NUMBERS 13-07-00301-CV

COURT OF APPEALS

THIRTEENTH DISTRICT OF TEXAS

CORPUS CHRISTI - EDINBURG

CENTOCOR, INC. **Appellant,**

v.

PATRICIA HAMILTON,
THOMAS HAMILTON, AND
MICHAEL G. BULLEN, M.D., **Appellees.**

On appeal from County Court at Law No. 4
of Nueces County, Texas.

O P I N I O N

Before Justices Yañez, Rodriguez, and Vela
Opinion by Justice Yañez

Our medical-legal jurisprudence is based on images of health care that no longer exist. At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed. The patient usually paid a small sum of money to the doctor. Neighborhood pharmacists compounded prescribed medicines. Without being pejorative,

> it is safe to say that the prevailing attitude of law and medicine was that the "doctor knows best."
>
> Pharmaceutical manufacturers never advertised their products to patients, but rather directed all sales efforts at physicians. In this comforting setting, the law created an exception to the traditional duty of manufacturers to warn consumers directly of risks associated with the product as long as they warned health-care providers of those risks.
>
> For good or ill, that has all changed. Medical services are in large measure provided by managed care organizations. Medicines are purchased in the pharmacy department of supermarkets and often paid for by third-party providers. Drug manufacturers now directly advertise products to consumers on the radio, television, the Internet, billboards on public transportation, and in magazines.

Perez v. Wyeth Labs., 734 A.2d 1245, 1246-47 (N.J. 1999) (citation omitted).

Against this backdrop, we are called upon to decide whether a drug manufacturer can rely on its adequate warnings to physicians to satisfy its duty to warn the ultimate consumer, the patient, when it directly advertises to the patient in a misleading fashion. We hold it cannot.

Patricia and Thomas Hamilton sued Centocor, Inc. and others after Patricia suffered from a drug-induced lupus-like syndrome allegedly caused by her use of Remicade, a drug Centocor manufactured. Patricia was shown a video that she alleged over-emphasized the benefits of Remicade but intentionally omitted warnings about the adverse side-effects she suffered. A jury found in favor of the Hamiltons on all issues presented. The trial court entered judgment on the jury's verdict in Patricia's favor for $4,687,461.70 in actual and punitive damages, and in Thomas's favor for $120,833.71 in actual and punitive damages, based on the jury's finding of fraud. By numerous issues, Centocor argues that (1) the "learned intermediary" doctrine precludes the Hamiltons' claims because Centocor adequately warned Patricia's physicians; (2) the Hamiltons failed to present legally and

factually sufficient evidence of causation; (3) the evidence of fraud by omission is legally and factually insufficient; (4) the Hamiltons cannot maintain a cause of action for implied misrepresentation, and their implied misrepresentation claims fail individually; (5) the Hamiltons failed to present expert testimony on the standard of care; (6) there is no cause of action for negligent misbranding; (7) the distribution of the videotape did not constitute negligent undertaking; (8) the evidence of future damages is legally and factually insufficient; (9) Thomas cannot recover on his derivative claims; and (10) the judgment should be remitted because the trial court misapplied the punitive damages cap.

Today we recognize an exception to the learned intermediary doctrine when a drug manufacturer directly advertises to its consumers in a fraudulent manner.[1] We further hold that the causation evidence and the evidence of fraud is legally and factually sufficient to support the judgment. We hold, however, that Patricia did not present sufficient evidence of future pain and mental anguish damages. Finally, we hold that the trial court properly applied the punitive damages cap. Accordingly, we reverse the trial court's award of future pain and mental anguish damages, modify the judgment to reflect this change, and affirm as modified.

I. BACKGROUND

A. Crohn's Disease and Remicade

According to Patricia's gastroenterologist, Ronald Hauptman, M.D., Crohn's disease is an autoimmune disease that causes a chronic inflammation of the intestines. It can

[1] The Hamiltons filed a conditional cross-appeal arguing that if the "learned intermediary" doctrine applies to non-prescribing doctors, then this Court should grant a new trial for Hamilton's claims against Michael Bullen, M.D. Because we recognize an exception to the "learned intermediary" doctrine in this case, we do not reach this conditional cross-issue. *See* TEX. R. APP. P. 47.1.

involve any part of the gastrointestinal tract from the mouth to the anus, but it primarily involves the distal small bowel and the colon. Crohn's disease begins with a "flare" of inflammation that causes serious pain in the intestines, which typically increases in severity and duration.

There is currently no "cure" for Crohn's disease; however, there are several treatment options. Dr. Hauptman testified that the treatment for a patient's Crohn's disease depends on the severity of the disease both before and at the time of treatment. The goal of treatment is to control the intestinal inflammation.

In recent medical history, steroids were the first drugs used to treat Crohn's disease. For example, during a "flare" of the disease, prednisone is a steroid treatment that can be used to reduce inflammation. As technology advanced, drugs called "5-ASA" were developed, which are anti-inflammatory medications doctors use to maintain remission of the disease. Later, immunosuppressants were developed in an attempt to address the immune system problem and suppress the inflammatory component that attacks the bowel. Imuran is an immunosuppressant frequently used for this purpose.

If left untreated, Crohn's disease can cause the patient to lose the ability to digest food. A severe flare, without effective treatment, can result in a patient requiring surgery to remove inflamed portions of the bowel, which is called a "resection." Additionally, a colostomy can be performed, where the bowel is diverted to exit the abdomen. A colostomy bag is then attached that permits the patient to pass stools into the bag, which must be drained by the patient, instead of the normal waste elimination process.

Centocor is a subsidiary of Johnson & Johnson, Inc. In November 1998, Centocor received approval from the federal Food and Drug Administration ("FDA") for the drug

Remicade, which was approved to treat Crohn's disease. Later, Remicade was approved to treat rheumatoid arthritis. Remicade is an immunosuppressant. It works by binding to and blocking the harmful effects of tumor necrosis factor ("TNF"), a substance naturally produced by the body that causes inflammation.

Centocor called Barbara Matthews, M.D., to testify at trial about the approval process at the FDA. Dr. Matthews worked for the FDA between 1994 and 2000 and was the clinical reviewer for Centocor's application for FDA approval of Remicade. According to Dr. Matthews, when a drug is approved, the drug manufacturer drafts what is called a "package insert," which contains warnings and other information about the drug. The FDA reviews the proposed package insert and makes revisions. After the package insert is approved, it is typically revised over time as new information becomes available.

On August 8, 2001, the Remicade package insert warned of lupus-like syndrome as follows:

> **PRECAUTIONS:**
> **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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> . . . .
>
> **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.
>
> Of Crohn's disease patients treated with REMICADE who were evaluated for antinuclear antibodies (ANA), 34% developed ANA between screening and last evaluation. Anti-dsDNA antibodies developed in approximately 9% of Crohn's disease patients treated with REMICADE. The development of anti-dsDNA antibodies was not related to either the dose or duration of REMICADE treatment. However, baseline therapy with an immunosuppressant in Crohn's disease patients was associated with the reduced development of anti-dsDNA antibodies (3% compared to 21% in patients not receiving any immunosuppressant). Crohn's disease patients were approximately 2 times more likely to develop anti-dsDNA antibodies if they were ANA positive at study entry.
>
> In clinical studies, three patients developed clinical symptoms consistent with 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*).

Dr. Matthews explained that if a risk associated with a drug's treatment is included on the package insert, that risk is reasonably associated with the treatment.

B. Evidence of Centocor's Marketing Strategy

As of June 2000, Centocor's marketing strategy included a two-pronged approach that included educating physicians to "refine their definition of the target Remicade patient" and to teach patients to "demand Remicade." Centocor's goal was to make Remicade "top of mind" for every rheumatoid arthritis patient. A chart admitted into evidence shows Centocor's plan for addressing patients, and it states that the goal is to "[m]ake the consumer aware the [medical] problem is treatable" and to "[e]ncourage the patient to request a specific drug."

Centocor also required its sales associates to sell a specific number of vials of

Remicade to doctors' offices. David Dullnig, Centocor's local Regional Training Manager for sales, testified that as of August 2002, his goal was to "work on [doctors] being more aggressive in prescribing Remicade." One of these strategies included encouraging doctors to provide Remicade infusions in their office to maximize the profits the doctors could realize from prescribing Remicade. Dr. Hauptman testified that a representative from Centocor approached him to discuss the economic benefits that could be obtained because Medicare and Medicaid will pay for Remicade infusions; thus the doctors could make money from prescribing Remicade and providing the infusions in their offices.

Centocor also attempted to minimize negative publicity about the potentially dangerous side effects of Remicade. The Hamiltons called Thomas Schiable, the vice president of medical affairs for Centocor, who testified about a scientific study scheduled to be published in the New England Journal of Medicine on February 13, 2003, demonstrating that problems with Remicade had been understated. Instead of addressing the substantive safety concerns raised in the article, Centocor's "Communications Program" recognized that the New England Journal of Medicine "traditionally garners significant media attention," which includes multiple stories filed by the Associated Press. Centocor's stated objectives in responding to the negative article were to: (1) neutralize the commercial impact of the publication, (2) confine the story to one news cycle, and (3) provide context to the stories that appear. Furthermore, Centocor planned to "[d]ecrease/eliminate news value by pre-positioning data as a 'non-story' with key media." Dr. Matthews testified that it would be "highly unusual" for a drug company to undertake a program to dilute the effect of a negative peer review article.

C. Drug-Induced Lupus-Like Syndrome

At trial, there were numerous descriptions of "lupus-like syndrome." Dr. Hauptman and Mary Olsen, M.D., an expert hired by Centocor but called by the Hamiltons, testified that lupus-like syndrome has characteristics similar to the autoimmune disorder systemic lupus erysthematosus ("SLE"), but it is caused by a drug.[2] As soon as the offending agent is removed, the symptoms go away.

According to all of the doctors that testified on the subject, diagnosis of lupus-like syndrome can be difficult. They generally agreed that the symptoms of "lupus-like syndrome" include weight gain, joint pain and swelling, fatigue, unusual weakness, rash, oral ulcers, fever, leukopenia,[3] and pericarditis.[4] A patient with Crohn's disease or with rheumatoid arthritis, another auto-immune disease, could present with similar symptoms, like joint pain.

Laboratory tests can be conducted to check for anti-nuclear antibodies ("ANA") and double-stranded DNA antibodies ("anti-dsDNA" or "double-stranded DNA antibodies"). Adriana Pop-Moody, M.D., testified that the ANA test is "like a screen test" for lupus, but it is not definitive. According to Atilla Ertan, M.D., the most important test for diagnosing lupus-like syndrome is the double-stranded DNA antibody test. Dr. Ertan testified that if a patient tests positive for double-stranded DNA antibodies, the test is suggestive of lupus-

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[2] During the trial, the witnesses referred to "lupus-like syndrome" and "drug-induced lupus" interchangeably.

[3] Leukopenia means a "[l]ower than the normal amount of white blood cells." *See* MedicineNet.com, Definition of Leukopenia, http://www.medterms.com/script/main/art.asp?articlekey=4149 (last visited Feb. 11, 2010).

[4] Pericarditis is defined as "[i]nflammation of the lining around the heart (the pericardium) causing chest pain and accumulation of fluid around the heart (pericardial effusion)." *See* MedicineNet.com, Definition of Pericarditis, http://www.medterms.com/script/main/art.asp?articlekey=4833 (last visited Feb. 11, 2010).

like syndrome. Dr. Olsen also testified that a test can be conducted for "antihistone antibodies," which would also be suggestive of a drug-induced lupus-like syndrome.

Difficulties arise in diagnosing a patient on Remicade with a positive ANA test and a positive double-stranded DNA antibody test because patients receiving Remicade may test positive for these antibodies without having lupus-like syndrome. Thus, Dr. Olsen explained that to diagnose lupus-like syndrome, a doctor must look at both the laboratory test results and the clinical presentation of symptoms. According to Dr. Olsen, because a positive ANA and double-stranded DNA antibody test may be produced by the Remicade itself, a test that is positive for antihistone antibodies gets her attention and indicates lupus-like syndrome.

D. Patricia's Medical History Prior to 2001

Patricia has a complicated medical history. At the time of trial, Patricia was forty-seven years old and had suffered from Crohn's disease for most of her life. She was finally diagnosed in 1977, when she was seventeen years old. Over the course of the disease, Patricia had undergone multiple surgeries, involving the removal of sections of her bowel, colon, and rectum; she also had a permanent colostomy. During one of the surgeries, Patricia contracted hepatitis C from a blood transfusion. Patricia also was diagnosed with sarcoidosis.[5]

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[5] Sarcoidosis is defined as

> [a] disease of unknown origin that causes small lumps (granulomas) due to chronic inflammation to develop in a great range of body tissues. Sarcoidosis can appear in almost any body organ, but most often starts in the lungs or lymph nodes. It also affects the eyes, liver and skin; and less often the spleen, bones, joints, skeletal muscles, heart and central nervous system (brain and spinal cord). In the majority of cases, the granulomas clear up with or without treatment. In cases where the granulomas do not heal and disappear, the tissues tend to remain inflamed and become scarred (fibrotic).

E. Ronald Hauptman, M.D.

On June 1, 2000, Patricia became a patient of Dr. Hauptman, a gastroenterologist then practicing in Corpus Christi, for her Crohn's disease. At that time, Patricia was taking various medications related to her medical conditions, including the immunosuppressant Imuran. Patricia reported to Dr. Hauptman that she was not taking any 5-ASA medications because she had an allergic reaction to those type of drugs in the past. In addition to Crohn's disease, Patricia reported a history of bleeding from a duodenal ulcer, hepatitis C, gastroesophageal reflux disease, sarcoidosis, and hormonal replacement therapy. Furthermore, Patricia reported to Dr. Hauptman that she had rheumatoid arthritis.

Patricia testified that prior to moving to Corpus Christi, she had seen a rheumatologist[6] in Tyler, Texas, for pain she was experiencing in her hands. The rheumatologist told her that "any soft tissue swelling was rheumatoid arthritis." However, laboratory testing for rheumatoid arthritis was not conducted on Patricia at that time. Patricia explained that she reported this as part of her history to Dr. Hauptman because she did not want to leave out anything that might be important. She stated that the joint pain she experienced was not significant and that at the time she first went to Dr. Hauptman, she was not taking any medication for joint pain.[7] Dr. Hauptman's notes from Patricia's first visit state that she reported a "rheumatoid arthritis history" and stated that

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See MedicineNet.com, Definition of Sarcoidosis, MedicineNet.com, http://www.medterms.com/script/main/art.asp?articlekey=13430 (last visited Feb. 11, 2010).

[6] According to the testimony at trial, rheumatology is a field of internal medicine specializing in treating, among other things, joint pain, inflammation, and auto-immune diseases, including lupus and sarcoidosis.

[7] Dr. Hauptman's records indicate that at the time Patricia first came to his office, she was taking Celebrex. Michael Guirl, M.D., testified that Celebrex is an anti-inflammatory medication that is used to treat a variety of conditions, including arthritis.

“her hands and hips bother her the worst.”

Dr. Hauptman referred Patricia to a primary care physician, Robb Sherron, M.D., and to a respiratory therapist, identified only as Dr. Miller, for her sarcoidosis. Dr. Miller performed lab work on June 19, 2000. At that time, Patricia tested negative for rheumatoid factor, which is the indicator for rheumatoid arthritis. Dr. Hauptman conceded that he never saw any laboratory testing that indicated that Patricia had rheumatoid arthritis. Additionally, Patricia’s chest x-ray showed no signs of sarcoidosis. During this time, Patricia's Crohn's disease was asymptomatic.

In September 2001, Patricia's Crohn's disease again became symptomatic. In December 2001, after conducting diagnostic tests, Dr. Hauptman determined that Patricia was suffering a “moderate flare" of her Crohn's disease. Based on her existing medical regimen and her reported allergic reaction to the 5-ASA category of drugs, Dr. Hauptman testified that Patricia's only two treatment options were steroids or Remicade.

Dr. Hauptman claimed that he discussed both options with Patricia. He testified that Patricia did not want to take steroids because she did not like how she felt when she took them. Although Patricia claimed that Dr. Hauptman did not offer her a course of steroids as an option, she agreed that she probably told Dr. Hauptman that she did not like steroids. Dr. Hauptman testified that he also discussed the risks of using Remicade, including the risk of developing a lupus-like syndrome. Patricia and Thomas, however, denied that Dr. Hauptman ever discussed the risk of lupus-like syndrome. Patricia testified that in December 2001, she did not know what lupus or lupus-like syndrome was, and that having that knowledge would have been important to her. Dr. Hauptman prescribed an induction series of three doses of Remicade to be administered at an infusion clinic over a six-week

period from December 19, 2001, to January 30, 2002.

F. The Centocor Video

Dr. Hauptman referred Patricia to the infusion clinic of Michael G. Bullen, M.D., to receive the Remicade infusions.[8] Patricia first went to the clinic on December 17, 2001, to receive a tuberculosis test, which must be performed before Remicade can be started. At that time, Polly Swinney, a nurse at the infusion clinic, took a history from Patricia. Swinney noted that Patricia reported a history of arthritis, but Patricia did not report any pain associated with the arthritis at the time she first came to the clinic.

Dr. Bullen testified that because the decision to take Remicade has already been made by the time a patient arrives at his infusion clinic, he does not typically warn patients about adverse side effects, except to provide them information about reactions that might occur during the infusion process. Dr. Bullen testified that he has a computer that prints out drug information sheets. He claimed that when Patricia came to the infusion clinic on December 19, 2001, for her first infusion, he gave Patricia one of these sheets. He did not have a copy of the exact sheet that he gave Patricia, explaining that the computer is now updated with new information. However, a copy that he printed out in 2004 right before trial did not contain a warning about lupus-like syndrome. Dr. Bullen testified that he did not warn Patricia about lupus-like syndrome.

Swinney stated that she does not review drug package inserts with patients, and she did not review the package insert for Remicade with Patricia at any time. Rather, she completes a "Patient Teaching Checklist," which requires her to advice patients of only the

[8] Testimony at trial established that an infusion involves placing a catheter into the patient's arm with intravenous tubing and infusing the medication directly into the patient's vein.

following side effects: “headache, chills, fever, nausea, vomiting, dyspnea, vertigo, upper respiratory infections, hypertension, [and] hypotension.” Swinney testified that these side effects were expected and watched for during the infusion process itself.

In addition to the checklist, Swinney showed patients a video produced by Centocor. On December 19, 2001, while Patricia was receiving her first infusion, she was shown the Centocor video, which Dr. Bullen referred to as a “treatment companion” kit. Dr. Bullen testified that the purpose of the video was to show “some of the effects of the drug on certain people. . . . It's very dramatic in some people.”

The video was shown to the jury. It begins by showing a woman with her family (“Patient 1"). Patient 1 states that she has had

> this condition for a while now, and it’s stopped me from doing the everyday things that I used to do all the time. I have two children, and [it] was very hard for me to fulfill what they expected their mom to do. My quality of life was deteriorating, and I was not happy.

Next, a man appears (“Patient 2"). He states: “I’ve tried several different drugs. Some were more successful than others, but none really lasted a long time.” A different woman then appears (“Patient 3"). She is shown moving about her kitchen normally, opening the refrigerator. Patient 3 claims she was “not able to do a lot of things that I would have liked to have done. I felt like my life was limited.”

Patient 1 appears again and states:

> We couldn’t control what I had and the doctors really were trying many different medications for me. And basically things just went from bad to worse. The decision to try Remicade was made with my doctors. It was presented to me that this might help.

While Patient 1 is speaking, she is shown walking normally down the street and into a building. A nurse appears and explains that the infusions can take place in a hospital or

an infusion clinic. Patient 1 enters an infusion clinic and is greeted by a nurse in a friendly manner.

A doctor appears, identified as Alan Safdi, M.D., who explains that Remicade is administered by intravenous infusion. Dr. Safdi explains the infusion process, and Patient 1 begins receiving an infusion. She is smiling and looks comfortable. She says that the worst part of the procedure is inserting the needle into a vein. Dr. Safdi explains that the infusion lasts two to three hours. The three patients then take turns explaining how, during the infusion process, people sleep, eat, watch television, read, or make friends. The video paints a portrait of a relaxed atmosphere.

Patient 1 explains that a doctor comes to check on her during her infusions. She states that he is checking to see if "anything immediate is happening during the infusion." Dr. Safdi then states:

> Physicians should discuss with their patients all potential side effects that may occur during these infusions. There are reports of serious infections, including sepsis and tuberculosis, that may be life threatening. So if you are prone to or have a history of infections, currently have one or develop one while taking Remicade, tell your doctor right away. Also tell your doctor before beginning treatment if you have had recent close contact with or if you have had past exposure to people with tuberculosis, or if you have any other reason to believe you may be at risk. There are also reports of serious infusion reactions like hives, difficulty breathing, and low blood pressure. If you have a demyelinating disease such as multiple sclerosis, tell your doctor before you are treated. In rare cases people with demyelinating disease who were treated with Remicade have seen their symptoms intensify. Up to one in four people experienced the following side effects in clinical studies: upper respiratory infections, headache, nausea, cough, sinusitis, or mild reactions to the infusion such as rash or itchy skin. But the vast majority of patients, in our experience, have no problems with the infusion.

Dr. Safdi explains that after the infusion, patients are kept at the infusion center for thirty minutes for observation and that most people drive themselves home. Patient 2 says

that after his infusions, he can do whatever he wants, like “grab something to eat. I can go back to work if I like. I can go to the park, whatever I would ordinarily have done.” The video shows Patient 1 getting up from the chair in the infusion center and leaving.

Dr. Safdi then says:

> After the infusion there are very little side effects that people need to watch for. If they have any discomfort, we ask them to give us a call. But those reactions, again, are extremely rare. And the vast majority of patients really experience no side effects.

The video again shows Patient 1 walking down the street. She says:

> I usually feel really good after the infusion and then when I get home I realize I’m tired. My husband will come home early from work and let me rest a little bit. But that’s about it. And then I start feeling better. Really better. And that’s what I look forward to.

Dr. Safdi appears again and explains that patients may not have a “peak” effect for a week or two after infusion. He says that the drug is “quite effective.” A disclaimer appears on the screen that says, "RESULTS MAY VARY.”

Patient 1 is shown again walking down the street and purchasing flowers, then she meets her family. She picks up her children and hugs them. Then she states, “Remicade is the drug that helped me get better. People who [sic] want to know if that’s going to make them feel better, and for me, it worked.”

Patient 2 is shown getting on and off a subway train and jogging up the stairs out of the subway station. He claims, “Since I began taking the drug, the quality of my life has definitely improved.” Dr. Safdi then exclaims, “I’m extremely enthusiastic about this whole new class of drugs! We’ve helped people with disease that hasn’t responded to other forms of therapy.” Patient 3 appears in her kitchen making coffee. She states, “I would definitely tell someone to try Remicade. It’s definitely helped me.” Dr. Safdi then says,

"This is a new era for medicine. This type of therapy. And it's provided a lot of people tremendous benefit. And I wouldn't be scared of the infusion process in and of itself." Patient 2 is shown throwing a ball with his dog. He states, "It's been nothing but a great success for me."

Finally, Patient 1 is shown walking down some stairs holding her children's hands. She easily picks one of her children up. She states, "The fact that there is no cure for my condition makes it very difficult, but having a drug that's going to give me back my quality of life is the best that we could ask for."

At the end of the video, a disclaimer rolls down the screen that says:

> If you have any questions after watching this video, talk to your healthcare provider. You can also visit our website at www.remicade.com for more information on REMICADE.
>
> This video should not be used as a substitute for talking with your doctor.

Indications

> REMICADE (infliximab) is indicated for the treatment of rheumatoid arthritis and Crohn's disease.

Rheumatoid arthritis

> REMICADE, in combination with methotrexate, is indicated for reducing the signs and symptoms and inhibiting the progression of structural damage in patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to methotrexate.

> Crohn's Disease
>
> REMICADE is indicated for the reduction in signs and symptoms of Crohn's disease in patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapies. The safety and efficacy of therapy continued beyond a single dose have not been established.
>
> REMICADE is indicated for the reduction in the number of draining

> enterocutaneous fistulae in patients with fistulizing Crohn's disease. The safety and efficacy of therapy continued beyond three doses have not been studied.
>
> REMICADE should not be administered to patients with known hypersensitivity to any murine proteins or other component of the product.
>
> There are reports of serious infections, including sepsis and tuberculosis, that may be life-threatening. So, if you are prone to or have a history of infections, currently have one, or develop one while taking REMICADE, tell your doctor right away. Also tell your doctor before beginning treatment if you have had recent close contact with, or if you have had past exposure to people with tuberculosis, or if you have any other reason to believe you may be at risk. There are also reports of serious infusion reactions with hives, difficulty breathing, and low blood pressure. If you have a de-myelinating disease such as multiple sclerosis, tell your doctor before you are treated. In rare cases, people with de-myelinating disease who were treated with REMICADE have seen their symptoms intensify. Up to one in four people experienced the following side effects in clinical studies: upper respiratory infections, headache, nausea, cough, sinusitis or mild reactions to the infusion such as rash or itchy skin. (Please see the accompanying Full Prescribing Information).

It is undisputed that the video did not list lupus-like syndrome as a potential side effect. Patricia said that after watching the video, she "felt very good about Remicade treatment." She explained, "I thought it was going to change my life and make me feel great like all the people in the video." Patricia stated that she did not have any concerns about taking additional infusions after watching the video and did not believe she needed to do any additional research. Thomas testified that he watched the video with Patricia at the infusion clinic. He stated that the video "didn't really address anything about safety, but everybody seemed to be very happy to have it, on the videotape."

Swinney testified that the videotapes from Centocor come in boxes wrapped in cellophane and that the boxes containing the videos usually come with "the video, a couple of brochures in there to tell about the drug . . . and it usually comes with the package insert

that comes also with the medications." She stated that the package insert "tells all sorts of things about the medication itself: [h]ow it was manufactured, some of the testing that was done, the side effects, adverse reactions, all those sorts, and the dosing." She testified that the "full prescribing information" refers to the package insert. Swinney admitted, however, that she opened the box and removed the videotape to show Patricia the video. Swinney claimed that after Patricia watched the video, Swinney put the video back in the box and gave Patricia the box to take home.

Patricia came back to the infusion center for two more infusions of Remicade, one on January 2, 2002, and another on January 30, 2002. At some point in between the first and second infusions, Swinney gave Patricia a different Centocor video to take to her sister, who had rheumatoid arthritis. This video was marked as Plaintiff's Exhibit 35. The box containing this video has a plastic sleeve on the inside cover that contains the package insert for Remicade.

The video shown to Patricia at the infusion center, however, was marked as Plaintiff's Exhibit 34. It does not have a plastic sleeve on the inside to hold any written materials, and the box only contains the video. Swinney admitted that if any written materials were in the box, she would have had to remove them to access the video. Swinney claimed that after she showed the video to Patricia, she put the video back in the box and placed the written information on top before she shut the box. Patricia, however, testified that she was not offered any written materials along with the video. Patricia denied that the box Swinney gave her containing the video she watched had any written information in it. Patricia stated that she never opened the box again after watching the video at the infusion center, and if there was any written information provided, it would

have been in the box when she gave it to her lawyer.

Swinney testified that after starting the videotape, she did not review any other materials with Patricia, and she did not give her any written materials regarding the side effects of Remicade. Swinney further stated that she did not discuss the possibility of lupus-like syndrome with Patricia.

Initially, Patricia had a good response to the Remicade therapy. After her first infusion, Swinney called Patricia to see how she was doing, and Patricia reported that she was already feeling better. At her second infusion, Patricia told Swinney that "she hadn't felt better in a long time and that she [felt] like she was getting relief from her arthritis pain as well as her Crohn's disease." After two infusions, Dr. Hauptman performed a colonoscopy that indicated to him that Patricia's Crohn's disease was in remission. At her third infusion on January 30, 2002, Patricia reported to Swinney that she was still feeling much better. At that point, Patricia believed that she would only receive three Remicade infusions and would be done. It is undisputed that since receiving Remicade, Patricia has not had any problems related to her Crohn's disease, which is still in remission.

G. Patricia's Decline and Treatment by Adriana Pop-Moody, M.D.

Patricia explained that in March 2002, she began having "all kinds of joint pain and was having a lot of difficulties." She testified that she had a rash all over her body, her throat hurt, and she was hurting all over. Thomas testified that Patricia was in so much pain that she could not dress herself or perform her normal functions. She went to see Dr. Sherron, her family practitioner. He ordered blood work, and Patricia then tested positive for rheumatoid factor and for ANA. Dr. Sherron referred Patricia to Dr. Pop-Moody, a rheumatologist. Patricia first visited Dr. Pop-Moody on April 3, 2002.

Dr. Pop-Moody sent a letter to Dr. Sherron after Patricia's first visit. She summarized the appointment and her view of Patricia's condition:

> Mrs. Hamilton has had Crohn's disease since the age of 6 and for many years she had joint pains. Initially the hands were involved. She had swelling and pain then the right foot and the right hip. She did not have lots of functional limitation and lots of discomfort in the joints[,] and they all got better when she was having the treatment done for Crohn's with steroids or Imuran. In December and January she received the Remicade treatment. She received three doses. The first and second doses were two weeks apart[,] and the third was one month apart[,] and the Crohn's symptoms improved dramatically along with the joint symptoms. Approximately eight weeks after the last dose of Remicade she had a big flare-up of joint pains[,] and new joints are involved this time. The hands and the right foot are very inflamed, very painful[,] but now she has shoulder pain with diminished range of motion, ankle pain and swelling, wrist and neck pain, thoracic pain[,] and also low back pain. She reached the point that she could hardly use her hands. Also, she cannot dress herself, not having enough range of motion in the shoulders.

Dr. Pop-Moody testified that Patricia told her that the three doses of Remicade had dramatically alleviated her arthritis pain, but in the two months since her last treatment, she had experienced a "flare" of arthritis pain. Dr. Pop-Moody prescribed a low dosage of prednisone, which is a steroid. She also prescribed further infusions of Remicade. Patricia testified that, at that point, she believed that she had developed rheumatoid arthritis and would be on Remicade for the rest of her life.

At Dr. Pop-Moody's direction, Patricia received an infusion of Remicade on April 10, 2002. Patricia testified that when she received a Remicade infusion, she would have a period of relief where she could resume her normal activities. After the infusion in April, Patricia misunderstood that she was supposed to slowly taper-off her prednisone, and she stopped the medication too early. She suffered a severe flare of arthritis starting on May 12, 2002. Her pain was so bad that she could not sleep, could barely walk, and could

barely get in and out of cars. Dr. Pop-Moody prescribed prednisone again, and Patricia got slightly better.

Patricia's second infusion of Remicade under Pop-Moody's care was on May 23, 2002. When she saw Dr. Pop-Moody on June 27, 2002, Dr. Pop-Moody observed that Patricia was doing "better on Remicade," but for the week prior to the visit, Patricia's hands had become stiff and painful with some loss of grip strength. Dr. Pop-Moody testified that she conducted lab work, and Patricia was positive for ANA. Dr. Pop-Moody explained that she was not concerned with lupus-like syndrome at this point:

> Everybody has the perception—and doctors, lots of doctors, if you have positive—are positive ANA, hey, I might have lupus. . . . And also, it's not only that, there is another test which is more specific for lupus. So the ANA test, it's like a screen test for lupus, and if you have a positive and you have no symptoms, because there are very good criteria to diagnose lupus, then you're gonna go further down, and they're trying to see if you have any other antibodies, auto, —we call it "autoantibodies" of immunity, —autoantibodies, which could suggest that you have a connect tissue disease, and lupus is number one. Now, what is very particular for all these medications, for the Remicade and for Imuran and Humira, all of them, they are—they have a degree of immunogenicity, as he mention [sic], many times. And you are gonna have this test positive, too. 17—I think the number went a little bit higher, because now they see more and more, about 19 percent of patients who are on this medication are gonna have this positive test for lupus. Now when we go to double-stranded DNA, because I did that, too, she had—but it had no significance. 20 percent of these patients are gonna have a positive and we are gonna just watch and see what's happening. But, you know, as we mentioned, we knew that the lupus-like syndrome is very rare, but you get prepared for it. You get your stuff there and you watch it, because this is what you need to do.

At that point, Dr. Pop-Moody planned to begin weaning Patricia off of her prednisone and to continue giving her Remicade treatments every two months.

Patricia had a third Remicade infusion under Dr. Pop-Moody's care on July 10, 2002. She finished taking prednisone on July 28, 2002. Dr. Pop-Moody saw her again on

August 9, 2002. Dr. Pop-Moody testified that after stopping the prednisone, Patricia started experiencing more pain in her shoulders, elbows, wrists, and hands. Dr. Pop-Moody's notes indicate that Patricia was "very stiff in the morning and pretty uncomfortable[,] and at night she has problems sleeping due to the pain." Her notes also indicate that "[t]he labs done on 6/27 showed a positive ANA and anti-[ds]DNA was also positive at 35. She had normal complements and the ENA screen was within normal limits." Her notes state that Patricia had "[p]ositive serology for SLE."

Dr. Pop-Moody explained that these test results were not enough to diagnose Patricia with lupus-like syndrome because according to her, twenty percent of patients on Remicade will test positive for ANA and double-stranded DNA antibodies. Dr. Pop-Moody prescribed a shot of kenalog instead of prednisone and decided to continue Remicade treatments every two months.

Patricia had another Remicade infusion on August 28, 2002, and she saw Dr. Pop-Moody on September 20, 2002. Dr. Pop-Moody testified Patricia had an "excellent response" to this treatment, but by the time another treatment was due, Patricia was again experiencing pain. Dr. Pop-Moody testified that at that time, she did not foresee Patricia ever being able to stop treatment with Remicade.

Patricia's fifth Remicade infusion prescribed by Dr. Pop-Moody was on October 14, 2002. At an office visit on November 15, 2002, Patricia reported that she was experiencing a "flare of arthritis all over for the last ten days." Patricia told Dr. Pop-Moody that the Remicade enabled her to function fully and normally, but it was only effective in controlling her arthritis pain for a few weeks following each treatment. At that time she was experiencing neck pain, shoulder pain, and wrist and hand pain with swelling. Her hips,

knees, ankles, and feet were very painful and stiff. At this point, Dr. Pop-Moody decided to increase the dose of Remicade and decrease the interval between infusions. Her notes indicate that she believed that Patricia "functions very well with this medication[,] and it is worth it to change the schedule of administration."

Patricia's sixth Remicade infusion under Dr. Pop-Moody's care was on November 25, 2002, and her seventh infusion was on January 9, 2003. At an office visit on January 17, 2003, Patricia 's joint pain had improved. However, Patricia reported that she had an upper respiratory infection in the first part of January involving a cough, fever, chest pressure, and another flare of joint pain. She had been admitted to the emergency room and was diagnosed with pericarditis. Patricia reported that after receiving Remicade on January 9, her joint pain was much improved, and she generally felt better. Dr. Pop-Moody's notes indicate that she believed the "[a]cute pericarditis [was] most likely viral in nature. There is a possibility of an autoimmune pericarditis as well." Dr. Pop-Moody decided to continue the Remicade infusions.

Dr. Pop-Moody saw Patricia again on January 24, 2003. At this time, Patricia reported feeling fatigued and was experiencing more shortness of breath than previously. Dr. Pop-Moody noted that an echocardiogram was performed that showed a small pericardial effusion. Patricia had suffered weight loss of twelve pounds. In her assessment, Dr. Pop-Moody noted that the pericarditis was "most likely viral in nature but in the presence of diagnosis of sarcoidosis[,] a flare-up of this condition should be considered too even though the patient received immunosuppression and also the Remicade treatment." Dr. Pop-Moody again prescribed prednisone, and she saw Patricia again on January 31, 2002, to monitor her prednisone use.

On February 20, 2003, Patricia had an eighth infusion of Remicade prescribed by Dr. Pop-Moody. On March 27, 2003, Patricia called Dr. Pop-Moody's office to report that she was running a high fever and had pain all over her body. At an office visit on April 4, 2003, Patricia again complained of joint pain in her shoulders, neck, wrists, hands, and ankles. Patricia reported having a fever of 102 degrees and chest pain on the left side of her chest, which was exacerbated by breathing and movement. Patricia had seen Dr. Sherron on March 31, 2003, who performed an echocardiogram and a chest x-ray. There were no signs of pleurisy[9] or pericarditis at that time. Dr. Pop-Moody's assessment was that "there [was] a question between rheumatoid arthritis and enteropathic arthritis. The patient has positive serologies for rheumatoid factor[,] which makes the diagnosis of rheumatoid arthritis more likely[,] but at the same time she has inflammatory bowel disease which could present the same way too." Additionally, Dr. Pop-Moody's notes reflected "[p]ositive serology for SLE which could be induced by Remicade[,] but now there are other questions about her developing clinical lupus in view of previous pericarditis and the chest pain which she had recently which are highly suggestive of pleurisy."

Dr. Pop-Moody testified that at that time, she believed that the development of lupus-like syndrome associated with Remicade was an extremely rare situation, and it was "[l]ow on the differential." She stated that based on the package insert's description of only three cases of lupus, she believed it was extremely unlikely that Patricia had lupus-like syndrome. Nevertheless, Dr. Pop-Moody's notes indicate that she discussed the possibility

[9] Pleurisy is defined as "[i]nflammation of the pleura, the linings surrounding the lungs." *See* MedicineNet.com, Definition of Pleurisy, http://www.medterms.com/script/main/art.asp?articlekey=4948 (last visited Feb. 11, 2010).

of lupus-like syndrome with Patricia:

> I discussed with the patient all these possibilities[,] and we might need to stop the Remicade at this point. Positive serology for lupus is not unusual with the Remicade[,] but developing symptoms of lupus would indicate that the patient has the condition and then the Remicade infusions won't be so helpful. At the present moment, she doesn't want to give up the Remicade infusion because she is feeling very well for about five to six weeks after the infusion[,] and we decided to go ahead with this infusion[,] and after that we really need to weigh the advantages or disadvantages of alpha inhibition in her case[,] and we (me and the patient) need to make a joint decision about the future of her treatment.

Dr. Pop-Moody testified that she decided to run more lab work to test Patricia's ANA levels and to look for "complements," which she explained were important to diagnosing lupus-like syndrome. She explained that if the "complements" go down and the double-stranded DNA goes up, then she would be worried.

On April 7, 2003, Patricia had a ninth infusion of Remicade under Dr. Pop-Moody's care. Dr. Pop-Moody received a call from Patricia on April 21, 2003, and Patricia asked if she could lower her prednisone dosage because she was feeling better. Dr. Pop-Moody agreed, but on April 23, 2003, Patricia came to Dr. Pop-Moody complaining of pain in her chest when she took a deep breath. Dr. Pop-Moody's notes indicate that she received the test results from the lab work she ordered earlier in April:

> With the last visit I repeated a rheumatoid factor[,] and surprisingly the rheumatoid factor is negative. The ANA panel showed again a positive ANA and positive double [stranded] DNA at a lower titer. This time it was 28[,] and the patient had a titer of more than 35 one year ago. Also, the complements were within normal limits.

Dr. Pop-Moody's assessment and diagnosis in her notes show that by the end of April 2003, she was seriously considering whether Patricia may have SLE or drug-induced lupus:

> Inflammatory arthritis most likely enteropathic arthritis. Initially we considered rheumatoid arthritis due to the positivity of rheumatoid factor which almost excluded an enteropathic arthritis which belongs to the group of seronegative spondyloarthopothy which are supposed to be seronegative. Many times when we are dealing with autoimmune diseases you can see the switching of serologies with the same clinical complaints. The positivity of ANA and anti-DNA was considered up until now being induced by TNF alpha therapy but in view of the pericarditis which the patient had in the month of February, the possibility of SLE is raised. There are reports cases [sic] to develop clinical SLE meanwhile they are taking TNF alpha inhibition. I discussed with the patient extensively all of these possibilities[,] and still we do not have a firm diagnosis of lupus due to the fact that the time when she had the pericarditis she did have symptoms of an upper respiratory infection. The patient is aware of the fact that the TNF alpha therapy can induce a lupus flare which we have as an underlying condition[,] but at the present moment she does not want to stop the Remicade treatment because this stabilized her Crohn's symptoms which were very pronounced. She had repeated surgeries done for it[,] and she does not want to return to that situation again. Also, the joint pains and stiffness are very well controlled with Remicade[,] and this enables her to integrate normally in her life so she is very reluctant to stop the medication especially if I do not have anything else to offer her. Consequently she is going to read more about SLE symptoms[,] and we will follow her very closely.

Dr. Pop-Moody testified that she gave Patricia literature on lupus and that Patricia was going to read it. She claimed that she advised Patricia of the symptoms of lupus-like syndrome, such as rashes and "chest pains which come and go, and they hurt you when you take a deep breath." Dr. Pop-Moody admitted that the increased joint pain that Patricia experienced could be from drug-induced lupus-like syndrome.

Thomas recalled that Patricia came home from an appointment with Dr. Pop-Moody with a pamphlet on lupus, and he stated that Patricia "was supposed to go through these lupus symptoms and decide whether or not—or to decide whether or not she was having any of these symptoms. This way, they could talk about it next time they met." Patricia testified that she recalled Dr. Pop-Moody discussing lupus with her in the Spring of 2003, although she did not specify the exact date. However, Patricia denied that Dr. Pop-Moody

informed her that the Remicade could be causing drug-induced lupus; she testified that she decided to continue on Remicade because she believed, at that time, that Remicade was the only option to provide her with any relief. She testified that she did not know that Remicade was the cause of her problems at that time.

Dr. Pop-Moody's notes, however, were sent to Dr. Sherron, and in her analysis, she noted that Patricia was considering legal action against Centocor:

> I do not know if you are aware that she is looking for legal action against Centacor [sic]. The patient wants to have part of her co-pay paid by Centacor [sic] because she thinks that she started having the joint complaints so pronounced only after the Remicade was given to her. In my opinion she benefitted from Remicade extremely due to the stabilizing of her Crohn's symptoms and also of the joint symptoms but we are in a sensitive situation and she has to take the responsibility to go ahead with this treatment as long as we have a suspicion of lupus and not to make anybody responsible in case we have more complications. I am not sure how she is going to react to these problems but I want you to be informed about all these developments.

Patricia explained that "at that time my understanding was I would be on this drug indefinitely and the Remicade had actually caused the flare of rheumatoid arthritis that I was now suffering from and having to be treated with the same drug." She believed that she would have to continue Remicade indefinitely.

On May 13, 2003, Patricia had her tenth Remicade infusion, followed by another infusion on June 10, 2003. On June 27, 2003, Patricia saw Dr. Pop-Moody. Patricia reported that prior to her infusion on June 10, she experienced aches in almost all of her joints and had prolonged stiffness in the morning. Patricia also complained of shortness of breath but no chest pain. Dr. Pop-Moody testified that at that time, there was nothing indicating to her that Patricia had SLE or drug-induced lupus-like syndrome.

Patricia had three more Remicade infusions on July 8, August 5, and September

2, 2003. Dr. Pop-Moody examined Patricia after her infusion on September 2. Dr. Pop-Moody noted that the August infusion only provided relief for two weeks, and then Patricia had a big flare of joint pains and swelling in the shoulders, hands, knees, hips, and feet. Dr. Pop-Moody's notes indicate that the "joint pains are getting more and more pronounced." They also indicate that Dr. Pop-Moody decided to stop the Remicade therapy while Patricia sought a second opinion: "We had an extensive discussion about the situation that at the present time there is no use for Remicade anymore. . . . I am reluctant to provide her with this medication anymore without having a second opinion."

Dr. Pop-Moody testified that by this time, Patricia's flares of joint pain were becoming more intense, and the duration of the relief periods following each treatment was becoming shorter. Dr. Pop-Moody referred Patricia to a group of physicians at the University of Texas Health Science Center in Houston for consultation and treatment.

H. The Houston Doctors

On September 30, 2003, Patricia went to the University of Texas Health Science Center in Houston and saw Maureen D. Mayes, M.D.; Noranna B. Warner, M.D.; and Leslie Wilson, M.D. Thomas claimed that he first heard the term "drug-induced lupus" in Houston from Dr. Warner. Patricia testified that it was not until she went to Houston that she discovered that the Remicade was causing her problems.

Dr. Mayes and Dr. Wilson wrote a letter to Dr. Pop-Moody on September 30 after seeing Patricia. The doctors made the following assessment:

> 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 a systemic lupus erysthematosus. The clinical picture is less consistent with ~~sarcoidosis~~[10] or arthritis associated with sarcoidosis. The clinical presentation could be consistent with enteropathic arthritis. This could be arthritis associated with hepatitis C virus.
>
> 2. Leukopenia—possibly secondary to lupus-like syndrome or a side effect of Imuran. . . .

The doctors decided to discontinue further treatment with Remicade because Patricia apparently was no longer benefitting from it. Instead, they prescribed increased dosages of other medications Patricia had taken off and on, including prednisone. The doctors planned to follow Patricia's serologies for the next few months to monitor her "ANA, anti double stranded DNA, and anti histone level."

At a second visit on October 15, 2003, Patricia 's condition had improved. In a letter to Dr. Pop-Moody, the Houston doctors wrote:

> 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.
>
> Today, the patient states that she is much improved since her previous visit. She was able to go to the zoo earlier this week and was able to walk around for approximately 4 hours without significant joint pain. She has resumed her daily activities including dressing herself and caring for herself without needing assistance from her husband. The patient states that she has no

[10] "Sarcoidosis" is scratched through on the document with an ink pen. We are unable to tell from the record who scratched through the word.

> significant morning stiffness at this time. She occasionally has some pain in her shoulders and upper extremities but feels that she is much improved since her last visit.
>
> . . . .
>
> 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.

It was undisputed that after Patricia stopped taking the Remicade, her arthritis pain improved completely. Patricia testified that, had she known that Remicade could cause lupus-like syndrome, she would have asked more questions before making a decision to take Remicade.

I. Expert Testimony on Patricia's Diagnosis

Dr. Ertan testified as an expert for Centocor. He reviewed the notes from the Houston doctors, and he stated that he agreed with them that Patricia appeared to have lupus-like syndrome. Additionally, Dr. Olsen was hired by Centocor to provide expert testimony, but she was called by the plaintiffs to testify as an adverse witness. Dr. Olsen testified that it was her opinion that Patricia had drug-induced lupus. She explained:

> In terms of diagnosing a lupus presentation, there are certain clinical criteria that are used. That includes symptoms, signs, and then there's laboratory studies. In terms of drug-induced, obviously, it's not only the diagnosis of lupus, but whether there was a drug pre [sic] that set it off. And then once you remove the offending drug symptoms go away. And then there can be, in addition, certain antibodies in drug-induced lupus called "antihistone antibodies" that are important. So in terms of the rationale for lupus—I'm still flipping through my pages, here. I might have in this paragraph new features, including joint swelling, positive ANA, positive double-stranded DNA, positive antihistone antibody, leukopenia, lyphoepenia, rash, history of oral ulcers, fever and seritosis with a pericardial effusion. All of those are clinical features that could be suggestive of lupus, and antihistone antibody, specifically drug-induced lupus. There was some pleuritic chest pain. There

> can be serositis or pleurisy in lupus. However, she did have the complicating history of sarcoid, so one with good emphasis [would] know whether that could be sarcoid or lupus-related. But those were the rationale for that.

Dr. Olsen testified that she believed Patricia's symptoms revealed a discernible case of lupus-like syndrome in January 2003, when Patricia developed pericarditis. Dr. Olsen explained why she believed that was a determinative factor:

> Because prior to that, her joint complications had certainly worsened, but it was not clear-cut what that worsening was due to. Certainly, rheumatoid arthritis would have been an initial consideration, because she did have a bilateral symmetric polyarticular synovitis process, which is a classic feature for rheumatoid. Certainly, it could have been enteropathic arthritis. I find that a little less likely, because of her treatment of multiple joints. And some of the other serologic features, her blood test features, her painful ANA positivity, and [anti-]dsDNA positivity, in the study of TNF blocker use can be seen just along for the ride and not actually be pathogenic, so those features still don't make you have to reassess the situation. But a pericardial effusion does get one's attention to say, well, what could this be due to? Is it an infection? Is it related to the arthritis? Rarely in rheumatoid it can occur. Is it related to perhaps a drug-induced lupus? Yes, it could be seen in that. So one would have to be rethinking it at that point.

Dr. Olsen testified that she believed early on, Patricia received some relief from the Remicade, but later, as the pain worsened, Dr. Olsen believed that more of the relief was coming from steroids. James Wild, M.D., Dr. Bullen's expert witness who was called as an adverse witness by the Hamiltons, testified that a patient who receives steroids and Remicade could believe that the relief she were getting was coming from the Remicade therapy when, in fact, the Remicade was making it worse. When asked if he believed if "information to a patient who has conditions like Mrs. Hamilton had, that Remicade therapy could induce lupus, could have influenced—could influence that patient in deciding not to take the Remicade," Dr. Wild stated, "Possible, yes."

David Trock, M.D., an expert for the Hamiltons who was called as an adverse

witness by Centocor, also testified through his deposition testimony that he believed that Patricia developed "systemic lupus . . . in the middle of 2002." When asked how to distinguish systemic lupus from drug-induced lupus and whether Patricia had drug-induced lupus-like syndrome, Dr. Trock explained:

> Well, a few things to consider. [Patricia] did fulfill the 1982 ACR criteria for lupus in the year, certainly in early 2003. If it's necessary to distinguish drug-induced lupus from systemic lupus there are a few things that are ordinarily done. And one of them is to determine if there's an offending agent responsible, to withdraw it, and see what happens to the patient. And as far as I'm aware of the record, that's what happened. So she did indeed have lupus in probably as early as mid 2002, and the notion of drug-induced lupus along the way. I'm not exactly sure when but certainly in January of '03 when she was admitted to a hospital with pericarditis, to me it was no more question. The setting of the right serology, lyphopenia, leukopenia, and pericarditis that she at least had lupus, be it drug-induced or systemic, at that time it wasn't clear. But in retrospect I would say that it was drug-induced because the presence of histone antibodies and the clinical improvement upon stopping the offending agent which in this case was Remicade.

Dr. Trock then stated that it was his opinion that Patricia had drug-induced lupus, which manifested itself physically in Patricia by the arthritic pain she experienced and the pericarditis.

J. The Jury's Findings and the Judgment

The Hamiltons sued Centocor on March 19, 2003,[11] and later named Dr. Hauptman, Dr. Pop-Moody, Dr. Bullen, and Dr. Bullen's infusion clinic as defendants. The petition alleged that Centocor committed fraud, among other causes of action.[12] The Hamiltons alleged that Dr. Hauptman, Dr. Pop-Moody, and Dr. Bullen failed to adequately warn her

[11] We note that although Hamilton filed suit against Centocor on March 19, 2003, she continued to take infusions of Remicade through September 2, 2003.

[12] The Hamiltons also alleged causes of action for negligence, gross negligence, and misrepresentation.

of the risks associated with Remicade and failed to obtain her informed consent to such treatment. Following a jury trial, the trial court granted a directed verdict in favor of Dr. Bullen and his infusion clinic.

The jury found that Centocor was liable for fraud.[13] It 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 $65,908.00 in past medical care expenses. The jury also awarded Thomas $50,000.00 for loss of consortium and household services. The jury apportioned liability for Hamilton's damages as follows: Centocor, 85%; Dr. Pop-Moody, 10%; and Dr. Hauptman, 5%. The jury found that the fraud was established by clear and convincing evidence, and it awarded Patricia $15 million and Thomas $1 million in exemplary damages for Centocor's fraudulent conduct.

Before entry of judgment, Drs. Hauptman and Pop-Moody settled with the Hamiltons, and the Hamiltons non-suited those defendants.[14] The trial court applied settlement credits and apportioned responsibility, entered judgment against Centocor based on the fraud claim, and awarded actual and punitive damages and interest, for a total award of $4,687,461.70 to Patricia and $120,833.71 to Thomas against Centocor. The judgment states that in the alternative, the Hamiltons should recover actual damages under the various other theories presented to the jury. This appeal ensued.

II. LEARNED INTERMEDIARY DOCTRINE

[13] The jury also found Centocor liable for negligent misbranding, negligent marketing to Patricia's doctors, misrepresentation to Patricia's doctors, and negligent undertaking. Because we affirm the judgment on the basis of the fraud finding, we do not address the other causes of action found by the jury.

[14] Dr. Pop-Moody settled with the Hamiltons for $50,000, and Dr. Hauptman settled for a confidential amount.

Within its first, second, third, and fourth issues, Centocor argues that the "learned intermediary" doctrine precludes the Hamiltons' recovery because, as a matter of law, Centocor's warnings to Patricia's physicians were adequate. Centocor argues that it had no duty to warn Patricia directly. For the reasons explained below, we disagree, and we recognize an exception to the doctrine when a drug manufacturer engages in direct-to-consumer advertising that fraudulently touts the drug's efficacy while failing to warn of the risks.

A. Origins of the "Learned Intermediary" Doctrine in Texas

The "learned intermediary" doctrine in Texas can be traced back to this Court's opinion in *Gravis v. Parke-Davis & Co.,* 502 S.W.2d 863, 869-71 (Tex. Civ. App.–Corpus Christi 1973, writ ref'd n.r.e.). In that case, the plaintiff had surgery to correct an intestinal obstruction. *Id.* at 864-65. She received a spinal anesthetic for the surgery that was composed of a combination of three drugs—novocaine, dextrose, and adrenaline—and pentothal sodium. *Id.* The novocaine and dextrose were manufactured by Winthrop Laboratories and Sterling Drug Company; the adrenaline was manufactured by Parke-Davis and Company; and the pentothal sodium was manufactured by Abbott Laboratories. *Id.* at 865.

After the surgery, the plaintiff could not move her legs, and she suffered from bladder dysfunction, phlebitis of the left leg, high blood pressure, and other problems with her lower extremities. *Id.* She sued Winthrop Laboratories, Sterling Drug Company, and Parke-Davis, alleging that they were strictly liable for her injuries. *Id.* at 864. The trial court granted summary judgment for the defendants, and we reversed the summary judgment

and remanded for trial. *Id*. At the conclusion of the case in chief, the drug companies moved for a directed verdict, which the trial court granted. *Id.* The plaintiff then appealed to this Court. *Id.*

A doctor testified at trial that Winthrop Laboratories included a warning in its package insert for the novocaine. *Id.* at 866. The package insert, which was directed at physicians, warned as follows:

> In isolated instances one or several of the following complications or side effects may be observed during or after spinal anesthesia.
>
> Cauda equina and lumbosacral cord complications (usually consisting of arachnoiditis and demelinization) [r]esult in loss or impairment of motor and sensory function of the saddle area (bladder, rectum) and one or both legs. These complications have occurred after the use of most, if not all, spinal anesthetics. The loss or impairment of motor function may be permanent, or partial recovery may slowly occur. Various explanations for such complications have been advanced, such as hypersensitivity or intolerance to the anesthetic agent with a resultant myelolytic or neurotoxic effect; pooling or relatively high concentrations of anesthetic solution around the cauda equina and spinal cord before diffusion; and accidental injection of irritating antiseptics or detergents (as when syringes are incompletely cleansed or when the ampule storage solution enters a cracked ampule). Hence, many anesthesiologists prefer to autoclave ampules in order to destroy bacteria on the exterior before opening.
>
> In an article on the hazards of lumbar puncture[,] Dripps and Vandam (J.A.M.A. 147:1118, Nov. 17, 1951) pointed out that prolonged and occasionally permanent sensory or motor abnormalities may result from direct trauma to nerve roots when the puncture is performed. In some of the reported cases of neurologic sequelae it was found that the disturbance was due to preexisting disease of the vertebral column or central nervous system (for example, cord tumors, malignant metastases, multiple sclerosis).

Id. at 866-67.

The package insert further warned:

> CONTRAINDICATIONS AND PRECAUTIONS
>
> With the exception of infection in or about the lumbar area and certain

> serious diseases of the central nervous system or of the lumbar vertebral column, most anesthesiologists consider the following conditions to be only relative contraindications. The decision whether or not to use spinal anesthesia in an individual case depends on the physician's appraisal of the advantages as opposed to the risk and on his ability to cope with the complications that may arise.

Id. at 867.

On appeal, the plaintiff argued that the trial court erred in granting a directed verdict because the drug companies failed to warn her of a possible injury, even though the product itself was not defective. *Id.* at 869. We held that the drug companies have a duty to warn about dangers and risks associated with the use of their products, but that their duty can be satisfied by warning physicians, who are "learned intermediaries" between the drug company and the patient:

> Another question before us is whether the manufacturer was required to warn Mrs. Gravis of the dangers in the drugs. The brochure accompanying the ampules of novocaine gave the medical personnel involved detailed instructions and warnings concerning the handling and administration of the drug. The warnings were directed to the attending physician. We believe that it was unreasonable to suppose that a drug manufacturer must go beyond the physician and give actual warnings to the patient. Once the physician has been warned, the choice of which drugs to use, and the duty to explain the risks involved, is his. These drugs were manufactured for administration only by a physician or other authorized person. Generally speaking, only a physician would understand the propensities and dangers involved. The doctor is a learned intermediary between the manufacturer and the ultimate consumer. If the doctor has been properly warned of the possible side effects, then we believe it is his duty to convey this warning on to the patient compatible with such a reasonable disclosure as the law imposes. *See Karp v. Cooley*, 349 F. Supp. 827 (S.D. Tex. 1972) and authorities cited therein. In the *Cooley* case it was suggested that some disclosures may so disturb the patient [that] they serve as a hindrance to needed treatment. *See also Hall v. United States*, 136 F. Supp. 187 (W.D. La. 1955).
>
> In this case, the physician, the anesthetist, and the hospital have settled with the plaintiff in another lawsuit. The question is moot as to whether the specific doctor or others breached their duty to warn Mrs. Gravis.

> We hold that it is unreasonable to demand that the manufacturer of drugs specifically warn each and every patient that receives drugs prescribed by the physician or other authorized persons. 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 relieve[s] the drug company in their duty to warn or to provide a product free of defects.

Id. at 870.

The Texas Supreme Court first acknowledged the "learned intermediary" doctrine in *Alm v. Aluminum Co. of Am.,* 717 S.W.2d 588, 591-92 (Tex. 1986).[15] In that case, Alm was injured when a bottle cap exploded off of a 7-Up bottle, hitting him in the face and injuring his eye. *Id.* at 590. Aluminum Company of America ("Alcoa") had manufactured a bottle-capping machine and sold it to JFW Enterprises ("JFW"), who used the machine to cap soda bottles. *Id.* at 589. Alcoa warned JFW that a blow-off could occur if the closure was improper or the glassware was not to specification, but it did not warn of personal injuries, and JFW did not warn consumers about the possibility of injuries. *Id.* at 593. Alm sued Alcoa, and Alcoa argued that it had relied on JFW to warn the ultimate consumers. *Id.* at 591.

Relying on *Gravis* and federal case law, the Texas Supreme Court recognized that in some circumstances, a manufacturer of a product may rely on an intermediary to pass

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[15] In two prior cases, the Texas Supreme Court held that a drug manufacturer could be liable for injuries where it misrepresented to or failed to properly warn physicians of a risk associated with a drug. *See Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978); *Crocker v. Winthrop Labs., Div. of Sterling Drug, Inc.*, 514 S.W.2d 429, 433 (Tex. 1974). Those cases, however, did not expressly state or apply what later became known as the "learned intermediary" doctrine, which, as we explained in *Gravis*, allows a drug manufacturer to satisfy its duty to warn the ultimate consumer by warning physicians. *See Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App.–Corpus Christi 1973, writ ref'd n.r.e.).

along a warning to the ultimate consumer:

> We agree that 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.
>
> In some situations, courts have recognized that a warning to an intermediary fulfills a supplier's duty to warn ultimate consumers. For example, when 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).

As the supreme court explained in *Alm,* a drug manufacturer has a duty to warn the ultimate consumers of its products about dangers associated with the products, and the "learned intermediary" doctrine is merely a means of showing that the drug company complied with its duty. *Wyeth-Ayerst Labs. Co. v. Medrano,* 28 S.W.3d 87, 91 (Tex. App.–Texarkana 2000, no pet.) ("The learned intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's duty to warn ultimate consumers.") (citing *Alm*, 717 S.W.2d at 591). Thus, to the extent that Centocor argues that it owed no duty to Patricia, it misconstrues the law. The duty to warn the ultimate consumer was always there—the only question is whether Centocor can rely on its adequate warnings to physicians to satisfy that duty when it directly advertises to the

patient in a misleading fashion.

To understand the answer to that question, we examine the theoretical underpinnings of the "learned intermediary" doctrine and its recognized exceptions, as well as the current landscape of medical treatment and direct-to-consumer advertising, to determine if the concerns giving rise to the "learned intermediary" doctrine remain applicable when a drug manufacturer directly markets its products to consumers.

B. The Theoretical Underpinnings of the Doctrine

From the case law, we can glean several rationales for applying the "learned intermediary doctrine. First, courts have held that the choice of which drugs to prescribe properly belongs to the doctor because prescription drugs are manufactured for administration only by a physician or other authorized person. *Gravis*, 502 S.W.2d at 870. We held in *Gravis* that "[t]he entire system of drug distribution in America is set up so as to place the responsibility of distribution and use upon professional people." *Id.* Because only a doctor can prescribe medicine, the argument goes, a doctor should receive the warning and pass it along to his or her patients. *Id.*

Second, Texas courts have held that "only a physician would understand the propensities and dangers involved." *Id.*; *see Alm*, 717 S.W.2d at 592.

> This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products. 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.

Medrano, 28 S.W.3d at 91 (quoting *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974)); *see* Patrick Cohoon, *An Answer to the Question of Why the Time Has Come to Abrogate the Learned Intermediary Rule in the Case of Direct-to-Consumer Advertising of Prescription Drugs*, 42 S. TEX. L. REV. 1333, 1336 (2001).

Third, courts around the country have been reluctant to interfere with the physician-patient relationship by requiring a direct warning from the manufacturer to the patient because warnings that contradict the advice given by a physician may undermine the patient's confidence in the physician. *See* Lars Noah, *This is Your Products Liability Restatement On Drugs*, 74 BROOK. L. REV. 839, 891 (2009); Cohoon, 42 S. TEX. L. REV. at 1336. This Court recognized in *Gravis* that some disclosures may so disturb patients that they may hinder needed treatment. *Gravis*, 502 S.W.2d at 870.

Fourth, it has been assumed that doctors are in a better position to warn their patients than the drug manufacturers, who typically do not have effective means to communicate with the patients. Noah, 74 BROOK. L. REV. at 891-92; Cohoon, 42 S. TEX. L. REV. at 1336. "Finally, because of the complexity of risk information about prescription drugs, comprehension problems would complicate any effort by manufacturers to translate physician labeling for lay patients." Noah, 74 BROOK. L. REV. at 892; *see* Cohoon, 42 S. TEX. L. REV. at 1336-37.

C. Recognized Exceptions and the Restatement (Third) of Torts: Products Liability

Over the years, various courts have recognized exceptions to the learned intermediary doctrine in certain settings, where the above premises underlying the doctrine did not apply. For example, as early as 1968, the Ninth Circuit held that the manufacturer

of a polio vaccine retained a duty to warn the ultimate consumer because in the mass immunization clinics where the vaccine was administered, a physician was not present to weigh the risks and benefits of the drug for each patient. *See Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968); *see also Reyes*, 498 F.2d at 1276-78; *cf. Hurley v. Lederle Labs. Div. of Am. Cyanamid, Inc.*, 863 F.2d 1173, 1178-79 (5th Cir. 1984) (holding learned intermediary theory applied in case involving DPT vaccine, which was prescribed and administered under supervision of physician).[16]

Additionally, several courts have recognized an exception to the "learned intermediary" doctrine in oral contraceptives cases. These cases reason that: (1) patients take contraceptives as a matter of choice; (2) patients personally select their contraceptives; (3) physicians play a reduced role in the decision-making process; and (4) often, these drugs are marketed directly to consumers without communicating the harmful side effects in a meaningful way. *See, e.g., Odgers v. Ortho Pharms. Corp.*, 609 F. Supp. 867, 872 (E.D. Mich. 1985); *Stephens v. G.D. Searle & Co.*, 602 F. Supp. 379, 382 (E.D. Mich. 1985); *MacDonald v. Ortho Pharms. Corp.*, 475 N.E.2d 65, 74 (Mass. 1985); *see also* Cohoon, 42 S. TEX. L. REV. at 1337-38.

In other words, in situations where an exception to the "learned intermediary" doctrine has been recognized, courts have focused on (1) the extent to which the doctor

[16] In 1986, however, the National Childhood Vaccination Act was passed, which rejected the "mass immunization" exception to the learned intermediary doctrine with respect to manufacturers of childhood vaccines because of the "supposed risk to manufacturers." Patrick Cohoon, *An Answer to the Question of Why the Time Has Come to Abrogate the Learned Intermediary Rule in the Case of Direct-to-Consumer Advertising of Prescription Drugs*, 42 S. TEX. L. REV. 1333, 1338 (2001) (citing 42 U.S.C. § 300aa-22(c)); *see also In re Swine Flu Immunization Program*, 533 F. Supp. 703, 717 (D. Utah 1982) (discussing the Swine Flu Act and that it resulted because drug manufacturers refused to sell swine-flu vaccinations unless the government provided liability protection).

is involved in the decision-making process and the selection of the drug itself; and (2) whether there is a reasonable likelihood that warnings will be adequately conveyed to the patient. The American Law Institute recognized this trend in the case law when it adopted section 6(d) of the Restatement (Third) of Torts: Products Liability:

> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
>
> (2) *the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.*

RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 6(d) (1997) (emphasis added).

As the comments explain, section 6(d)(1) reflects the traditional "learned intermediary" doctrine, while section 6(d)(2) recognizes that drug manufacturers retain a duty to warn the consumer when the physician's role in evaluating and making a decision as to the choice of drug is diminished:

> The obligation of a manufacturer to warn about risks attendant to the use of drugs and medical devices that may be sold only pursuant to a health-care provider's prescription traditionally has required warnings directed to health-care providers and not to patients. 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. Subsection (d)(1) retains the "learned intermediary" rule. However, in certain limited therapeutic relationships the physician or other health-care provider has a much-diminished role as an evaluator or decisionmaker. In these instances it may be appropriate to

impose on the manufacturer the duty to warn the patient directly.

Id. cmt. b. The comments further recognize the exceptions to the "learned intermediary" doctrine that have developed in the case law:

> Warnings and instructions with regard to drugs or medical devices that can be sold legally only pursuant to a prescription are, under the "learned intermediary" rule, directed to health-care providers. Subsection (d)(2) recognizes that direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider. An example is the administration of a vaccine in clinics where mass inoculations are performed. In many such programs, health-care providers are not in a position to evaluate the risks attendant upon use of the drug or device or to relate them to patients. When a manufacturer supplies prescription drugs for distribution to patients in this type of unsupervised environment, if a direct warning to patients is feasible and can be effective, the law requires measures to that effect.

Id. cmt. e.

Comment e to section 6 further explains that the American Law Institute recognized the argument that when a drug manufacturer directly advertises to consumers, it has a duty to warn the consumer of dangers inherent in the drug's use. *Id.* The Institute, however, determined it best to leave the issue to the developing case law:

> Although the learned intermediary rule is generally accepted and a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider, arguments have been advanced that in two other areas courts should consider imposing tort liability on drug manufacturers that fail to provide direct warnings to consumers. In the first, governmental regulatory agencies have mandated that patients be informed of risks attendant to the use of a drug. A noted example is the FDA requirement that birth control pills be sold to patients accompanied by a patient package insert. In the second, manufacturers have advertised a prescription drug and its indicated use in the mass media. Governmental regulations require that, when drugs are so advertised, they must be accompanied by appropriate information concerning risk so as to provide balanced advertising. The question in both instances is whether adequate warnings to the appropriate health-care provider should insulate the manufacturer from tort liability.

> Those who assert the need for adequate warnings directly to consumers contend that manufacturers that communicate directly with consumers should not escape liability simply because the decision to prescribe the drug was made by the health-care provider. Proponents of the learned intermediary rule argue that, notwithstanding direct communications to the consumer, drugs cannot be dispensed unless a health-care provider makes an individualized decision that a drug is appropriate for a particular patient, and that it is for the health-care provider to decide which risks are relevant to the particular patient. The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.

Id.[17] Thus, the Institute refused to take a position on direct-marketing claims and has left it up to courts, such as ours, to resolve the issue, which we do next.

D. Changes in Pharmaceutical Advertising and the Provision of Healthcare

When the "learned intermediary" doctrine was first developed, drug manufacturers did not advertise to the general public. *State ex. Rel. Johnson & Johnson Co. v. Karl*, 647 S.E.2d 899, 907 (W. Va. 2007) (citing Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 FOOD & DRUG L.J. 422, 424 (2002); Ozlem A. Bordes, *The Learned Intermediary Doctrine and Direct-to-Consumer Advertising: Should the Pharmaceutical Manufacturer Be Shielded from Liability*, 81 U. DET. MERCY L. REV. 267, 274-75 (Spring 2004)). "Significant changes in the drug industry have post-dated the adoption of the learned intermediary doctrine in the majority of states in which it is followed." *Id*. In particular, those changes have

[17] 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 a warning accompanying a prescription drug "in its distribution" is adequate if it is approved by the FDA. TEX. CIV. PRAC. & REM. CODE ANN. § 82.007 (Vernon 2005). This statute became effective after this suit was filed and is not retroactive in its application; thus, it has no application to this case. Act of June 11, 2003, 78th Leg., R.S., ch. 204, § 23.02, 2003 TEX. SESS. LAW SERV. 898-99 (2003). Moreover, it is not clear that this statute was intended to cover something other than a package insert, which accompanies a prescription drug "in its distribution," and there was no evidence presented at trial that the video shown to Patricia was ever approved by the FDA.

included "the initiation and intense proliferation of direct-to-consumer advertising, along with its impact on the physician/patient relationship . . . ." *Id.*

The first drug manufacturer to advertise directly to consumers was Upjohn Company, when it advertised for the men's hair-loss treatment, Rogaine. *See* Jon D. Hanson & Douglas A. Kysar, *Taking Behavioralism Seriously: Some Evidence of Market Manipulation*, 112 HARV. L. REV. 1420, 1456 (1999). Upjohn's advertisement asked the question, "Can an emerging bald spot . . . damage your ability to get along with others, influence your chance of obtaining a job or date or even interfere with your job performance?" *Id.* "Another ad featured an attractive female stating unequivocally, 'I know that a man who can afford Rogaine is a man who can afford me.'" *Id.*

Commentators have noted that since the first direct-to-consumer advertisement in the 1980s, "'almost all pharmaceutical companies have engaged in this direct marketing practice.'" *Id.* (quoting Barbara J. Tyler & Robert A. Cooper, *Blinded by the Hype: Shifting the Burden When Manufacturers Engage in Direct to Consumer Advertising of Prescription Drugs*, 21 VT. L. REV. 1073, 1096 (1997)). In fact, "from 1995 to 1996, drug companies increased advertising directed to consumers by ninety percent." *Perez*, 734 A.2d at 1251. By 1997, annual "advertising costs of pharmaceutical products surpassed the half-billion dollar mark for the first time, 'easily outpacing promotional efforts directed to physicians.'" *Id.* (quoting Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 GA. L. REV. 141, 141 (1997)). And in 2001, pharmaceutical companies spent $2.38 billion on direct-to-consumer marketing. Palumbo & Mullins, 57 FOOD & DRUG L.J. at 423.

One need only turn on the television to see the effects. *See* Bordes, 81 U. DET. MERCY L. REV. at 275. "Anyone who watches television is regularly bombarded with a variety of pharmaceutical products which suggest that the ultimate consumer ask his physician to prescribe a particular advertised product." *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 771 (Ky. 2004) (Winterscheimer, J., dissenting). It is no wonder that pharmaceutical companies have expanded their advertising because, according to estimates, consumers now spend more than $1 trillion on health-care products and services per year, with roughly $70 billion being spent on prescription drugs. Cohoon, 42 S. TEX. L. REV. at 1353. And as more advertising is directed at consumers, those expenditures increase. *See Perez*, 734 A.2d at 1252.

Alongside the increase in direct marketing, the practice of medicine has dramatically changed. Although a doctor still must write a prescription for prescription drugs, "[i]nformed consent now requires a patient-based decision rather than the paternalistic approach of the 1970s." *Id.* at 1255; *see also Karl*, 647 S.E.2d at 910. Physicians no longer make the final decision as to whether a patient will take a drug—patients make those decisions. *See* Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 FOOD DRUG COSM. L.J. 829, 831 (1991). Moreover, the time doctors spend with their patients, and thus the time spent in a serious discussion of the risks of pharmaceuticals, has changed—managed care has reduced the time allotted per patient to ten- or fifteen-minute appointments, and now patients spend more time in waiting rooms than they do with their doctor. *See Perez*, 734 A.2d at 1255. "'In a 1997 survey of 1,000 patients, the F.D.A. found that only one-third had received information from their

doctors about the dangerous side effects of drugs they were taking.'" *Id.* (quoting Sheryl Gay Stolberg, *Faulty Warning Labels Add to Risk in Prescription Drugs*, N.Y. TIMES, June 4, 1999, at A27).

The impact of advertising on the physician-patient relationship has been dramatic. In 1982, the FDA formally requested a moratorium on direct advertising in order to allow it to study the issue. Palumbo & Mullins, 57 FOOD & DRUG L.J. at 424. The FDA studies revealed that consumers who viewed advertising for prescription drugs typically "retained more information about the benefits of the products than the risks." *Id.* (citing Louis A. Morris & Lloyd G. Millstein, *Drug Advertising to Consumers: Effects of Formats for Magazine and Television Advertisements*, 39 FOOD & DRUG L.J. 497 (1984)). The FDA also found that "consumers wanted more information about prescription drugs and would view direct-to-consumer advertising favorably." *Id.* (citing Louis A. Morris, David Brinberg & Ron Klimberg et al., *The Attitudes of Consumers Toward Direct Advertising of Prescription Drugs,* 101 PUB. HEALTH REP. 82 (1986)).

After years of patients being subjected to direct advertising,

> physicians state that they are increasingly asked and pressured by their patients to prescribe drugs that the patient has seen advertised. For example, the diet drug combinations known as fen-phen was prescribed despite little hard scientific evidence of its potential side effects. Physicians are under attack for prescribing pills too often and too readily to inappropriate patients. Physicians argue it is not their fault; rather, they claim pushy patients, prodded by [direct-to-consumer] advertisements, pressed, wheedled, begged and berated them for quick treatments . . . . Physicians claim that it is impossible to compete with pharmaceutical companies' massive advertising budgets, and resign themselves to the fact that if consumers make enough noise, they will eventually relent to patient pressure.

Tamar V. Terzian, Note, *Direct-to-Consumer Prescription Drug Advertising,* 25 AM. J. L. &

MED. 149, 157-58 (1999).

E. The Theoretical Underpinnings of the Doctrine Do Not Apply When a Manufacturer Directly Markets to the Patient

The changes in the delivery of healthcare brought about by direct marketing and managed care demonstrate that the theoretical underpinnings of the "learned intermediary" doctrine do not apply when a drug manufacturer directly markets to its consumers, the patients. First, although a doctor must still write a prescription for prescription drugs, it is clear that many doctors are not spending the amount of time necessary to pass along warnings by pharmaceutical companies. *See Perez*, 734 A.2d at 1255. The problem this creates is compounded by the fact that patients now make the ultimate decisions regarding the drugs they will take and often ask for drugs by name. *Id.* Second, drug manufacturers who directly market their products to consumers are hard-pressed to argue that only a physician would understand the propensities and dangers involved and that they lack effective means to communicate directly with consumers. In fact, by directly marketing to consumers and providing warnings in those advertisements, drug manufacturers have completely undermined their own arguments. *See id.* at 1256. Third, and similarly, "it is illogical that requiring manufacturers to provide direct warnings to a consumer will undermine the patient-physician relationship, when, by its very nature, consumer-directed advertising encroaches on that relationship by encouraging consumers to ask for advertised products by name." *Id.* (quoting Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 WM. MITCHELL L. REV. 931, 956 (1993) (footnotes omitted)). In sum, the premises underlying the doctrine are unpersuasive when considered in light of direct marketing to patients. *Id.*

The situation presented is more similar to the recognized exceptions to the doctrine, where courts considering the issue have found it was unreasonable for a manufacturer to rely on an intermediary to convey a warning, given that direct advertising and changes in the provision of healthcare impact the doctor's role and promote more active involvement by the patient. *See supra* Part II.C. Under these circumstances, we hold that when a pharmaceutical company directly markets to a patient, it must do so without fraudulently misrepresenting the risks associated with its product. Accordingly, we overrule Centocor's first, second, third, and fourth issues to the extent those issues rely on the learned intermediary doctrine.[18]

III. EVIDENCE OF CAUSATION

By its second and fourth issues, Centocor argues that the judgment should be reversed because Patricia failed to present legally and factually sufficient evidence that (1) Remicade caused the injuries she allegedly suffered, and (2) different warnings by Centocor would have prevented those injuries.

A. Standard of Review

When conducting a legal sufficiency review, we view the evidence in the light most favorable to the verdict to determine whether the evidence at trial would allow reasonable

[18] As a corollary, Centocor argues as part of its first issue that because Patricia's doctors knew about the risk of lupus-like syndrome, the doctor's knowledge negates causation in a warning defect claim. That is true in cases where the duty to warn can be satisfied by adequately warning a learned intermediary. *See Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 912 (Tex. App.–El Paso 1989, writ denied). However, we 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. In other words, it is Patricia's knowledge that is relevant, not her doctors' knowledge. Likewise, within its second issue, Centocor argues that there was no expert testimony establishing that a different warning would have changed Patricia's doctors' decision to prescribe Remicade. Because we have held that Centocor cannot rely on its warnings to her physicians to shield it from liability in this case, we overrule those issues.

and fair-minded people to reach the verdict under review. *City of Keller v. Wilson,* 168 S.W.3d 802, 827 (Tex. 2005). We "must credit favorable evidence if reasonable jurors could, and disregard contrary evidence unless reasonable jurors could not." *Id.* We will sustain a challenge to the legal sufficiency of evidence only if: (1) there is a complete absence of evidence of a vital fact; (2) the court is barred by rules of law or of evidence from giving weight to the only evidence offered to prove a vital fact; (3) the evidence offered to prove a vital fact is no more than a mere scintilla; or (4) the evidence establishes conclusively the opposite of a vital fact. *Id.* at 810. More than a scintilla of evidence exists, and the evidence is legally sufficient, if the evidence furnishes some reasonable basis for differing conclusions by reasonable minds about a vital fact's existence. *Lee Lewis Constr. Co. v. Harrison*, 70 S.W.3d 778, 782-83 (Tex. 2001). However, "when the evidence offered to prove a vital fact is so weak as to do no more than create a mere surmise or suspicion of its existence, the evidence is no more than a scintilla and, in legal effect, is no evidence." *Ford Motor Co. v. Ridgway*, 135 S.W.3d 598, 601 (Tex. 2004) (citing *Kindred v. Con/Chem, Inc.*, 650 S.W.2d 61, 63 (Tex. 1983)).

In conducting a factual sufficiency review, we do not substitute our judgment for that of the jury; rather, we view all the evidence in a neutral light to determine whether the evidence is so weak or the finding is so contrary to the great weight and preponderance of the evidence as to be manifestly unjust, shock the conscience, or clearly demonstrate bias. *See City of Keller*, 168 S.W.3d at 826; *Golden Eagle Archery, Inc. v. Jackson*, 116 S.W.3d 757, 761 (Tex. 2003); *Pool v. Ford Motor Co.*, 715 S.W.2d 629, 635 (Tex. 1986); *Villagomez v. Rockwood Specialties, Inc.*, 210 S.W.3d 720, 749 (Tex. App.–Corpus Christi

2006, pet. denied).

B. Remicade as the Cause of Patricia's Symptoms

Centocor contends that there was no evidence, direct or otherwise, that the drug Remicade caused Patricia's injuries. Specifically, Centocor argues that Patricia did not present any evidence of causation by introducing epidemiological studies showing that Remicade increased the risks of her alleged injuries. Additionally, Centocor argues that "[n]o competent witness testified that taking Remicade caused Hamilton's alleged injuries; instead, the jury was left to make that conclusion based on the timing of events" because the evidence showed only that (1) Patricia took Remicade, and (2) some time after taking Remicade, she suffered various injuries.

Before we address the merits of these arguments, we note that Centocor did not raise these arguments 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 agree with Centocor that there is no legally sufficient evidence of causation on this ground, we may only grant Centocor a new trial. *See Werner v. Colwell*, 909 S.W.2d 866, 870 n.1 (Tex. 1995).

Centocor argues that Patricia did not present epidemiological studies to prove that Remicade can cause lupus-like syndrome in the general population in order to show general causation. *See Merrill Dow Pharms., Inc. v. Havner*, 953 S.W.2d 706, 714 (Tex. 1998) (addressing use of epidemiological studies as evidence of causation). It is true that Patricia did not present epidemiological studies to prove general causation. Centocor, however, does not address on appeal evidence showing general causation, some of which

Centocor itself presented at trial. *Medina v. Hart*, 240 S.W.3d 16, 22-24 (Tex. App.–Corpus Christi 2007, pet. denied) (holding that while expert testimony was usually required to establish negligence and causation, testimony admitted by defendant, which defendant did not address on appeal, could support the verdict).

For example, first, the package insert issued by Centocor and approved by the FDA acknowledges that lupus-like syndrome is a risk associated with taking Remicade. The package insert itself described findings from Centocor's clinical trials prior to FDA approval that found that some patients may rarely suffer from lupus-like syndrome as a result of Remicade. Centocor's witness, Dr. Matthews, testified that if a risk associated with a drug's treatment is included on the package insert, that risk is "reasonably associated" with the treatment.

Second, Patricia's doctors repeatedly testified that they *knew* of the risks of Remicade treatment—specifically, the risk of lupus-like syndrome. In fact, Centocor argued as much in its brief: "In this case, the undisputed evidence at trial proved that Hamilton's doctors knew about the risks of Remicade treatment, particularly of lupus-like syndrome." BRIEF OF APPELLANT at 14. For example, when asked what Dr. Bullen knew about lupus, he answered, "Well, I knew [Remicade] caused a lupus-like illness. It's very rare, but it caused a lupus-like problem, not lupus." Dr. Hauptman testified that the "rare side effect of lupus was brought up with Mrs. Hamilton," and he explained that he got the notion that the side effect was rare from the package insert and also from literature published by doctors who were sponsored by Centocor.

More importantly, however, Centocor itself put on expert testimony that demonstrated that Remicade could cause lupus-like syndrome. Centocor read Dr. Trock's

deposition into the record. Dr. Trock testified that in the general population, "about one out of every 400 women of child-bearing age may get concurrent lupus" along with their Crohn's disease. That converts to a percentage of 0.25% of the population. Later in the testimony, Dr. Trock testified that in recent trials, the number of patients treated with Remicade who developed lupus-like syndrome went "up to two or three per 100," which converts to a percentage of 2% or 3%. Next, Centocor read the deposition of Herbert Bonkovsky., M.D. He testified that lupus is a "rare but recognized complication of the administration of [Remicade] . . . ." Centocor itself put on this testimony, and it does not point to any contrary evidence in the record. *See Havner*, 953 S.W.2d at 717. Centocor has not explained why this evidence could not have supported the jury's verdict, and we now hold that it is both legally and factually sufficient to support the verdict. *See Medina*, 240 S.W.3d at 22-24.

Centocor next argues that Patricia did not put on evidence of specific causation, proving that Remicade caused *her* drug-induced lupus-like syndrome. It concedes that "[e]vidence of an event followed closely by manifestation of or treatment for conditions which did not appear before the event raises suspicion that the event at issue caused the conditions." *Guevara v. Ferrer*, 247 S.W.3d 662, 668 (Tex. 2007). Centocor argues, however, that "suspicion has not been and is not legally sufficient to support a finding of legal causation." *Id.* Centocor argues that besides sequence-of-events evidence, Patricia did not present any evidence that Remicade caused her injuries; thus, Patricia did not prove specific causation. To reach this conclusion, again, Centocor ignores most of the evidence in the record, including evidence from its own experts.

First, Dr. Ertan was an expert witness for Centocor. He testified that he was the

principal investigator for Centocor when it tested Remicade's efficacy in treating Crohn's disease and that he agreed with Patricia's doctors in Houston that Patricia developed drug-induced lupus-like syndrome. Second, Centocor's other expert witness, Dr. Olsen, testified that she diagnosed Patricia with drug-induced lupus-like syndrome caused by her Remicade treatment. Finally, Dr. Trock testified that he diagnosed Patricia with drug-induced lupus-like syndrome caused by her Remicade treatment. Centocor does not point to any contrary evidence in the record. Centocor does not discuss this evidence, which we hold is legally and factually sufficient to support the verdict. *See Medina*, 240 S.W.3d at 22-24.

C. Inadequate Warning as a Cause of Patricia's Injuries

Finally, Centocor argues that there is no evidence that a different warning by Centocor would have prevented Patricia's injuries and that the allegedly fraudulent statements in the video did not cause Patricia to take Remicade because she watched the video after Dr. Hauptman prescribed Remicade while she was receiving a Remicade infusion. Centocor further argues that there is no evidence that Patricia would have acted differently had a different warning been provided because even after Patricia became aware of the risk of lupus-like syndrome, which it argues occurred when Dr. Pop-Moody discussed lupus with her in the spring of 2003, Patricia continued to receive Remicade infusions. However, once again, Centocor does not address all the evidence in the record that could have supported the jury's verdict.

Patricia denied that Dr. Pop-Moody told her that Remicade could be *causing* her lupus-like syndrome, and Dr. Pop-Moody's notes indicate that she told her only that "[p]ositive serology for lupus is not unusual with the Remicade but developing symptoms

of lupus would indicate that the patient has the condition and then the Remicade infusions won't be so helpful." Thus, it is not clear, as Centocor seems to argue, that in the spring of 2003, Patricia was aware that additional infusions might worsen her problems.

To the contrary, Dr. Pop-Moody's notes and Patricia's testimony indicated that at that time, she did not want to stop treatment with Remicade because she believed it was the only thing giving her relief from her symptoms. And the evidence showed that, albeit for a short amount of time after each infusion, Patricia did have some relief from her symptoms. Patricia testified that after watching the Centocor video, she did not believe she had to do any further research or ask any more questions, and she also testified that had she been warned of lupus-like syndrome, she would have asked more questions. It is also reasonable to assume that, had Patricia been adequately warned, she would not have been under the impression that Remicade was the instrument of her relief from her joint pain. Centocor does not address this testimony or explain why it did not support the verdict.

Furthermore, the fact that Patricia watched the video after Dr. Hauptman first prescribed Remicade does not necessarily undermine a finding of causation. The evidence at trial showed that Dr. Hauptman prescribed an induction series of three infusions of Remicade over a six-week period. Patricia denied that Dr. Hauptman discussed lupus-like syndrome with her at the time he prescribed the Remicade. Patricia saw the video during her first infusion prescribed by Dr. Hauptman. She testified that after watching the video, she "felt very good about Remicade treatment." She explained, "I thought it was going to change my life and make me feel great like all the people in the video."

The facts of this case show that at the time Dr. Hauptman prescribed the Remicade, Patricia believed she would only need three infusions. However, after those first three infusions she began experiencing severe joint pain, and she visited Dr. Pop-Moody, who advised that Patricia continue the Remicade infusions indefinitely. Thus, Patricia was again required to make a decision as to whether to take Remicade infusions *after* watching the video. She testified that she did not have any concerns about taking additional infusions after watching the video, which convinced her that she did not need to do any additional research. Once again, Centocor does not address why this evidence does not support the judgment, and we believe this evidence was legally and factually sufficient to demonstrate causation. *See Medina*, 240 S.W.3d at 22-24; *see, e.g., Merck & Co., Inc. v. Garza,* 277 S.W.3d 430, 438 (Tex. App.–San Antonio 2008, pet. granted) (holding that where a doctor continued prescription of drug prescribed by prior doctor, and enlarged time period of prescription, the relevant issue was whether adequate warning would have prevented second prescription).

In sum, we overrule Centocor's second and fourth issues because we hold that the evidence, most of which Centocor completely ignores, is legally and factually sufficient to support the finding of causation. *See Medina*, 240 S.W.3d at 22-24.

IV. Adequacy of the Warning

By its third issue, Centocor argues that its warning was adequate. First, Centocor asserts that Patricia failed to present legally and factually sufficient evidence that the warnings were inadequate because no expert testified that the Remicade warnings were inadequate. Second, Centocor argues that the risk of lupus-like syndrome did not make

Remicade unreasonably dangerous. We disagree.

A. Expert Testimony

First, Centocor argues that it "unquestionably" provided warnings to Patricia, including a package insert and a videotape, and that Patricia was required to prove that these warnings were inadequate. Centocor, however, ignores significant testimony from its own expert witness, Dr. Matthews, that satisfied this requirement.

Testimony from Dr. Matthews, Centocor's expert, confirms that the complete absence of a warning in the video regarding lupus-like syndrome failed to satisfy Centocor's duty to warn a patient directly of known side effects. Dr. Matthews testified at length about what information must be included in advertisements by pharmaceutical companies. Patricia introduced a copy of chapter 21 of the Code of Federal Regulations, section 202.1, which governs advertisements by drug companies. *See* 21 C.F.R. § 202.1 (2002). Dr. Matthews explained that this regulation would apply to the video produced by Centocor and shown to Patricia at the infusion clinic.

Dr. Matthews testified that advertisements for drugs, including the Centocor video, are required to include "fair balance" information, and she referred to 21 C.F.R. section 202.1(e)(3)(i) and (iii), which provides:

> (3) *Scope of information to be included; applicability to the entire advertisement.* (i) The requirement of a true statement of information relating to side effects, contraindications, and effectiveness applies to the entire advertisement. Untrue or misleading information in any part of the advertisement will not be corrected by the inclusion in another distinct part of the advertisement a brief statement containing true information relating to side effects, contraindications, and effectiveness of the drug. If any part or theme of the advertisement would make the advertisement false or misleading by reason of the omission of appropriate qualification or pertinent information, that part or theme shall include the appropriate qualification or pertinent information, which may be concise if it is supplemented by a

> prominent reference on each page to the presence and location elsewhere in the advertisement of a more complete discussion of such qualification or information.
>
> . . . .
>
> (iii) *The information relating to side effects and contraindications shall disclose each specific side effect and contraindications (which include side effects, warnings, precautions, and contraindications and include any such information under such headings as cautions, special considerations, important notes, etc; see paragraph (e)(1) of this section) contained in the required, approved, or permitted labeling for the advertised drug dosage form(s);* . . . .

Id. § 202.1(e)(3)(i), (iii) (emphasis added).

Dr. Matthews stated that an advertisement must include true information regarding "side effects, warnings, precautions, contraindications, and includes any such information under such headings as cautions, special considerations, important notes, and so forth, and effectiveness." Dr. Matthews then admitted that an advertisement is not a true statement if "it is false or misleading with respect to side effects, contraindications, or effectiveness." She agreed that an advertisement is also misleading if it "fails to present a *fair balance* between information relating to side effects and contraindications and information related to effectiveness of the drug." (Emphasis added). Dr. Matthews testified, however, that an advertisement is not misleading if the "presentation of true information relating to side effects and contraindications is comparable in depth and detail with the claims for effectiveness and safety."

Most importantly, with respect to side effects, Dr. Matthews explained that advertisements must include information that is "consistent with what's in the labeling, the package insert." Dr. Matthews agreed that the intent of the regulations of drug advertising

was not to require patients to read package inserts, which she referred to as the "labeling" instead of advertising. However, she clarified that the package insert interrelates with drug advertising because "it has to be what's in the label."

Dr. Matthews then testified that she believed that the video was not misleading, and included "fair balance" information, because the "theme" of the video was the infusion process. She disagreed that the video showed more information about Remicade's effectiveness than warnings about the drug. Dr. Matthews agreed that there was no warning about lupus-like syndrome, but she claimed that the video was fairly balanced because it "said to also ask your physician and then to reference the package insert, which I was under the impression when you saw the video you were given a little card and then also the package insert."

It was undisputed that the video itself did not provide a warning about lupus-like syndrome. And Patricia testified that the package insert was not included with the video she watched. The box containing the video did not have a plastic sleeve to hold a package insert, as did a later video produced by Centocor. Centocor does not address this evidence, which allowed the jury to conclude that Patricia received no warning about lupus-like syndrome from the video it directly marketed to her or from any accompanying documentation.

In this case, we hold that Dr. Matthews's testimony, put on by Centocor, satisfied the requirement of expert testimony on how to judge the adequacy of the warning, and the only issue left for the jury to decide was whether the facts were as Centocor's expert assumed them to be. For example, in *Medina v. Hart*, a medical malpractice case, Hart sued his doctor, Dr. Medina, after he received second and third-degree burns during a

surgery to remove a kidney stone. 240 S.W.3d at 18-19. Dr. Medina had placed an IV bag filled with fluid under Hart's right arm to position and cushion Hart during the surgery. *Id.* at 18. When Hart awoke from surgery, he had burns under his right arm where the IV bag had been placed. *Id.* at 19.

Dr. Medina testified at trial. She admitted that it was her duty to ensure that her patient would not be injured during surgery, which included the duty to properly position the patient for surgery. *Id.* at 20. She admitted that it would be a breach of the standard of care to place a hot IV bag under a patient's arm during surgery. *Id.* She also admitted that somehow the IV bag she placed under Hart's arm became heated and caused Hart's burns. *Id.* The main dispute at trial, therefore, was over how the bag became heated. *Id.* at 21. Dr. Medina testified that the bag was not hot when she placed it under Hart's arm, but Hart's wife testified that a nurse told her that the bag had been heated and wrapped in a towel prior to being placed under Hart's arm. *Id.* Hart's wife testified that a nurse told her about a conversation she had with Dr. Medina during which Dr. Medina became agitated after the nurse questioned whether the bag had been heated. *Id.* Dr. Medina's assistant then stated, "I wish some people would just simply tell the truth." *Id.*

On appeal, Dr. Medina argued that there was no expert testimony on standard of care, breach, and causation. *Id.* at 22. We held that Dr. Medina had judicially admitted negligence and causation by stating that placing a heated bag under a patient's arm would be negligent and could cause a burn like Hart's. *Id.* at 24. We further held that the only issue in dispute was one of fact which was for the jury to decide—how and when the bag became hot. *Id.*

In this case, Dr. Matthews, Centocor's expert, testified that a warning in an advertisement must include the information in the package insert. She testified that she believed that the warnings in the video were adequate because she assumed that a patient watching the Centocor video would also receive the package insert, which would provide the complete warning. In contrast to this, the jury also heard testimony from Patricia stating that the package insert was not included along with the video. *See Burroughs Wellcome Co. v. Crye*, 907 S.W.2d 497, 499-500 (Tex. 1995) (holding expert's conclusion could be disregarded when based on assumed facts not supported by testimony at trial). The jury was entitled to rely on Dr. Matthews's opinion that an adequate warning must include the information in the package insert, and resolve the fact issue of whether or not the video included such information. It resolved that issue in Patricia's favor. *Id.* We overrule Centocor's issue in this regard.

B. Unavoidably Unsafe Product

Next, Centocor argues that Patricia failed to prove that the warnings made Remicade defective by rendering it unreasonably dangerous. Centocor argues that the undisputed evidence showed that drug-induced lupus-like syndrome was not dangerous because the symptoms are not "severe," in the sense that Patricia required hospitalization, and because discontinuing the Remicade treatment eliminated the symptoms. In addition, Centocor argues that Remicade "worked" by putting Patricia's Crohn's disease into remission and temporarily gave Patricia relief from her arthritis. Centocor acknowledges that Patricia suffered pain between infusions, but it urges the Court to hold "as a matter of law" that temporary pain is not the type of *danger* that makes a prescription drug defective,

citing section 402A of the Restatement of Torts (Second).[19]

First, we note that again, Centocor ignores much of the record to make its conclusions. Patricia's symptoms, while temporary, were certainly severe. Patricia could not dress herself because her shoulders were so painful. She also testified that she was afraid to drive her car because she was afraid that her pain would prevent her from operating it safely. Patricia's husband, Thomas, testified that she could no longer perform her daily functions, including caring for her colostomy. This pain, while temporarily relieved by the Remicade infusions, persisted from March of 2001 until October of 2003, when she was weaned off Remicade. And Centocor's argument that Patricia never had to be hospitalized is not supported by the record—Patricia was hospitalized when she suffered from pericarditis, which was a symptom of her lupus-like syndrome.

Nevertheless, assuming without deciding that Patricia had to prove that Remicade was unreasonably dangerous to recover on her fraud claim, Centocor does not cite any case law in support of its argument that a drug must cause a permanent side effect in order to be unreasonably dangerous as marketed, and we refuse to hold as much. Centocor argues that some products "cannot possibly be made entirely safe for all consumption, and any food or drug necessarily involves some risk of harm, if only from over-consumption." RESTATEMENT (SECOND) OF TORTS § 402A cmt. i (1965). Centocor further argues that there are some products which are "quite incapable of being made safe for their intended and ordinary use. . . . Such a product, properly prepared, and accompanied by proper

[19] Centocor argues in one sentence in this issue that the jury did not have the opportunity to determine if Remicade was defective because the trial court refused Centocor's proposed "marketing defect" instruction with respect to Centocor's negligence claim. Centocor, however, does not brief this as an issue and did not ask for this instruction with respect to the fraud claim, which is the cause of action on which the judgment is based. *See* TEX. R. APP. P. 38.1(i).

directions and warning, is not defective, nor is it unreasonably dangerous." *Id.* cmt. k.

Centocor relies on this language to argue that it has no liability because Remicade could not possibly be made entirely safe. The argument then progresses to Centocor's conclusion that it may sell a product that is dangerous even without an adequate warning, merely because the dangerous consequences are only temporary. But Centocor ignores the Restatement's solution to an unavoidably unsafe product—provide an adequate warning. *Id.* ("The seller of such products, *again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it,* is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk."). Comment k to section 402A may provide a defense to a design defect claim, but it certainly does not absolve a manufacturer of its liability for completely failing to warn of a dangerous side effect. *See* Carla P. Herron & Kelli L. Degeeter, *Can Texas Escape the Unavoidably Unsafe Medicine of Comment k by Adopting Section 8 of the Proposed Third Restatement of Torts?*, 49 BAYLOR L. REV. 73, 78 (1997) ("Thus, once comment k is applied, all questions of a product's design become irrelevant and the focus shifts to the adequacy, or reasonableness, of the warning of the product's risks."). Accordingly, we overrule Centocor's third issue.

V. Evidence of Fraudulent Intent[20]

Within its fourth issue, Centocor argues that there is no evidence that it intended

[20] Within its fourth issue, Centocor also makes several arguments regarding the learned intermediary doctrine and causation, which we have already addressed.

that Patricia rely on a material omission. Specifically, there is no evidence that Centocor intended for Patricia to take Remicade without adequate knowledge of the possible side effects. It asserts that the video directed patients to contact their physicians about possible side effects and contained the package insert that disclosed all of the associated side effects. Centocor further argues that, because the jury's finding of punitive damages was predicated on the fraud finding, the punitive damages award must be reversed. We disagree.

A misleading partial disclosure of information is actionable if it is made with the intent to induce action by another. *Sears, Roebuck & Co. v. Meadows*, 877 S.W.2d 281, 282 (Tex. 1994); *see Columbia/HCA Healthcare Corp*. *v. Cottey*, 72 S.W.3d 735, 745 (Tex. App.–Waco 2002, no pet.) ("The proper question as to the element of 'intent' is whether Cottey proved that, at the time he accepted employment, Appellants intended for Cottey to act or rely on their partial disclosure about the plan which omitted mention of the rescission provision."). "Intent is a fact question uniquely within the realm of the trier of fact because it so depends upon the credibility of the witnesses and the weight to be given to their testimony." *Spoljaric v. Percival Tours, Inc.*, 708 S.W.2d 432, 434 (Tex. 1986). Intent may be inferred from a party's actions before and after the fraudulent conduct and may be proven by the circumstances surrounding the fraud. *Id.*

Here, the video speaks for itself. Although the video does advise the patient that a doctor should explain Remicade's side effects, the video implies that all the side effects associated with the drug are addressed in the video because some of the side effects *are* actually addressed. This is particularly so because in the same discussion in which he advises viewers to consult their doctors, Dr. Safdi states that "the vast majority of patients,

in our experience, have no problems with the infusion." He further states that "[a]fter the infusion there are very little side effects that people need to watch for. If they have any discomfort, we ask them to give us a call. But those reactions, again, are extremely rare. And the vast majority of patients really experience no side effects." This implied that "discomfort" was the only side effect to watch for after the infusion process, which is demonstrably false given that the package insert warns of several other side effects that may occur after the infusion.

Dr. Bullen testified that the purpose of the video was to show the drug's effect on people, which was dramatic. In fact, the main thrust of the video was to show how well the patients felt on Remicade. Throughout the film, the patients are shown walking, running, carrying their children, and exclaiming how great they feel. Finally, the evidence showed that the package insert was not included with the video shown and given to Patricia. The statements regarding the efficacy of the drug is not balanced with any disclosure of the risk of lupus-like syndrome, or the other risks associated with the drug besides immediate reactions to the infusion process.

The evidence of Centocor's marketing strategies shows that this emphasis of the drug's efficacy and the omission of risk information was intended to induce doctors to prescribe Remicade and to induce patients to seek treatment with Remicade. As of June 2000, Centocor's marketing strategy included a two-pronged approach that included educating physicians to "refine their definition of the target Remicade patient" and to teach patients to "demand Remicade." First, Centocor sales representatives were instructed to work on making doctors "aggressive" in prescribing Remicade, and Centocor required its sales associates to sell a specific number of vials of Remicade to doctors' offices.

Centocor representatives even promoted the idea that doctors could maximize their profits from prescribing Remicade by providing in-office infusions that would be paid for by Medicare and Medicaid.

Second, Centocor's goal was to make Remicade "top of mind" for every rheumatoid arthritis patient. A chart admitted into evidence shows Centocor's plan for addressing patients, and it states that the goal is to "[m]ake the consumer aware the [medical] problem is treatable" and to "[e]ncourage the patient to request a specific drug." Obviously, the Centocor video was part of this marketing strategy.[21]

Furthermore, there was significant testimony about Centocor's attempts to minimize negative publicity about the dangerous side effects of Remicade. A scientific study published in the New England Journal of Medicine demonstrated that problems with Remicade had been understated. Instead of addressing the substantive safety concerns raised in the article, Centocor's "Communications Program" recognized that the New England Journal of Medicine "traditionally garners significant media attention," which includes multiple stories filed by the Associated Press. Centocor's marketing plan states as its objectives: (1) neutralize the commercial impact of the publication, (2) confine the story to one news cycle, and (3) provide context to the stories that appear. Furthermore, Centocor planned to "[d]ecrease/eliminate news value by pre-positioning data as a 'non-story' with key media." Dr. Matthews testified that it would be "highly unusual" for a drug

[21] The Hamiltons argue that an e-mail from Centocor's director of Immunology Marketing shows that Centocor's sales force "begged" to remove "fair balance" information from the "patient success story" videos because "patients were getting frightened." However, this e-mail was never admitted into evidence at trial; rather, it appears in the record as an attachment to the Hamiltons' response to Centocor's motion for new trial. As damaging as this e-mail is, we cannot consider it because it was not made part of the record at trial. *See Maximum Med. Improvement, Inc. v. County of Dallas*, 272 S.W.3d 832, 834 n.3 (Tex. App.–Dallas 2008, no pet.).

company to undertake such a program to dilute the effect of a negative peer review article.

All this evidence indicates an intent by Centocor to induce patients, like Patricia, to rely on its marketing materials, which omitted significant risk information, and to seek treatment with Remicade. Centocor does not address any of this testimony, which we hold is legally and factually sufficient to support a finding of fraudulent intent. Accordingly, we overrule Centocor's fourth issue.

VI. Evidence of Future Damages

The jury awarded Patricia $1 million in damages for physical pain and mental anguish that, in reasonable probability, Patricia will sustain in the future. By its tenth issue, Centocor argues that the evidence is legally and factually insufficient to support these damages. First, Centocor contends that Patricia's lupus-like syndrome was a temporary side effect that ceased when Patricia stopped taking Remicade, and that there was no evidence that this symptom would spontaneously reoccur. Centocor argues that there is no evidence that Patricia will suffer any physical pain in the future related to her Remicade treatments. Second, Centocor argues that there is no evidence of future mental anguish. It notes that Patricia did not testify that she would suffer mental anguish in the future, except that she feared adverse reactions in the future unrelated to her lupus-like syndrome. In response, Patricia argues that a plaintiff need not present direct evidence of the nature, duration, or severity of her mental anguish in order to recover because she suffered severe pain and disability in the past. We agree with Centocor and reverse the award of future pain and mental anguish.

A. Applicable Law

We apply the traditional legal and factual sufficiency standards outlined above in Part IV.A. To support an award of mental anguish damages, the plaintiff's evidence must describe "the nature, duration, and severity of their mental anguish, thus establishing a substantial disruption in the plaintiffs' daily routine." *See Fifth Club, Inc. v. Ramirez,* 196 S.W.3d 788, 797 (Tex. 2006) (quoting *Parkway Co. v. Woodruff*, 901 S.W.2d 434, 444 (Tex. 1995)). The Texas Supreme Court has held that "some types of disturbing or shocking injuries have been found sufficient to support an inference that the injury was accompanied by mental anguish." *Parkway*, 901 S.W.2d at 445. For example, as early as 1888, the Texas Supreme Court recognized that serious bodily injury "involving fractures, dislocations, etc." that result in "protracted disability and confinement to bed" necessarily result in some degree of physical and mental suffering. *See Brown v. Sullivan*, 71 Tex. 470, 10 S.W. 288, 290 (1888). To support an award for future mental anguish, a plaintiff must demonstrate "a reasonable probability" that he or she will "suffer compensable mental anguish in the future." *Adams v. YMCA of San Antonio,* 265 S.W.3d 915, 917 (Tex. 2008).

In *Ramirez*, the Texas Supreme Court applied the foregoing rules to an award of future mental anguish damages. 196 S.W.3d at 797. Ramirez attempted to enter a night club and engaged in an altercation with a private security guard working at the night club. *Id.* at 790. The security guard slammed Ramirez's head against a wall, knocking him unconscious, and then struck him several times. *Id.* Ramirez's skull was fractured as a result, and he suffered other injuries as well. *Id.* Ramirez sued the club and claimed future mental anguish damages. *Id.* On appeal, the club argued that there was no evidence to

support the award of future damages. *Id.* at 797-98. The Texas Supreme Court summarized the evidence on mental anguish as follows:

> Ramirez and his wife testified that Ramirez continued to be depressed, humiliated, non-communicative, unable to sleep, and angry, continued to have headaches and nightmares, and that his daily activities and his relationships with his wife and daughter continued to be detrimentally affected almost two years after the incident. Ramirez also presented evidence of the severity of the intentional beating by West, including significant injuries to his head and body, his loss of consciousness, and his visits to the hospital. The evidence shows the nature of Ramirez's mental anguish, its lasting duration, and the severity of his injuries, and is therefore legally sufficient to support future mental anguish damages.

Id. The court acknowledged that there was no direct evidence that Ramirez would, in reasonable probability, suffer compensable mental anguish in the future, but it held that the

> severe beating received by Ramirez provided an adequate basis for the jury to reasonably conclude that he would continue to suffer substantial disruptions in his daily routine of the kind described in his and his wife's testimony that he had already suffered in the past. The evidence in this case amounts to far more than worry that medical bills might not get paid . . . or that someone is disturbed and upset . . . .

Id. at 798.

B. Lupus-like Syndrome

Patricia does not dispute that after she stopped taking Remicade, her lupus-like syndrome, and the pain associated with it, went away. There was no testimony presented at trial that lupus-like syndrome would reappear after discontinuing Remicade therapy. Nevertheless, Patricia argues that her pain and temporarily disabling injuries are more than adequate to support the jury's future damage award. Relying on *Ramirez*, Patricia argues that she did not have to present direct evidence that she would, in reasonable probability,

suffer mental anguish in the future because that is no longer required when a plaintiff suffers personal injuries. We disagree that *Ramirez* stands for that proposition.

Although Patricia suffered pain and disability while on Remicade, the pain and suffering she felt stopped once the Remicade discontinued. Moreover, Patricia did not present any testimony regarding the mental anguish that she suffered after she stopped taking Remicade, if any, or that she anticipated mental anguish in the future. Patricia's injuries certainly support an inference that she suffered physical pain and mental anguish in the past, and Centocor does not dispute that, but her injuries were not the sort of "shocking" injuries that would support an inference of future mental anguish.

Courts have allowed an inference of future mental anguish in cases involving the serious injury or death of a family member and mishandling of a corpse. *See Parkway*, 901 S.W.2d at 445; *see also Serv. Corp. Int'l v. Guerra*, No. 13-07-00707-CV, 2009 WL 3210940, at *4 (Tex. App.–Corpus Christi Oct. 8, 2009, pet. filed) (mem. op.). In *Ibrahim v. Young,* the Eastland Court of Appeals opined that *Ramirez* does not extend this inference to every personal injury case claiming future damages, but only to those in which the injuries are "shocking" or "disturbing." 253 S.W.3d 790, 807 (Tex. App.–Eastland 2008, pet. denied). In *Ibrahim,* the plaintiff sued her employer and a furniture manufacturer for injuries she sustained when her office chair broke and she fell. *Id.* at 795. She received an award of future mental anguish damages, but she provided no direct evidence to show that she would suffer mental anguish damages in the future. *Id.* at 807. On appeal, she equated her injuries with those suffered by the plaintiff in *Ramirez*. *Id.* at 806. The Eastland Court of Appeals held that

> *Fifth Club* does not stand for the proposition that mental anguish damages can be inferred in all personal injury cases. The court's holding was premised on the existence of a disturbing or shocking injury. Falling off of an office chair is not the type of shocking or disturbing injury that we believe the supreme court had in mind.

Id. at 807.

We agree that *Ramirez*, and other cases in which future mental anguish can be presumed, are distinguishable from Patricia's fraud claim. Patricia's injuries were not as "shocking" or "disturbing" as losing a family member, having a corpse mishandled, or having a skull cracked by being slammed into a concrete wall. In the absence of any testimony about mental anguish and physical pain she would suffer in the future, the award of future damages must be reversed.

C. Liver Injury

Along with her claims based on lupus-like syndrome, Patricia spent a large amount of time at trial arguing that Centocor misrepresented the risk of injury to her liver, and it failed to warn her that Remicade could worsen her pre-existing hepatitis C. Patricia argues that Remicade altered her DNA in a manner that renders her ineligible to take some transplant medications in the future, in the event she ever needs a liver transplant. She did not present any evidence, however, that she 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. Centocor argues that under *Temple-Inland Forest Products Corp. v. Carter*, Patricia cannot base her award of future pain and suffering or future mental anguish on her "fear" that she might suffer an adverse event in the future that has not presently manifested. *See* 993 S.W.2d

88, 93 (Tex. 1999). We agree.

In *Carter*, the Texas Supreme Court held that workers who were exposed to asbestos could not recover damages for their fear of the possibility of developing an asbestos-related injury in the future. *Id.* The court explained the policy behind this holding as follows:

> In almost all instances involving personal injury, the law allows for the recovery of accompanying mental anguish damages, even if the mental anguish is not itself physically manifested. But if bodily injury is at most latent and any eventual consequences uncertain, as when a person's exposure to asbestos has not produced disease, then the case for recovery of mental anguish damages is much weaker. A person exposed to asbestos can certainly develop serious health problems, but he or she also may not. The difficulty in predicting whether exposure will cause any disease and if so, what disease, and the long latency period characteristic of asbestos-related diseases, make it very difficult for judges and juries to evaluate which exposure claims are serious and which are not. This difficulty in turn makes liability unpredictable, with some claims resulting in significant recovery while virtually indistinguishable claims are denied altogether. Some claimants would inevitably be overcompensated when, in the course of time, it happens that they never develop the disease they feared, and others would be undercompensated when it turns out that they developed a disease more serious even than they feared. Also, claims for exposure could proliferate because in our society, as the Supreme Court observed, "contacts, even extensive contacts, with serious carcinogens are common." Indeed, most Americans are daily subjected to toxic substances in the air they breathe and the food they eat. Suits for mental anguish damages caused by exposure that has not resulted in disease would compete with suits for manifest diseases for the legal system's limited resources. If recovery were allowed in the absence of present disease, individuals might feel obliged to bring suit for such recovery prophylactically, against the possibility of future consequences from what is now an inchoate risk. This would exacerbate not only the multiplicity of suits but the unpredictability of results.

Id. For the same reasons, we hold that Patricia's future pain and mental anguish award cannot be predicated on her fear of developing a liver injury, when she did not present any evidence of a present injury to her liver. Furthermore, her fear that she may not be able to take transplant medication is premised on the idea that she will need a transplant in the

future, which she did not prove. Accordingly, we sustain Centocor's tenth issue and reverse the award of future pain and mental anguish damages.

VII. Thomas's Derivative Claims

By its eleventh issue, Centocor argues that because Thomas's claims are derivative of Patricia's claims and Patricia cannot recover, we must reverse the award of loss of consortium and household services to Thomas. Because we have sustained Patricia's fraud claim, however, Centocor's argument has no merit. Accordingly, we overrule Centocor's eleventh issue.

VIII. Punitive Damages

By its twelfth issue, Centocor argues that the trial court misapplied the punitive damages cap when calculating the final damages. Specifically, Centocor complains that the trial court applied the cap to the total damages awarded to the Hamiltons without taking into account that Centocor was only found 85% liable for the damages. The Hamiltons do not dispute that the caps apply to the judgment but argue that (1) Centocor waived this argument because it never raised it in the trial court, and (2) the trial court properly applied the caps.

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 $65,908.00 in past medical care expenses. The jury awarded Thomas $50,000.00 for loss of consortium and household services. The trial court applied the formula set out in section 41.008 of the civil practice and remedies code, which allows recovery of two times the amount of economic damages plus an amount equal to any non-economic damages found

by the jury, not to exceed $750,000. *See* TEX. CIV. PRAC. & REM. CODE § 41.008 (Vernon Supp. 2009).[22] The economic damages were $65,908, which was doubled to $131,816. Then the trial court added $750,000, for a total award of $881,816.00 in punitive damages to the Hamiltons.

Assuming that Centocor properly preserved this issue, the trial court properly applied the exemplary damages cap. Exemplary damages are calculated on a per defendant basis. *See Seminole Pipeline Co. v. Broad Leaf Partners, Inc.,* 979 S.W.2d 730, 751-52 (Tex. App.–Houston [14th Dist.] 1998, no pet.); *see also Wackenhut Corp. v. De la Rosa*, No. 13-06-00692-CV, 2009 WL 866791, at *48 (Tex. App.–Corpus Christi Apr. 2, 2009, no pet.). The Fourteenth Court of Appeals in *Seminole Pipeline* relied on the plain language of the statute, which, at that time, said that "exemplary damages awarded *against a defendant* may not exceed four times the amount of actual damages." 979 S.W.2d at 751. The current version keeps the same language except changes the amount of the cap. *See* TEX. CIV. PRAC. & REM. CODE § 41.008(b). The court further relied on statements by the statute's legislative sponsor, who provided the following example of how the cap should apply, and indicated that the cap applies without reference to the proportion of liability assigned to a particular defendant:

> The plaintiff's actual damages are $100,000. Plaintiff is 20% responsible for the loss; defendant A is 30% responsible; and defendant B is 50% responsible. The jury imposes punitive damages against defendant A in the amount of $250,000 and against defendant B in the amount of $1,000,000. According to Senator Montford, the plaintiff is entitled to collect punitive

[22] The prior, 2001 version of this statute applies to the Hamiltons' claims. We note, however, that the statutory amendments since 2001 have not altered the damage cap amounts. *Compare* Act of May 21, 2001, 77th Leg., R.S., ch. 643, § 3, 2001 TEX. SESS. LAW. SERV. 1136, 1137 (Vernon 2001); *with* Act of June 2, 2003, 78th Leg., R.S., ch. 204, § 13.06, 2003 TEX. SESS. LAW. SERV. 847, 888 (Vernon 2003); *with* Act of May 17, 2007, 80th Leg., R.S., ch. 593, § 3.03, 2007 TEX. SESS. LAW. SERV. 1122, 1132 (Vernon 2007).

damages of $650,000, namely, $250,000 from defendant A and $400,000 (4 x $100,000) from defendant B.

Seminole Pipeline, 979 S.W.2d at 751 n.21. Accordingly, we hold that the trial court properly applied the punitive damages cap, and we overrule Centocor's twelfth issue.

IX. Conclusion[23]

We have overruled Centocor's challenges to the judgment on the Hamiltons' fraud claim, except that we have sustained Centocor's challenge to the $1 million future damages award. We modify the judgment against Centocor to delete the award of $1 million in future pain and mental anguish damages, and we affirm the judgment as modified.

Linda R. Yañez
Justice

Delivered and filed
the 4th day of March, 2010.

[23] In its remaining issues, Centocor challenges the alternative bases for the judgment. Specifically, by its fifth issue, Centocor argues that the judgment should be reversed because Patricia's claims for implied misrepresentation under section 402B of the Restatement (Second) of Torts, as stated in Questions 3 and 4 of the jury charge, cannot be maintained because section 402B only applies to express misrepresentations. By its sixth issue, it argues that those claims fail on the evidence. Centocor argues in its seventh issue that the Hamiltons' negligence claims should be reversed because Patricia failed to present expert testimony on the standard of care and breach of that standard. By its eighth issue, Centocor argues that negligent misbranding is not recognized as a cause of action in Texas. Centocor's ninth issue argues that the distribution of a videotape does not constitute a negligent undertaking as a matter of law. Because we have sustained the verdict on Patricia's fraud claim, we need not address these issues. *See* TEX. R. APP. P. 47.1.