulations prevent prescription type drugs from being purchased by individuals without the advice, guidance and consent of licensed physicians and pharmacists. These professionals are in the best position to evaluate the warnings put out by the drug industry. Our holding in no way relieves the drug company in their duty to warn or to provide a product free of defects.

Id. Since the Thirteenth Court of Appeals' opinion in *Gravis*—the same court from which we consider the instant case—many Texas courts of appeals have applied the learned intermediary doctrine in prescription drug products-liability cases. *See, e.g.*, *Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 91 (Tex. App.—Texarkana 2000, no pet.) ("In prescription drug cases, the courts have found that it is reasonable for the manufacturer to rely on the health care provider to pass on its warnings. This is reasonable because the learned intermediary understands the propensities and dangers involved in the use of a given drug, and as the prescriber, he stands between this drug and the ultimate consumer.").[16]

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[16] *See also Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 467 (Tex. App.—Austin 2000, pet. denied) (applying the learned intermediary doctrine to shield pharmacists from an independent duty to warn of dangers associated with prescription drugs); *Guzman v. Synthes (USA)*, 20 S.W.3d 717, 720 n.2 (Tex. App.—San Antonio 1999, pet. denied) ("[W]here, as here, the product is meant only for administration by a physician, the physician is integrally involved in deciding what type of medical device to use on the patient, and the physician is in a better position than the patient to understand the dangers and propensities of the possible devices, the supplier satisfies its duty by warning and instructing the treating physician."); *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 662 (Tex. App.—Houston [14th Dist.] 1998, no pet.) ("The learned intermediary doctrine arises when a product manufacturer has little or no contact with the ultimate user. The third party intermediary decides whether to purchase and prescribe the medicine, taking into account the risk and benefit to the patient, as well as the characteristics of the particular drug."); *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied) ("Under the doctrine, the manufacturer has a duty to adequately warn the physician; the physician then chooses the type and quantity of drug to be prescribed to an individual patient. The physician must use his comprehensive training and experience in conjunction with his knowledge of the individual patient in determining the suitability of a medication. The physician assumes the duty to warn the patient of dangers associated with a particular prescribed drug."); *Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 911 (Tex. App.—El Paso 1989, writ denied) (noting that the pharmaceutical company "had a duty to warn the physician of the dangers of [the drug], and once the physician is warned, the choice of which drugs to use and the duty to explain the risks become that of the physician"); *Khan v. Velsicol Chem. Corp.*, 711 S.W.2d 310, 313 (Tex. App.—Dallas 1986, writ ref'd n.r.e.) (applying the doctrine and noting that the doctrine had "consistently been limited in its application in Texas and elsewhere to the prescription drug, physician-patient relationship"); *Cooper v. Bowser*, 610 S.W.2d 825,

We first discussed the doctrine in *Alm v. Aluminum Co. of America*, a case involving an aluminum bottle cap manufacturer's duty to warn end users of hazards associated with its product. 717 S.W.2d at 590–92. Alm sued the manufacturer of soda bottle caps, claiming that an aluminum bottle cap popped off a soda bottle and struck him in the eye. *Id.* at 590. Alm claimed that Alcoa, the manufacturer of the machine that fastened the caps to the soda bottles, had a duty to warn him of the risk that a cap could pop off. *Id.* Although Alcoa manufactured the bottle-fastening machine, the machine was owned and operated by an independent bottler. *Id.* at 589–90. Alcoa did not control the bottling process or sell the bottled soda, nor did it have any practical way of reaching consumers with any warning. *Id.* at 592. Because of Alcoa's limited connection to the end user of the consumer product, we recognized the need for an intermediary:

> [A] manufacturer or supplier may, in certain situations, depend on an intermediary to communicate a warning to the ultimate user of a product. However, the mere presence of an intermediary does not excuse the manufacturer from warning those whom it should reasonably expect to be endangered by the use of its product. The issue in every case is whether the original manufacturer has a reasonable assurance that its warning will reach those endangered by the use of its product.

Id. at 591. We then analogized Alm's position to that of a bulk supplier "who sells a product to another manufacturer or distributor who in turn packages and sells the product to the public." *Id.* at 592. Because the bulk-supplier rationale applied to Alcoa's duty to warn in that case, we explained:

> Alcoa should be able to satisfy its duty to warn consumers by proving that its intermediary was adequately trained and warned, familiar with the propensities of the

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830–31 (Tex. Civ. App.—Tyler 1980, no writ) (adopting *Gravis* and noting that "a drug manufacturer must warn the physician of the dangers of its product, and once the physician is warned, the choice of which drugs to use and the duty to explain the risks become that of the physician").

> product, and capable of passing on a warning. But, if Alcoa failed to adequately warn and train [the intermediary] or if [the intermediary] was incapable of passing on the received warning, Alcoa would not have discharged its duty to the ultimate consumer.

Id. While Alcoa did not have a duty to warn Alm directly, it still had a duty to warn the bottler, and we concluded that the record contained some evidence to support the jury's finding that Alcoa's warning to the bottler was inadequate. *Id.* at 593–95.

Although *Alm* did not apply the learned intermediary doctrine within the context of a pharmaceutical manufacturer's duty to warn consumers of dangers associated with prescription drugs, we noted that other courts had done so:

> [W]hen a drug manufacturer properly warns a prescribing physician of the dangerous propensities of its product, the manufacturer is excused from warning each patient who receives the drug. The doctor stands as a learned intermediary between the manufacturer and the ultimate consumer. Generally, only the doctor could understand the propensities and dangers involved in the use of a given drug. In this situation, it is reasonable for the manufacturer to rely on the intermediary to pass on its warnings. However, even in these circumstances, when the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user.

Id. at 591–92 (citations omitted).

More recently, we addressed the learned intermediary doctrine's relevance in *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170, 185–96 (Tex. 2004). In that case, we considered whether a supplier of flint used for an abrasive blasting agent had a duty to warn its customers' employees of foreseeable dangers associated with the product, given the customer-employers' knowledge of those dangers. *Id.* at 172–73. We discussed relevant provisions from the Second and Third *Restatements of Torts* and noted that, in situations that did not meet the generally accepted

exceptions to a manufacturer's duty to warn, the court must consider six balancing factors adopted from the *Restatement* to determine the scope of a supplier's duty to warn the ultimate user of its product:

> (1) the dangerous condition of the product; (2) the purpose for which the product is used; (3) the form of any warnings given; (4) the reliability of the third party as a conduit of necessary information about the product; (5) the magnitude of the risk involved; and (6) the burdens imposed on the supplier by requiring that he directly warn all users.

Id. at 190 (quoting *Goodbar v. Whitehead Bros.*, 591 F. Supp. 552, 557 (W.D.Va. 1984), *aff'd sub nom. Beale v. Hardy*, 769 F.2d 213 (4th Cir. 1985)); *see also Restatement (Third) of Torts: Products Liability* § 2 cmt. i (1998); *Restatement (Second) of Torts* § 388 cmt. n (1965). We noted that each of these factors "must be weighed against each other, the measure being reasonableness in the circumstances." *Humble Sand*, 146 S.W.3d at 190. Because the record lacked "any evidence that, in general, warnings by flint suppliers could effectively reach their customers' employees actually engaged in abrasive blasting," we were unable to determine whether the suppliers had a duty to warn the customers' employees directly and, accordingly, remanded the case for a new trial. *Id.* at 173.

As in *Alm*, we again recognized in *Humble Sand* that other courts have applied the learned intermediary doctrine within the prescription drug context and explained: "The rationale for this 'learned intermediary' rule is not that a direct warning from manufacturers to patients is infeasible, in the practical, physical sense of that word, but that it is better for the patient for the warning to come from his or her physician." *Id.* at 190–91; *see also Restatement (Third) of Torts: Products Liability* § 6 cmt. b ("The rationale supporting this 'learned intermediary' rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the

relative advantages and disadvantages of a given form of prescription-based therapy. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.").

Until now, we have not considered a case that squarely presents the applicability of the learned intermediary doctrine within the context of prescription drug products-liability cases. For reasons stated in *Humble Sand*, *Alm*, and *Gravis*, we hold that a prescription drug manufacturer fulfills its duty to warn end users of its product's risks by providing adequate warnings to the intermediaries who prescribe the drug and, once fulfilled, it has no further duty to warn the end users directly. *See Humble Sand*, 146 S.W.3d at 190–91; *Alm*, 717 S.W.2d at 591–92; *Gravis*, 502 S.W.2d at 870. But as we have previously indicated, when the warning to the prescribing physician is inadequate or misleading, the prescription drug manufacturer remains liable for the injuries sustained by the patient. *See Alm*, 717 S.W.2d at 592.

Our decision to apply the learned intermediary doctrine in the context of prescription drugs, prescribed through a physician-patient relationship, not only comports with our prior references to the doctrine and many years of Texas case law, but it places us alongside the vast majority of other jurisdictions that have considered the issue.[17] Our sister states have overwhelmingly adopted the

[17] The highest courts of at least thirty-five states have adopted some form of the learned intermediary doctrine within the prescription drug products-liability context or cited favorably to its application within this context. *See, e.g.*, *Springhill Hosps., Inc. v. Larrimore*, 5 So. 3d 513, 517–18 (Ala. 2008); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 & n.17 (Alaska 1992); *West v. Searle & Co.*, 806 S.W.2d 608, 613–14 (Ark. 1991); *Brown v. Superior Court*, 751 P.2d 470, 477 n.9 (Cal. 1988); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 836–39 (Conn. 2001); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 399–401 (Del. 1989); *Mampe v. Ayerst Labs.*, 548 A.2d 798, 801–02, 802 n.6 (D.C. 1988); *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989); *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595–96 (Ga. 2003); *Craft v. Peebles*, 893 P.2d 138, 155–56 (Haw. 1995); *Sliman v. Aluminum Co. of Am.*, 731 P.2d 1267, 1270–71 (Idaho 1986); *Hansen v. Baxter Healthcare Corp.*, 764 N.E.2d 35, 42 (Ill. 2002); *Humes v. Clinton*, 792 P.2d 1032, 1039–41 (Kan. 1990); *Hyman & Armstrong, P.S.C. v. Gunderson*, 279 S.W.3d 93, 109–10, 112 (Ky. 2008), *cert.*

learned intermediary doctrine in this context and, to date, only one state has rejected the doctrine altogether. *See State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 913–14 (W. Va. 2007). The underlying rationale for the validity of the learned intermediary doctrine remains just as viable today as stated by Judge Wisdom in 1974:

> Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

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dismissed, 130 S. Ct. 30 (2009); *Rite Aid Corp. v. Levy-Gray*, 894 A.2d 563, 577 (Md. 2006); *MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 68 (Mass. 1985), *cert. denied*, 474 U.S. 920 (1985); *Mulder v. Parke Davis & Co.*, 181 N.W.2d 882, 885 & n.1 (Minn. 1970); *Janssen Pharmaceutica, Inc. v. Bailey*, 878 So. 2d 31, 57 (Miss. 2004); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143, 146–47 (Mo. 1967); *Stevens v. Novartis Pharm. Corp.*, 247 P.3d 244, 257 (Mont. 2010), *cert. denied*, 131 S. Ct. 2938 (2011); *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 841–42 (Neb. 2000); *Allison v. Merck & Co.*, 878 P.2d 948, 958 n.16 (Nev. 1994) (plurality opinion), 878 P.2d at 969 (Rose, C.J., dissenting) (also following the learned intermediary doctrine); *Perez*, 734 A.2d at 1257 (applying the doctrine but adopting a DTC advertising exception); *Spensieri v. Lasky*, 723 N.E.2d 544, 549 (N.Y. 1999); *Howland v. Purdue Pharma L.P.*, 821 N.E.2d 141, 146 (Ohio 2004); *Edwards v. Basel Pharm.*, 933 P.2d 298, 300–01 (Okla. 1997); *McEwen v. Ortho Pharm. Corp.*, 528 P.2d 522, 528–30 (Or. 1974); *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385–86 (Pa. 1991); *Madison v. Am. Home Prods. Corp.*, 595 S.E.2d 493, 496 (S.C. 2004); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994); *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928–29 (Utah 2003); *Pfizer, Inc. v. Jones*, 272 S.E.2d 43, 44–45 (Va. 1980); *Terhune v. A. H. Robins Co.*, 577 P.2d 975, 978 (Wash. 1978); *Rohde v. Smiths Med.*, 165 P.3d 433, 436 n.5 (Wyo. 2007); *see also Smith v. E. R. Squibb & Sons, Inc.*, 273 N.W.2d 476, 479 (Mich. 1979) (citing favorably to the learned intermediary doctrine). *But see In re Certified Questions*, 358 N.W.2d 873, 877–78 (Mich. 1984) (referencing that court's prior statement in *Smith* and noting that other Michigan appellate courts follow the learned intermediary doctrine, but stating that its reference in *Smith* was dictum and it "did not establish or represent a rule of law" for the State of Michigan).

Additionally, we note that scores of other intermediate state courts and federal courts applying state law have also recognized the validity of the learned intermediary doctrine within the context of prescription drugs, the physician-patient relationship, and the drug manufacturer's duty to warn. *See, e.g.*, *In re Norplant Contraceptive Prods. Liab. Litig. (Norplant III)*, 215 F. Supp. 2d 795, 806–09 (E.D. Tex. 2002) (listing cases and noting that the learned intermediary doctrine either applied or was recognized without relevant exception in forty-eight states); Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R.5th 1 (1998) (listing cases).

Reyes, 498 F.2d at 1276. *Accord Bean*, 965 S.W.2d at 662 (adopting *Reyes*' rationale for the doctrine). *Cf. Diversicare Gen. Partner, Inc. v. Rubio*, 185 S.W.3d 842, 850 (Tex. 2005) ("The nature and intensity of care and treatment, including professional supervision, monitoring, assessment, quantities and types of medication, and other medical treatment are judgments made by professionals trained and experienced in treating and caring for patients and the patient populations in their health care facilities."). Because patients can obtain prescription drugs only through their prescribing physician or another authorized intermediary and because the "learned intermediary" is best suited to weigh the patient's individual needs in conjunction with the risks and benefits of the prescription drug, we are in agreement with the overwhelming majority of other courts that have considered the learned intermediary doctrine and hold that, within the physician-patient relationship, the learned intermediary doctrine applies and generally limits the drug manufacturer's duty to warn to the prescribing physician.

B. Recognized Exceptions to the Learned Intermediary Doctrine

Having concluded that the learned intermediary doctrine generally applies in the prescription drug context, we next consider whether some exception to the doctrine is warranted here, so that, despite the doctrine, Centocor retained a duty to warn the patient directly. In the more than forty-five years since courts first adopted the learned intermediary doctrine in the prescription drug context, the healthcare industry has experienced substantial changes, especially surrounding the marketing of prescription drugs. *See Vitanza*, 778 A.2d at 846 (citing *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966), as the first case to adopt the doctrine). In light of these changes, some courts and commentators, including the *Restatement*, have recognized limited exceptions to

the learned intermediary doctrine. *See, e.g.*, *Restatement (Third) of Torts: Products Liability* § 6 (1998); *see also, e.g.*, Timothy S. Hall, *Reimagining the Learned Intermediary Rule for the New Pharmaceutical Marketplace*, 35 SETON HALL L. REV. 193, 205–16 (2004) (discussing the recognized exceptions to the doctrine).[18]

The most recent exception to merit significant national attention is the DTC advertising or "mass marketing" exception. Despite the significant academic literature on the topic, only a few courts have recognized a DTC advertising exception to the learned intermediary doctrine when a

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[18] Other jurisdictions, including the Fifth Circuit in its application of Texas law, have recognized limited exceptions to the learned intermediary doctrine. Some courts have adopted an exception for mass inoculations. *See, e.g.*, *Reyes*, 498 F.2d at 1276–79, 1295 (applying Texas law and holding that the learned intermediary doctrine did not apply in the context of mass polio vaccine inoculations that were administered in the absence of a physician-patient relationship and that were "unavoidably unsafe," requiring "either a warning—meaningful and complete so as to be understood by the recipient—or an individualized medical judgment that this treatment or medication is necessary and desirable for this patient"). The Fifth Circuit, however, has limited the mass inoculation exception to situations where no physician-patient relationship exists. *See, e.g.*, *In re Norplant Contraceptive Prods. Litig. (Norplant II)*, 165 F.3d 374, 379 (5th Cir. 1999) (applying Texas law) ("[A]s long as a physician-patient relationship exists, the learned intermediary doctrine applies."); *Hurley v. Lederle Labs. Div. of Am. Cyanamid Co.*, 863 F.2d 1173, 1178 (5th Cir. 1988) (applying Texas law) (distinguishing its holding in *Reyes* where "the child's personal physician prescribed the shot, and the vaccine was administered under the supervision of the physician in his office by his nurse," because "there [was] no question . . . that a patient-physician relationship existed before and at the time the immunization was given"). A minority of other jurisdictions have recognized an exception for oral contraceptives. *See, e.g.*, *McDonald*, 475 N.E. 2d at 69–72. *But see In re Norplant Contraceptive Prods. Liab. Litig. (Norplant I)*, 955 F. Supp. 700, 707 (E.D. Tex. 1997), *aff'd*, 165 F.3d 374 (5th Cir. 1999) ("This court finds that there is no principled distinction to be drawn between prescription contraceptives and other prescription drugs insofar as application of the learned intermediary doctrine is concerned, as long as a physician is involved. The physician has the duty as the learned intermediary to make an individualized balancing of the risks and benefits of any prescription drug contemplated for a particular patient and to advise the patient of possible adverse reactions."); *see also Medrano*, 28 S.W.3d at 92 (rejecting the contraceptive and DTC advertising exceptions where the patient received the Norplant implant from an advanced practice nurse because "[i]rrespective of the origin of the [allegedly inadequate warning or misleading information], it still went through the learned intermediary to get to [the patient]," and, therefore, because "the information reached [the patient] because of the physician-patient relationship," the learned intermediary doctrine applied). Additionally, a few courts have also recognized other less common exceptions for (1) contraceptive devices, *see, e.g.*, *Hill v. Searle Labs.*, 884 F.2d 1064, 1070–71 (8th Cir. 1989); (2) overpromoted drugs, *see, e.g.*, *Proctor v. Davis*, 682 N.E.2d 1203, 1215 (Ill. App. Ct. 1997), *appeal denied*, 689 N.E.2d 1146 (Ill. 1997); and (3) drugs withdrawn from the market, *see, e.g.*, *Nichols v. McNeilab, Inc.*, 850 F. Supp. 562, 565 (E.D. Mich. 1993). Because the unique circumstances and specific types of prescription drugs at issue in those cases are not before us, we need not determine whether Texas law should recognize exceptions to the learned intermediary doctrine in other contexts.

drug manufacturer directly markets to the consumer. In 1997, the Oklahoma Supreme Court recognized a marketing exception to the learned intermediary doctrine when the FDA mandated that the manufacturers, through their product labels, must communicate warnings directly to patients. *Edwards v. Basel Pharm.*, 933 P.2d 298, 301 (Okla. 1997). While this decision did not abrogate the learned intermediary doctrine on the basis of DTC advertising, soon thereafter, the New Jersey Supreme Court adopted a sweeping DTC advertising exception to the learned intermediary doctrine in *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245, 1246–47 (N.J. 1999). *Perez* involved a prescription contraceptive called Norplant—a "hybrid" medical device that consists of a drug capsule that is surgically implanted in the patient's arm. *Id.* at 1247. The plaintiffs alleged that Wyeth Laboratories had conducted a massive advertising campaign, "which it directed at women rather than at their doctors," and sought damages because the DTC warnings failed to mention serious side effects including pain and permanent scarring attendant to the removal of the drug capsule. *Id.* at 1248. The New Jersey Supreme Court examined the theoretical underpinnings for the learned intermediary doctrine within the context of the dramatic changes associated with DTC advertising and determined that "[c]onsumer-directed advertising of pharmaceuticals thus belies each of the premises on which the learned intermediary doctrine rests." *Id.* at 1256. As a result, the court held that the learned intermediary doctrine no longer provided complete protection to pharmaceutical manufacturers that provided adequate warnings to physicians on the risks and benefits of a drug when that company chose to market directly to consumers. *Id. But see id.* (noting that its decision differed from the Fifth Circuit's holding in *Norplant II*, 165 F.3d at 379–80, and that, under Texas law, the learned intermediary doctrine applied in the context of the Norplant contraceptive). The

Perez court did, however, recognize that a drug manufacturer's compliance with "FDA advertising, labeling, and warning requirements" created a "rebuttable presumption that the [manufacturer's] duty to consumers is met."[19] *Id.* at 1259.

In the more than twelve years since *Perez*, many courts have declined to follow the New Jersey Supreme Court's sweeping departure from the learned intermediary doctrine. *But cf. Murthy v. Abbott Labs.*, ___ F. Supp. 2d ___ 4:11-CV-105, 2012 WL 734149 (S.D. Tex. Mar. 6, 2012) (citing cases that rejected *Perez*, but relying on the appellate court's holding in *Centocor* to hold that Texas law recognizes a DTC advertising exception); *see also Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) ("Since *Perez* was decided, no court—including any Florida court—has recognized the DTC exception to the learned intermediary doctrine, and several courts have expressly rejected the DTC exception."). *Cf. Karl*, 647 S.E.2d at 913 (decided after *Beale* and adopting *Perez*'s reasoning but, instead of adopting a DTC exception to the doctrine, rejecting the learned intermediary doctrine entirely). Even the Fifth Circuit has expressed that it is "skeptical that a Texas court would adopt [an overpromotion] exception" to the learned intermediary doctrine, which is closely akin to the DTC advertising exception. *Ebel v. Eli Lilly & Co.*, 321 F. App'x 350, 355 n.2 (5th Cir. 2009); *see also Beale*, 492 F. Supp. 2d at 1377–78 (discussing the overpromotion exception).

[19] Effective September 1, 2003, the Texas Legislature adopted section 82.007 of the Texas Civil Practice and Remedies Code, which created a rebuttable presumption that compliance with FDA-approved guidelines shields the "health care provider, manufacturer, distributor, and prescriber" from liability for "allegations involving failure to provide adequate warnings or information." TEX. CIV. PRAC. & REM. CODE § 82.007. Because this statute became effective after this suit was filed, it is inapplicable to this case.

To date, West Virginia is the only state whose highest court has followed the New Jersey Supreme Court's holding in *Perez*. *See Karl*, 647 S.E.2d at 912–l3.[20] In *State ex rel. Johnson & Johnson Corp. v. Karl*, the West Virginia Supreme Court relied on the *Perez* court's reasoning to reject the learned intermediary doctrine entirely: "Given the plethora of exceptions to the learned intermediary doctrine, we ascertain no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized." *Id.* at 910–11, 913. While *Karl* is the only instance where the highest court of another state has followed *Perez*, at least five other jurisdictions have expressly declined to adopt a DTC advertising exception to the learned intermediary doctrine.[21]

C. The DTC Advertising Exception Does Not Apply

At issue in this case is whether the court of appeals erred in adopting the DTC advertising exception to the learned intermediary doctrine. Not until the court of appeals' holding below had any Texas court adopted a DTC advertising exception to the learned intermediary doctrine.

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[20] Additionally, at least one federal district court has adopted the *Karl* court's reasoning and made an *Erie* determination that the New Mexico Supreme Court would not adopt the learned intermediary doctrine. *See Rimbert v. Eli Lilly & Co.*, 577 F. Supp. 2d 1174, 1214–15 (D.N.M. 2008) (applying *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938)).

[21] *See Beale*, 492 F. Supp. 2d at 1376–77 ("It is now eight years since *Perez* was decided, and no other state has followed suit. Given Florida's longstanding recognition of the learned intermediary doctrine, I conclude that it would be unlikely that the Florida Supreme Court would recognize the DTC exception."); *Porter v. Eli Lilly & Co.*, 2008 WL 544739, at *8–9 (N.D. Ga. Feb. 25, 2008) (unreported decision), *aff'd*, 291 F. App'x 963 (11th Cir. 2008); *Allgood v. GlaxoSmithKline PLC*, 2008 WL 483574, at *3–4 (E.D. La. Feb. 20, 2008) (unreported decision), *aff'd sub nom. Allgood v. SmithKline Beecham Corp.*, 314 F. App'x 701 (5th Cir. 2009); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004), *aff'd sub nom. Meridia Prods. Liab. Litig. v. Abbott Labs.*, 447 F.3d 861 (6th Cir. 2006); *Cowley v. Abbott Labs., Inc.*, 476 F. Supp. 2d 1053, 1060 n.4 (W.D. Wis. 2007) (applying North Carolina law).

See Centocor, 310 S.W.3d at 508.[22] We agree that it is important to prohibit pharmaceutical manufacturers from disseminating grossly misleading advertising, and we note that Congress has enacted a comprehensive regulatory scheme, implemented by the FDA, which is meant to control the design, implementation, and marketing of prescription drugs, including both criminal and civil penalties for manufacturers that violate these regulations.[23] *See, e.g.*, 21 U.S.C. §§ 331, 333, 335b. We acknowledge that some situations may require exceptions to the learned intermediary doctrine, but without deciding whether Texas law should recognize a DTC advertising exception when a prescription drug manufacturer distributes intentionally misleading information directly to patients or prospective patients, we hold that, based on the facts of this case, no exception applies.[24]

Here, the alleged harm was not caused by Centocor's direct advertising to Patricia. At trial, the Hamiltons admitted that the first time they heard of Remicade was when Patricia's husband, Thomas, saw a textual banner displayed on the bottom ticker of the CNN news channel, which stated that the FDA had approved Remicade for the treatment of Crohn's disease. This innocuous news report is a far cry from the basis for the *Perez* court's adoption of a DTC advertising exception where

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[22] We note that, since the appellate court's holding in *Centocor*, at least one federal district court applying Texas law has followed this approach and stated its belief that this Court "will likely agree with the Court of Appeals' reasoning in *Centocor, Inc.*" *Murthy v. Abbott Labs.*, ___ F. Supp. 2d ___ 4:11-CV-105, 2012 WL 734149, at *8 (S.D. Tex. Mar. 6, 2012).

[23] *See* 21 U.S.C. §§ 301–99; 21 C.F.R. § 202.1 (1998) (regulating prescription drug advertisements).

[24] The court of appeals' reasoning that the new era of DTC advertising relegates physicians to a mere dispensary role of prescriptions fails to consider the important professional and ethical standards the law requires of physicians. *See* 22 TEX. ADMIN. CODE § 190.8(1) (listing some examples of acts that constitute a "[f]ailure to practice in an acceptable professional manner consistent with public health and welfare," including "prescription of any dangerous drug or controlled substance without first establishing a proper professional relationship with the patient").

the pharmaceutical company "ma[de] direct claims to consumers for the efficacy of its product" through prescription drug advertisements. *Cf. Perez*, 734 A.2d at 1247. Instead of DTC advertising prompting her to request Remicade from her doctors, Patricia's claims rest on the video that she viewed after her doctor had prescribed Remicade and after the infusion process had begun. *Cf. Norplant I*, 955 F. Supp. at 708 ("The court agrees with those courts that view such patient materials as an informational supplement to the physician-patient relationship. Moreover, because these materials are distributed by the [prescribing] physician, the court is of the opinion that the physician, as the learned intermediary, has a duty to review the materials before passing them on to the patient in order to ensure that any such materials that the physician chooses to pass on will accurately inform the patient about the drug."); *Banner v. Hoffmann-La Roche Inc.*, 891 A.2d 1229, 1236 (N.J. App. Div. 2006), *cert. denied* 921 A.2d 447 (N.J. 2007) (refusing to extend the *Perez* DTC advertising exception because "the placement of informational brochures in a physician's office cannot fairly be equated with a course of mass advertising or be deemed direct-to-consumer advertising so as to remove the predicates of the learned intermediary doctrine").

Furthermore, the record indicates that this informational video is not the type of misleading DTC advertising that concerned the *Perez* court. According to Swinney, the nurse who remained present with Patricia during all of her Remicade treatments at Dr. Bullen's clinic, the videos were available to help patients feel more relaxed about the infusion process, by explaining some of the benefits and side effects of the treatment process. After viewing the video, Dr. Matthews testified that she considered the video to be an educational tool to help inform patients about the infusion process. And Patricia admitted that the first time she saw any literature about Remicade was when

she received her first Remicade infusion at Dr. Bullen's clinic. Both Patricia and Swinney testified that Patricia was already receiving her first infusion when the video started. On this record, the rationale for adopting a DTC advertising exception to the learned intermediary doctrine is simply non-existent. *See Norplant II*, 165 F.3d at 379 (rejecting the plaintiffs' argument for an "'aggressive' marketing" exception because of "the absence of any evidence on the record that any of the five plaintiffs actually saw, let alone relied, on any marketing materials issued to them by [the manufacturer]"); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 782 (S.D. Tex. 2008), *aff'd*, 321 F. App'x 350 (5th Cir. 2009) (rejecting the DTC advertising exception because there was no evidence that the plaintiff relied on the marketing website). *But see Medrano*, 28 S.W.3d at 93 n.5 (rejecting the DTC exception on the facts of that case while noting that the court could "foresee a situation where a manufacturer's direct contact with the consumer could be received and relied on by that consumer outside the learned intermediary context").[25]

Even so, we must believe that patients who seek prescription drugs based solely on DTC advertising will obtain them only when the prescribing physician has evaluated the potential risks and benefits for the particular patient. To safeguard the public from harmful products and misleading advertising, both the federal government and Texas law regulate the design, marketing, and distribution of prescription drugs. *See, e.g.*, 21 U.S.C. §§ 301–99 (Federal Food, Drug, and

[25] The court of appeals' opinion relied heavily on evidence of Centocor's marketing strategy. 310 S.W.3d at 483–84, 506–08, 514, 516–18. While the Hamiltons introduced evidence that Centocor engaged in a multi-pronged marketing strategy meant to increase sales, including efforts to educate doctors of the financial benefits of the drug, dilute the effect of a negative peer review article, and encourage patients to "demand Remicade," its general marketing strategy has no bearing on Patricia's case because she admitted that her discussions about Remicade and the information she received all came through her physicians who were fully aware of the risk of lupus-like syndrome.

Cosmetic Act); TEX. HEALTH & SAFETY CODE §§ 481.061, .071, .074; TEX. OCC. CODE § 562.056(a). Drug manufacturers that fail to comply with FDA regulations can face criminal fines and imprisonment as well as civil penalties. *See* 21 U.S.C. §§ 331, 333, 335b; 21 C.F.R. § 202.1. Although pharmaceutical companies have increased DTC advertising since courts first adopted the learned intermediary doctrine, the fundamental rationale for the doctrine remains the same: prescriptions drugs require a doctor's prescription and, therefore, doctors are best suited to communicate the risks and benefits of prescription medications for particular patients through their face-to-face interactions with those patients.

Without deciding whether Texas law should recognize any of the other exceptions to the learned intermediary doctrine, we find no reason to adopt an exception where the physician-patient relationship existed, the pharmaceutical company provided a warning to the patient's prescribing doctors that included the side effect of which the patient complains, and the patient had already visited with her prescribing physician and decided to take the drug before she saw the informational video at issue. Accordingly, we hold that it was error for the court of appeals to create a DTC or fraudulent advertising exception to the learned intermediary doctrine based on the facts of this case.

IV. The Learned Intermediary Doctrine Within the Prescription Drug Context Is Not a Common-Law Affirmative Defense

The parties dispute whether the learned intermediary doctrine is an affirmative defense, which would shift to Centocor the burden to plead, prove, and request jury findings on the learned intermediary doctrine at trial. We agree with Centocor that, within the prescription drug context, the learned intermediary doctrine is more akin to a common-law rule rather than an affirmative defense.

The Hamiltons rely heavily on the appellate court's holding in *Coleman v. Cintas Sales Corp.*, 40 S.W.3d 544, 551–52 (Tex. App.—San Antonio 2001, pet. denied). *Coleman* involved a products-liability action brought by an employee against a uniform company when his uniform caught fire. *Id.* at 547. Cintas Sales Corporation did not argue the learned intermediary doctrine before the trial court but argued to the court of appeals that it had no duty to Coleman because Coleman's employer served as a learned intermediary. *Id.* at 549. The court of appeals stated that the "'learned intermediary' [doctrine is a] defense[] that must be pled and proved by the manufacturer in the trial court," and because Cintas failed to raise this issue to the trial court in its motion for summary judgment, the issue was not properly preserved for consideration on appeal. *Id.* at 551.

We find *Coleman* distinguishable from the instant case. *Coleman* did not involve a products-liability claim arising from a drug manufacturer's failure to warn about the risks associated with its prescription drug. *See id.* at 547. As previously discussed in Part III, for more than forty-five years, courts have applied the learned intermediary doctrine within products-liability claims against prescription drugs manufacturers. *See, e.g.*, *Gravis*, 502 S.W.2d 870; *Cornish*, 370 F.2d at 85. We have repeatedly referenced the doctrine's commonly recognized application in the prescription drug context. *See Alm*, 717 S.W.2d at 591–92; *Humble Sand*, 146 S.W.3d at 185. As explained above, doctors have a legal duty to pass prescription drug warnings on to their patients. *See, e.g.*, TEX. CIV. PRAC. & REM. CODE § 74.104. And as the official comment to the *Restatement (Second) of Torts* notes, the learned intermediary doctrine applies particularly to the medical field and unavoidably unsafe products like prescription drugs, which, by law, cannot go from the manufacturer to the end

user except through a prescribing physician. *See Restatement (Second) of Torts* § 402A cmt. k. In other products-liability contexts, such as the sophisticated user or bulk supplier scenarios, however, the doctrine could apply to any type of product, not just those that are unavoidably unsafe, and the applicability of the learned intermediary doctrine in those contexts turns on whether the manufacturer's or supplier's reliance on the intermediary to warn the end user is reasonable. *See Alm*, 717 S.W.2d at 592 ("In determining whether a bulk supplier's duty to warn extends to ultimate users of a product, courts may consider whether the distributor is adequately trained, whether the distributor is familiar with the properties of the product and its safe use, and whether the distributor is capable of passing on its knowledge to consumers."). *Cf. Humble Sand*, 146 S.W.3d at 195 (placing the burden on the product supplier to prove that the warning the plaintiff claims the supplier should have given would not have been effectual).

In contrast to the non-prescription drug situation in *Coleman*, we find more persuasive the Sixth Court of Appeals' holding in *Wyeth-Ayerst Laboratories Co. v. Medrano*, 28 S.W.3d 87, 93–94 (Tex. App.—Texarkana 2000, no pet.), which directly addressed the issue in context of the plaintiff's failure-to-warn and Deceptive Trade Practices Act (DTPA) claims against the prescription drug manufacturer. In *Medrano*, the court held that the learned intermediary doctrine was not a common-law defense and that it, therefore, applied to all of the plaintiff's causes of action, including the DTPA claim. *Id.* at 94. The court reasoned:

> When the learned intermediary doctrine is asserted in a cause of action, it is used to show to whom a defendant, usually a prescription drug manufacturer, owes the duty to adequately warn. It is not used to show that the plaintiff has no valid case. Even when the learned intermediary doctrine applies, the manufacturer still has a duty to

> warn, and it can still be held liable directly to the plaintiff if the warning that it gave is inadequate.

Id. (citations omitted). The *Medrano* court's interpretation of the learned intermediary doctrine within the prescription drug context also comports with the Fifth Circuit's application of Texas law. *See, e.g.*, *Ackermann v. Wyeth Pharm.*, 526 F.3d 203, 207–08 (5th Cir. 2008) ("The learned-intermediary doctrine is not an affirmative defense. Under Texas law, it delineates to whom a defendant—usually a prescription drug manufacturer—owes the duty to warn, but it is not used to show that the plaintiff has no valid case."); *see also Norplant II*, 165 F.3d at 378 (making an *Erie* guess that Texas law considers the learned intermediary doctrine to be a common-law doctrine rather than a common-law defense).

Here, it is undisputed that Patricia received Remicade through a physician-patient relationship. As discussed hereafter in Part VI, the underlying basis for the Hamiltons' claims stems from Centocor's alleged failure to warn Patricia of the risks and dangers associated with Remicade. Therefore, as in most failure-to-warn cases, the Hamiltons had to prove that Centocor's warning was inadequate. *See, e.g.*, *Technical Chem. Co. v. Jacobs*, 480 S.W.2d 602, 605–06 (Tex. 1972); *Medrano*, 28 S.W.3d at 94. While the learned intermediary doctrine shifts the manufacturer's duty to warn the end user to the intermediary, it does not shift the plaintiff's basic burden of proof. *See Medrano*, 28 S.W.3d at 94. Doing so would create an anomalous situation where, once the defendant prescription-drug manufacturer invokes the learned intermediary doctrine, the plaintiff would be relieved of proving a key burden in any product warning case—that the product warning was inadequate. The burden on defendants in other industries to show reasonable reliance on an

intermediary to effectively deliver a warning has no application in products-liability cases against a prescription drug manufacturer when the plaintiff received the drug through the existence of a physician-patient relationship.[26]

V. The Non-Prescribing Physician Had No Duty to Warn

We now address the Hamiltons' conditional cross-issue. Because the learned intermediary doctrine applies and because we decline to adopt an exception to the doctrine in this context, the Hamiltons argue that we are implicitly expanding the doctrine and allowing drug manufacturers to bypass intermediary-prescribing physicians by sending informational videos and marketing materials to patients through non-prescribing, treating physicians and their clinics. By sending the Remicade patient video to Dr. Bullen, a non-prescribing physician, the Hamiltons claim that Centocor transferred its duty to warn to Dr. Bullen, who must warn Patricia of the risks associated with Remicade. In response, Dr. Bullen argues that the trial court correctly granted a directed verdict in his favor because, as a matter of law, he owed no duty to warn Patricia about medications that he did not prescribe. We agree with Dr. Bullen.[27]

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[26] Even if *Coleman* applied in this context and we considered the learned intermediary doctrine to be an affirmative defense, unlike the defendant in *Coleman*, Centocor has repeatedly asserted the doctrine both in the trial court and on appeal. Therefore, even under the *Coleman* holding, Centocor has properly pled and raised the learned intermediary doctrine, preserving it for us to consider on appeal.

[27] In the alternative, Dr. Bullen and amici TMA argue that we should not adopt the learned intermediary doctrine because the fundamental basis for the doctrine has changed with the evolving dynamics of contemporary society and the developing system of healthcare in the United States. For reasons stated above, we find this argument unpersuasive and, although future cases may give rise to the need for the courts to recognize an exception to the doctrine in other contexts, the learned intermediary doctrine generally applies within the context of the physician-patient relationship and the prescription drug manufacturer's duty to warn.

Despite the intricate web of modern healthcare providers and treatments, the bedrock of our healthcare system is the physician-patient relationship, and the ultimate decision for any treatment rests with the prescribing physician and the patient. As a matter of both necessity and practicality, the duty to warn the patient of the potential risks and possible alternatives to any prescribed course of action rests with the prescribing physician. *See Alm*, 717 S.W.2d at 591. The Hamiltons offer no case law in support of their duty-shifting position and we, too, have found none. While informational materials provided by healthcare providers, pharmaceutical and medical-device manufacturers, or the government are meant to educate patients and make them better informed about available treatment options,[28] a simple product brochure or short informational video cannot explain the complex intricacies of the human body or supplant the detailed, interconnected nature of the practice of medicine, which necessitates that an informed intermediary help determine the best course of treatment for a patient's particular symptoms. To hold that each healthcare provider owes a separate and individual duty to warn each patient of all possible risks associated with a treatment prescribed by any doctor would not only undermine the prescribing doctor's physician-patient relationship, but could thwart the efforts of prescription drug manufacturers to provide valuable educational information about available treatments. In most prescription drug contexts, the learned intermediary doctrine applies and the duty to warn the patient rests solely with the prescribing physician. *Cf. Torrington Co. v. Stutzman*, 46 S.W.3d 829, 837–38 (Tex. 2000) (discussing general

[28] *See, e.g.*, 21 U.S.C. § 355(r) (requiring the FDA to maintain a website that provides the official product label for all FDA-approved drugs and that will "improve[] [the] communication of drug safety information to patients and providers").

principles of duty and situations in which a party could undertake certain actions to assume a duty to another).

Here, the decision to prescribe Remicade to treat Patricia's condition was made well before she visited Dr. Bullen's infusion center and well before she saw Centocor's informational video. After reviewing Patricia's complicated medical history, tracking her symptoms, and confirming the Crohn's disease flare, Dr. Hauptman was faced with two available treatments—steroids or Remicade—and he and Patricia made the decision to try Remicade. While Dr. Bullen owed a duty to inform Patricia of the relevant risks associated with the treatment process, including the infusion method of delivery, and to obtain her informed consent to the treatment, which he properly performed, he owed no further duty to explain all of the potential risks associated with Remicade nor was he required to second-guess the professional judgment of Dr. Hauptman. *Cf. Morgan*, 30 S.W.3d at 467 (holding that a pharmacist did not owe a legal duty to warn a patient of all the possible adverse effects of a prescription drug).

Having satisfied his responsibilities, Dr. Bullen owed no additional duty to warn Patricia merely because he provided informational materials to her that he received from Centocor. Here, Centocor provided the materials as a supplement to the physician-patient relationship, not meant to supplant that relationship. Moreover, none of the allegedly misleading information from Centocor could change the fact that Patricia could not receive Remicade except through a prescription. On the facts of this case, we decline to carve out an additional exception to the learned intermediary doctrine or create a "shared intermediary" duty to warn that would (1) encourage prescription drug manufacturers to withhold educational materials from patients, and (2) require other healthcare

providers to second-guess the prescribing physician's decision and undermine the physician-patient relationship. Accordingly, we affirm the trial court's directed verdict in favor of Dr. Bullen, the infusion clinic, and its employees, and hold that, as a matter of law, Dr. Bullen owed no duty to warn Patricia of the potential side effect of lupus-like syndrome.[29]

VI. The Learned Intermediary Doctrine Applies to All of the Hamiltons' Claims

Because the learned intermediary doctrine applies, we must determine whether the doctrine applies to all of the Hamiltons' claims. Centocor argues that regardless of the pleadings and the questions submitted in the jury charge, all of the Hamiltons' claims, including common-law fraud by omission, were premised on Centocor's alleged failure to warn about Remicade's potential side effects. Therefore, Centocor contends that the learned intermediary doctrine applies to all of the Hamiltons' claims and, accordingly, that it had no duty to warn Patricia directly about Remicade's potential side effects. In response, the Hamiltons contend that it was their prerogative as the plaintiffs to plead and try their case under any theory of liability they chose. They argue that consumers routinely sue for common-law fraud when manufacturers' misrepresentations about their products cause harm, despite this Court's adoption of the *Restatement*'s position on strict products liability, and Texas courts have not imposed any additional burden on consumers to prove failure-to-warn elements from strict products-liability causes of action for common-law claims.

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[29] We do not hold that the non-prescribing, treating physician or the prescription drug manufacturer could never be held liable for information provided or positive representations made to the patient. On the facts of this case, however, the materials provided to Patricia by Centocor and through Dr. Bullen neither affected the decision to prescribe Remicade nor presented overtly false information. *Cf. Crocker v. Winthrop Labs., Div. of Sterling Drug, Inc.*, 514 S.W.2d 429, 433 (Tex. 1974).

Several federal courts applying Texas law have considered whether a patient can plead around the learned intermediary doctrine by bringing other common-law and non-products-liability claims against a prescription drug manufacturer. *See, e.g.*, *Norplant I*, 955 F. Supp. at 709. In *Norplant I*, the plaintiffs brought claims against a prescription drug manufacturer for "strict products liability, negligence, breach of implied warranty of merchantability, misrepresentation, and consumer fraud based upon the Texas [DTPA]" and alleged that the learned intermediary doctrine did not apply to "their claims for misrepresentation and violations of the DTPA arising out of a drug manufacturer's voluntary communications to consumers through physician-distributed materials." *Id.* at 709–10. Because the alleged misrepresentations and the allegedly false, misleading, and deceptive nature of the prescription drug manufacturer's materials were based on the manufacturer's failure to warn, the federal district court rejected the plaintiffs' argument:

> The gravamen of all of Plaintiffs' causes of action, including misrepresentation and violation of the DTPA, is that [the prescription drug manufacturer] failed to adequately warn of or disclose the severity of Norplant's side effects. Therefore, the learned intermediary doctrine applies to all of Plaintiffs' causes of action. Additionally, whether the failure to warn is couched as an affirmative misrepresentation or a misrepresentation by concealment, the allegation collapses into a charge that the drug manufacturer failed to warn. If the doctrine could be avoided by casting what is essentially a failure to warn claim under a different cause of action such as violation of the DTPA or a claim for misrepresentation, then the doctrine would be rendered meaningless.

Id. at 709; *see Ebel*, 536 F. Supp. 2d at 773 (applying Texas law) ("Where the crux of the suit is based on a failure to adequately warn, the learned intermediary doctrine may apply to strict liability, negligence, misrepresentation, and breach of warranty claims."); *see also Beale*, 492 F. Supp. 2d at 1372 (applying Florida law) (adopting *Norplant I*'s reasoning and listing other jurisdictions that have

applied the learned intermediary doctrine to all claims premised on the prescription drug manufacturer's alleged failure to warn); *Stafford v. Wyeth*, 411 F. Supp. 2d 1318, 1319–20 (W.D. Okla. 2006) (recognizing that all of the plaintiff's claims—negligence, design defect, failure to warn, and misrepresentation—hinged on the prescription drug manufacturer's alleged failure to warn). *But see Hill v. Wyeth, Inc.*, No. 4:03CV1526 JCH, 2007 WL 674251, at *2 (E.D. Mo. Feb. 28, 2007) (not reported) (applying Missouri law) (distinguishing *Norplant I* and refusing to dismiss all but the plaintiff's failure-to-warn claim because the plaintiff "clearly intend[ed] to pursue claims unrelated to" its failure-to-warn claim by alleging causes of action including breach of express and implied warranties and design defects). Moreover, Texas appellate courts have applied the learned intermediary doctrine to a variety of causes of action predicated on the alleged inadequacy of a prescription drug manufacturer's product warning. *See, e.g.*, *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 608 (Tex. App.—Waco 1993, writ denied) (involving a claim for breach of implied warranty of merchantability); *Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 910 (Tex. App.—El Paso 1989, writ denied) (involving negligence and strict liability claims).

We find the *Norplant I* court's application of Texas law persuasive. Here, the Hamiltons initially pled a strict liability claim for failure to warn and retained that claim in their amended petition, but they decided not to carry it forward in their proposed jury charge. Furthermore, the Hamiltons' fraud-by-omission claim is premised solely on its allegation that Centocor knowingly omitted material facts about Remicade's potential to cause lupus-like syndrome. In sum, the crux of the Hamiltons' claims rests on Centocor's alleged failure to provide an adequate warning of the potential risks and side effects associated with Remicade. We hold that when a patient alleges a

fraud-by-omission claim against a prescription drug manufacturer for alleged omissions about a prescription drug's potential side effects, (1) the patient cannot plead around the basic requirements of a failure-to-warn claim, and (2) the learned intermediary doctrine applies.[30] Therefore, the learned intermediary doctrine applies to all of the Hamiltons' claims.

VII. The Hamiltons Presented No Evidence That the Allegedly Inadequate Warning Was the Producing Cause of Patricia's Injuries

Although we conclude that the learned intermediary doctrine applies to all of the Hamiltons' claims and find no reason to adopt any exception to the learned intermediary doctrine based on the facts of this case, as in other products-liability cases premised on a product manufacturer's failure to warn, if the warning to the intermediary was inadequate or misleading, then the manufacturer remains liable for injuries sustained by the end user. *See, e.g.*, *Alm*, 717 S.W.2d at 592. The parties dispute whether Centocor's warnings to Patricia's prescribing physicians were adequate. Although the jury did not make a specific adequacy finding, all of the Hamiltons' claims require an implicit finding that Centocor's warnings to Patricia and her medical providers were inadequate. Specifically, the jury found that Centocor misrepresented to Dr. Hauptman and Dr. Pop-Moody the

[30] Here, the Hamiltons submitted a failure-to-disclose fraud claim to the jury as opposed to a fraud claim based on an affirmative misrepresentation. *See Bradford v. Vento*, 48 S.W.3d 749, 755 (Tex. 2001). Their claims are not that the Remicade warnings contained overt misrepresentations or inaccurate information, but that the omission of additional information made the warning inadequate. We need not decide whether the learned intermediary doctrine applies against a prescription drug manufacturer in a common-law fraud or misrepresentation claim based on an overt misrepresentation, such as where a drug manufacturer states that its drug is not addictive or where it grossly misstates the number of side effects observed in clinical trials. *Cf. Crocker*, 514 S.W.2d at 433 ("Whatever the danger and state of medical knowledge, and however rare the susceptibility of the user, when the drug company positively and specifically represents its product to be free and safe from all dangers of addiction, and when the treating physician relies upon that representation, the drug company is liable when the representation proves to be false and harm results.").

probability that Patricia could suffer from drug-induced, lupus-like syndrome through its omission of material information in the product warning.

Generally, "[t]he adequacy of a warning is a question of fact to be determined by the jury." *Alm*, 717 S.W.2d at 592; *see Bituminous Cas. Corp. v. Black & Decker Mfg. Co.*, 518 S.W.2d 868, 873 (Tex. Civ. App.—Dallas 1974, writ ref'd n.r.e.). But when the prescribing physician is aware of the product's risks and decides to use it anyway, any inadequacy of the product's warning, as a matter of law, is not the producing cause of the patient's injuries. *See, e.g.*, *Stewart*, 780 S.W.2d at 912; *Ethicon Endo-Surgery, Inc. v. Meyer*, 249 S.W.3d 513, 516 (Tex. App.—Fort Worth 2007, no pet.); *see also Ebel*, 536 F. Supp. 2d at 780 ("[W]here the physicians were unequivocal that new information about the risks would not have changed their decision to prescribe the medication, an inadequate warning was not the proximate cause of plaintiff's injury," and "where a physician testifies that he was aware of the risks of which plaintiff complains, it is then the plaintiff's burden to prove that a different warning would have changed the physician's decision to prescribe the medication." (citations omitted)); *Ackermann*, 526 F.3d at 209 ("We need not determine, however, whether the warning for risk level of suicide was misleading, because, as [the prescription drug manufacturer] contends, this appeal is resolved on the second prong of the analysis, namely, whether any defect in the [manufacturer's] warning was a substantial cause of [the plaintiff's injury]."). *Cf. McNeil*, 462 F.3d at 373 ("Where the physician would have adequately informed a plaintiff of the risks of a disease, had the label been sufficient, but fails to do so on that account, and where the plaintiff would have rejected the drug if informed, the inadequate labeling could be a 'producing' cause of the injury, because it effectively sabotages the function of the intermediary.").

Even assuming that the Hamiltons presented sufficient evidence to show that Centocor's warning to Patricia's prescribing physicians was inadequate, the Hamiltons still had to prove that the inadequate warning was the producing cause of Patricia's injuries.[31] *See, e.g.*, *Jacobs*, 480 S.W.2d at 605–06; *Medrano*, 28 S.W.3d at 94–95; *Rolen*, 856 S.W.2d at 609; *Stewart*, 780 S.W.2d at 911. It is undisputed that all of Patricia's medical providers were aware that Patricia could potentially develop lupus-like syndrome as a side effect of Remicade. The Hamiltons presented no evidence that Patricia's prescribing physicians or Patricia would have acted differently had Centocor provided a different warning that included post-approval information about lupus-like syndrome. Not only did the Hamiltons lack subjective evidence, but they presented no objective evidence that a different warning would have affected the decision of a reasonable doctor to prescribe Remicade for Patricia's condition.

To support their argument that Centocor's warning misrepresented the risks of contracting lupus-like syndrome, causing Patricia's doctors to prescribe the drug, the Hamiltons focused on the three cases of lupus-like syndrome reported on Centocor's 2001 package insert. The package insert stated: "In clinical studies, three patients developed clinical symptoms consistent with a lupus-like syndrome . . . . No cases of lupus-like reactions have been observed in up to three years of long-term follow-up." In an attempt to show that this warning was misleading, the Hamiltons introduced several documents indicating that Centocor was aware of more post-approval incidents of drug-

[31] Although the learned intermediary doctrine bars the Hamiltons' fraud-by-omission claim because Centocor owed no duty to warn Patricia directly, *see Bradford*, 48 S.W.3d at 755, causation is a necessary element of all of the Hamiltons' claims. *See, e.g.*, *Koenig v. Purdue Pharma Co.*, 435 F. Supp. 2d 551, 553–54 (N.D. Tex. 2006) (applying Texas law and citing cases).

induced lupus. Specifically, an internal Centocor e-mail referenced at least 174 reports of lupus-like syndrome associated with Remicade as of April 25, 2002.[32] Dr. Matthews's testimony and other trial exhibits indicated that the FDA was aware of these additional post-approval reports. According to Dr. Matthews—the only expert in the FDA approval process to testify about the Centocor package inserts—although it initially seemed "not very clear" whether the statement, "[n]o cases of lupus-like reactions," broadly encompassed all post-approval studies, on closer inspection, Dr. Matthews affirmatively stated that the warning "referr[ed] to the long-term follow-up" of the specific patients in the pre-approval clinical studies. Dr. Matthews testified that, based on her review of all the post-approval reports for Remicade through 2003, the warning provided in the 2001 package insert was adequate. Moreover, despite its knowledge of the post-approval reports, the FDA did not require Centocor to change its package insert at that time.

Even assuming that Centocor's knowledge of at least 174 post-approval reports of lupus-like syndrome and its failure to include that information in the package insert and the informational video made the warning to Patricia's prescribing physicians inadequate or misleading, the undisputed evidence indicates that, even with those cases, the risk of experiencing drug-induced lupus was still "rare." Experts from both sides testified that "rare" is commonly understood in the medical industry to mean less than 1% or 2% of all cases. The uncontroverted testimony of Dr. Matthews indicated that the 174 reported cases were out of nearly 500,000 patients who had received Remicade post-FDA approval—a mere 0.03% of all cases and well below the 1% definition of "rare." *Cf. McNeil*,

[32] According to that e-mail, Centocor's reviewing physician characterized the reported cases as follows: 8 definite lupus; 18 probable lupus; 67 unknown or insufficient information; 57 probably delayed hypersensitivity and not lupus; 16 other cases probably not lupus; and 9 definitely not lupus.

462 F.3d at 368 n.4 ("We do not mean to suggest that *de minimis* differences in risk would send the adequacy question to the jury . . . ."). Furthermore, Dr. Matthews testified that based on her review of all the post-approval data, at the time of trial, she believed the chance of developing lupus-like syndrome was still rare. Therefore, even if the patients in the 174 post-approval cases actually developed lupus-like syndrome because of Remicade and even if that information were included in the package insert, such *de minimis* differences in risk are legally insufficient to create a fact question for the jury. Patricia's prescribing physicians would still have been faced with a decision of whether to prescribe a drug with a known rare side effect—a risk they were well aware of when they chose to prescribe Remicade.

Moreover, the Hamiltons failed to show that the warning's alleged inadequacies regarding lupus-like syndrome would have changed Patricia's prescribing physicians' decision to prescribe Remicade in light of her complicated medical history and serious ailments. Dr. Hauptman testified that, based on his review of the academic literature, the Remicade package insert, and information he received from Centocor and through other experts at national meetings, he considered lupus-like syndrome to be a very rare side effect of the drug. Dr. Hauptman stated that he would want to know if Centocor was aware of more cases of patients contracting lupus-like syndrome and he believed reasonable patients would want to know if the risk had become "common or serious." The fact that Dr. Hauptman would consider all clinical trials and post-approval evidence does not prove that he would not have prescribed Remicade—one of only two available treatments for Patricia's Crohn's disease—if additional reports would not have changed the relative risk of the side effect. Even if the additional reports mentioned in the Centocor e-mail constituted valid and reliable evidence of

an elevated risk of developing lupus-like syndrome beyond that of a "rare" Remicade side effect, the fact that Dr. Hauptman would have considered such information, if included in the package insert, does not prove that the presence of such information would have changed his decision to prescribe Remicade to Patricia—a critical element of the Hamiltons' claims.

Dr. Pop-Moody also testified that she was aware Remicade could cause lupus-like syndrome, but considered the cases very rare or "[l]ow on the differential." When questioned about the three cases of lupus-like syndrome mentioned on the Remicade package insert, Dr. Pop-Moody testified that those were the only cases she was aware of at that time. Instead of proving that greater risk of lupus-like syndrome would have changed Dr. Pop-Moody's decision to prescribe Remicade, the Hamiltons elicited no evidence to that effect. Like Dr. Hauptman, Dr. Pop-Moody admitted that she would have considered all available and pertinent information when making her decision to prescribe Remicade to Patricia. Yet again, the assertion that a doctor would consider all available information about a prescription drug's risks and benefits before prescribing it does not prove that the alleged omission, which would not have changed the relative risk of contracting a potential side effect, was a producing cause of the patient's injuries.

Not only did the Hamiltons fail to prove that Dr. Pop-Moody would have changed her prescription had Centocor provided information suggesting a higher risk of lupus-like syndrome, but the record indicates the opposite. Although post-approval studies after the Hamiltons filed suit in 2003 showed more reports of lupus-like syndrome and an increase in the number of patients in the pre-approval clinical studies that developed lupus-like syndrome, at the date of trial in 2006, Dr. Pop-Moody stated that she continued to prescribe "a lot of Remicade" and that she believed it to be

an effective drug for many of her patients. Dr. Pop-Moody specifically warned Patricia that she might have SLE or lupus-like syndrome in April 2003, but despite this warning, Patricia chose to continue receiving Remicade treatments and Dr. Pop-Moody continued prescribing them to her. Patricia's actions indicate that, even if Centocor provided a different warning to her doctors, she would likely have continued Remicade treatments for her serious medical condition despite the risk of lupus-like syndrome. Patricia was also aware of other potentially serious, yet rare, side effects from Remicade, such as cancer, but chose to take the drug anyway.

Because Patricia's prescribing physicians were aware of the potential risk of contracting lupus-like syndrome but chose to prescribe it in spite of those risks, and because the Hamiltons failed to present any evidence that including additional post-approval reports in the warning would have caused Patricia's physicians to change their prescription, the Hamiltons failed to meet their burden of proof. *See Stewart*, 780 S.W.2d at 912; *see also Ackermann*, 526 F.3d at 208 ("If, however, 'the physician was aware of the possible risks involved in the use of the product but decided to use it anyway, the adequacy of the warning is not a producing cause of the injury' and the plaintiff's recovery must be denied." (quoting *Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999))). Accordingly, because there is no causation evidence to support the Hamiltons' claims, all of which are premised on Centocor's alleged failure to warn, the Hamiltons' claims must fail.[33] We therefore need not address Centocor's remaining issues.

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[33] Because Patricia's claims fail, Thomas cannot recover on his derivative claims for loss of consortium and loss of household services, nor can he recover exemplary damages for the fraud claim. *See Motor Exp., Inc. v. Rodriguez*, 925 S.W.2d 638, 640 (Tex. 1996); *Whittlesey v. Miller*, 572 S.W.2d 665, 667 (Tex. 1978); *see also Rosenzweig v. Dallas Area Rapid Transit*, 841 S.W.2d 897, 898 (Tex. App.—Dallas 1992, writ denied) (holding loss of consortium and loss of household services are derivative claims).

VIII. Conclusion

All of the Hamiltons' claims are premised on their theory that Centocor failed to adequately warn Patricia and her prescribing physicians of the risk that she could develop lupus-like syndrome from Remicade. Because the Hamiltons failed to meet their burden of proof on the causation element of their claims, as a matter of law, their claims fail. In sum, we hold that: (1) the learned intermediary doctrine generally applies within the context of the physician-patient relationship, and a prescription drug manufacturer fulfills its duty to warn its product's end users by providing an adequate warning to the prescribing physician; (2) the court of appeals erred by adopting a DTC advertising exception to the doctrine; (3) the learned intermediary doctrine is not a common-law affirmative defense, but a common-law rule and its applicability was not waived by Centocor; (4) Dr. Bullen, as the non-prescribing, treating physician, owed no duty to warn Patricia of the risks associated with Remicade beyond the risks directly attributable to the infusion process; (5) because all of the Hamiltons' claims are premised on Centocor's alleged failure to warn, the learned intermediary doctrine applies to all of their claims; and (6) the Hamiltons failed to introduce any evidence that the allegedly inadequate warning was the producing cause of Patricia's purported injuries. Accordingly, we reverse the portions of the court of appeals' judgment that are inconsistent with this opinion and render judgment that the Hamiltons take nothing.

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Paul W. Green
Justice

OPINION DELIVERED: June 8, 2012