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Supreme Court of Texas.
Centocor, Inc.
v.
Patricia Hamilton and Thomas Hamilton.
No. 10-0223.

December 8, 2011.

Appearances:

Robert M. Roach, Jr. of Roach & Newton, LLP, for Petitioner.

Craig T. Enoch of Enoch Kever PLLC, for Cross-Petitioners/Respondents; Thomas F. Nye of Gault, Nye & Quintana, LLP, for Cross-Respondent.

R. Brent Cooper of Cooper and Scully, PC, for Amici Curiae.

Before:

Chief Justice Wallace B. Jefferson; Nathan L. Hecht, Dale Wainwright, David M. Medina, Paul W. Green, Phil Johnson, Don R. Willett, Eva M. Guzman, and Debra H. Lehrmann, Justices.

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CHIEF JUSTICE WALLACE B. JEFFERSON: The Court is ready to hear argument in the first matter 10-0223, Centocor, Inc. v. Hamilton.

MARSHAL: May it please the Court, Mr. Roach will present argument for the Petitioner. The Petitioner has reserved five minutes for rebuttal.

ORAL ARGUMENT OF ROBERT M. ROACH, JR. ON BEHALF OF THE PETITIONER

ATTORNEY ROBERT M. ROACH: May it please the Court, this is your learned intermediary docket for the morning. I am honored actually to be able to defend the learned intermediary doctrine before this Court. I was the primary briefer in Alm v. Alcoa many years ago, when this Court first said that, it would adopt the learned intermediary doctrine. It did so on the basis of a case out of the Corpus Christi Court of Appeals in a prescription drug context. We are here because that same court has seen it fit to in its words, revolutionize the legal landscape for prescription drug cases. It has done so unwisely. It has done so without any authority. It has done so contrary to both the federal scheme and this State's expressed legislative policy. If Section 82.007 of the Texas Civil Practice and Remedies Code, which creates a rebuttable presumption that restricts manufacturers of drugs liability, if they can show that there was an adequate warning, demonstrates that this State is in favor of restricting of liability in prescription drug cases for manufacturers.

JUSTICE DAVID M. MEDINA: How does the fraud allegation play into all of this?

ATTORNEY ROBERT M. ROACH: The fraud allegation is nothing more than an attempt to artfully plead around the learned intermediary doctrine. They expressly said that, was their plan. They were not going to try this as a regular failure to warn case where they had to bring experts or prove through experts either an inadequate warning or causation.

JUSTICE DAVID M. MEDINA: Seems like pretty good strategy when there is perhaps some evidence to fraud.

ATTORNEY ROBERT M. ROACH: Fraud can't survive if the learned intermediary rule is still intact because if the learned intermediary rule is intact, then the manufacturer is out of the case.

JUSTICE DEBRA H. LEHRMANN: Well, what about if there's evidence that the warning that was given to the physician was not adequate. If there's evidence of that, then doesn't your argument just evaporate.

ATTORNEY ROBERT M. ROACH: No. Now let me say this. In any case where you can show, where the plaintiff can show that the warning to the doctor was inadequate, that gets you to the second issue. Okay. We don't have that in this case, but in the second issue is causation. You must also prove one of two things. Okay. You must either prove that the doctors did not already know about the warning independently, the risk independently or two and this is the most important, the plaintiff under all circumstances must be able to prove that the prescribing doctors would have changed their prescription decision.

JUSTICE DON R. WILLETT: Jumping back to duty leaving causation for a second, does a company satisfy its duty to warn by telling doctors the truth, but misleading customers directly?

ATTORNEY ROBERT M. ROACH: We discharge our duty if we adequately warn a doctor and if someone, if reasonable minds, let's say reasonable minds could disagree about whether the patient was misled. Okay. Under this system, both the federal system and the state system and I mean by the state legislature, if the manufacturer has discharged its duty and is restricted from liability even if the patient was misled factually as long as the doctors understood and that is the right way to do it because of the doctor's centrality.

JUSTICE DAVID M. MEDINA: That puts a huge burden on the doctors and you made the reference to non-prescribing doctors. Is there any exception to this rule?

ATTORNEY ROBERT M. ROACH: Well, in this particular case, Your Honor, we did not attempt to prove the learned intermediary doctrine through the non-prescriber, the infusionist Dr. Bullen. What we would say that there our understanding of the law in this State and elsewhere is that any doctor with a physician-patient relationship who's involved in a prescription decision is someone who you could prove the learned intermediary rule through. We did not attempt to prove that here, but we think the facts would support it and we don't think the law creates an exception for non-prescribers.

CHIEF JUSTICE WALLACE B. JEFFERSON: Should the Court be concerned at all with, take the most extreme case that the warning's adequate, but the marketing and the advertising to the consumers is grossly misrepresents other than the qualities or the safety of the product and drive the consumer to request this. Is there no remedy for that?

ATTORNEY ROBERT M. ROACH: There already is in place dramatic remedies for that, Your Honor, both at the federal and state level. The FDA scrupulously monitors drug advertising and there are sanctions both injunction's relief, civil penalties, I believe it's $250,000 for the first instance of a false or misleading advertisement by drug manufacturer and $500,000 penalty for a subsequent violation. There's also criminal sanctions available and under the Texas Health and Safety Code, there's a particular agency that has the same kind of authority and

their violation penalties are $25,000 for the first. You also have injunction relief and can bring criminal penalties. So false advertising does not go unremedied anywhere in this country or in this state.

JUSTICE DAVID M. MEDINA: But who's the beneficiary of those fines? The government, right?

ATTORNEY ROBERT M. ROACH: I assume, Your Honor, but I don't know.

JUSTICE DAVID M. MEDINA: So that closes cause of action to a plaintiff who's been harmed.

ATTORNEY ROBERT M. ROACH: If the plaintiff truly was harmed and I mean both by a breach of duty and by causation, then they have a remedy because we're assuming and in this case it's a fact that we had an adequate warning from the manufacturer to the doctor. The court of appeals' opinion makes it clear this is a case where there was an adequate warning to the doctor and the only issue is an inappropriate inquiry adequacy of the warning to the consumer. So here with an adequate warning to the doctor, if the doctor fails to convey, transmute that warning information into a safe, nonnegligent patient advice, then the patient does have recourse against that doctor, but doesn't have recourse against the manufacturer because the manufacturer had discharged its duty by an adequate warning to the doctor.

JUSTICE PAUL W. GREEN: So you say that once the duty is discharged by communicating an adequate warning to the prescribing doctor, after that it the company it's risk free in terms of advertising to the ultimate consumer.

ATTORNEY ROBERT M. ROACH: Well, risk free. I mean--

JUSTICE PAUL W. GREEN: There's a liability to the plaintiff.

ATTORNEY ROBERT M. ROACH: Yes, there is immunity, but while not effective in this case because this case was filed just before 82.007 became effective. Today, as the policy of the state of Texas is that there is a rebuttable presumption that in that situation Judge Green where there is an adequate warning, there is a rebuttable presumption, but a strong presumption that there will be no liability for the drug manufacturer.

JUSTICE DON R. WILLETT: No matter what the content of the marketing may be, they could have the most grossly misleading direct to consumer advertising imaginable, but if they tell the truth to the doctor, there's a strong presumption that they have no exposure?

ATTORNEY ROBERT M. ROACH: That's right just in the civil case, but as I answered Chief Justice Jefferson's question, they still have massive liability in your scenario for false grossly misleading advertising.

CHIEF JUSTICE WALLACE B. JEFFERSON: You said, it's a very strong presumption, but it's rebuttable.

ATTORNEY ROBERT M. ROACH: It is.

CHIEF JUSTICE WALLACE B. JEFFERSON: In what sense is a rebuttal?

ATTORNEY ROBERT M. ROACH: Well, the next part of the statute provides five ways for rebutting the presumption. I will tell this Court that the first one is really the only one that comes up in litigation and that is if you can show a fraud on the FDA to getting them to approve your advertising. Remember this advertising, maybe I should have said, this earlier, this advertising has to be approved by the FDA. There is a direct-to-consumer advertising statute and requirements and that is what the FDA's office monitors and polices closely.

JUSTICE DAVID M. MEDINA: There's many times that they approve a drug and advertisement only to be later found out to be wrong and the drug is taken off the market.

ATTORNEY ROBERT M. ROACH: It can happen. It absolutely can happen, but of course, when that does happen, there are remedies after the fact.

JUSTICE DEBRA H. LEHRMANN: Let me ask you something. According to what you're saying then the patient should only rely on the doctor. That the patient should rely on. So what's the point on advertising to the public? What's the point?

ATTORNEY ROBERT M. ROACH: Well, something that's in, I believe the PLAC brief. It could be the Pharma amicus brief, refers to a 2004 joint report by the Department of Justice and the FTC answering that question, to what extent is, what positive things, what negative things come from direct-to-consumer advertising and it found two good things most strongly and that was apart from finding no real problem, the two things was, number one, it encouraged discussions between patients and doctors about drugs, particular drugs, and the second thing is that it caused patients to go to doctors to discuss illnesses that they wouldn't have otherwise even talked to their doctor about. So you see an ad for a drug saying if you've got symptoms of X, Y and Z, this drug may be something you should talk to your doctor about. Apparently, there's a large number of people who would not go to a doctor and discuss and thus would have an undiagnosed problem but for those ads.

JUSTICE DAVID M. MEDINA: Did you have a chance to read the brief filed by the Texas Medical Association?

ATTORNEY ROBERT M. ROACH: I did.

JUSTICE DAVID M. MEDINA: And their urge of a court to affirm the lower court because of passing on the responsibility to the doctors just assumes to be like an undue burden.

ATTORNEY ROBERT M. ROACH: Yes and I would commend you, the Court's consideration the brief just filed a couple days ago by the Washington Legal Foundation, that amicus brief directly and exclusively deals with the claims of the TMA's amicus brief and does a marvelous job of debunking that on a lot of different levels. My overall reaction was I cannot believe that the Texas Medical Association, the largest beneficiary of tort-reform, appropriately so is basically trying to undue tort reform for drug manufacturers. They got their protection in House Bill 4 and House Bill 3 at the same time that 82.007 got created. They are essentially asking this Court to undo all those tort reform measures for drug manufacturers in a context where the manufacturer did nothing wrong. It's a context where the manufacturer did exactly what the current law requires it to do which is to adequately warn the doctors.

CHIEF JUSTICE WALLACE B. JEFFERSON: Well, but you say nothing wrong, assume what the manufacturer also does is in its advertising completely distort the effectiveness or the use of the drug to the consumer, that's something wrong.

ATTORNEY ROBERT M. ROACH: Well, if we're talking about another case, not this case, we can talk about that, but I was talking about this case, Your Honor, and said, in this case, TMA comes in and says, where there's no such claim, there's no dispute that the warning for the doctor was adequate and there's no claim of gross misleading distortion of anything. The hopefully issue in this case is a video that was not sent to the consumer. The court of appeals is wrong is saying it was sent to the consumer. It was sent to the doctor that did not mention the exact same warning that is in the package insert, the label, even though the evidence is clear that the box is supposed to contain that exact warning and her testimony is I didn't look in the box. The brief submitted by the Plaintiff says that, it wasn't there. Her testimony is I never looked in the box and the testimony also is that she was carrying around another box that had this video in it for her sister, who also suffered from rheumatoid arthritis and it was supposed to have the exact same warning that the doctor got, which is the only allegation that is in this case of any kind of distortion or false advertising.

JUSTICE DAVID M. MEDINA: Well, that's pretty big. You see some of these very nice well marketing videos and they think, for me, I think well this is great. I need to take this and you read the warning label and it says, this is going to kill me. I'm going to die if I don't take it so it's, that's what the issue is I think.

ATTORNEY ROBERT M. ROACH: That's exactly what the issue is, Justice Medina, and that's why the doctor is the central person. The doctor decides what does and does not get said, to the patient about those risks so that they don't unduly what's the language from this Court, hinder the doctor-patient relationship and scare off the patient from taking appropriate necessary prescribed drug treatments.

JUSTICE DALE WAINWRIGHT: What does this record show about the intended use of Centocor's video.

ATTORNEY ROBERT M. ROACH: That it was intended to make the person who had already been prescribed Remicade comfortable about the infusion process. If the Court hasn't looked at that, I highly recommend that it look at Exhibit 35, that video, because when I looked at it yesterday again, I would say conservatively to help them, I would say at most 10, 15% of that video is about the drug and the rest of it is all about the infusion process and a lot of people, myself included, not crazy about being hooked up to an IV.

JUSTICE DON R. WILLETT: Is failure to warn the one and only cause of action available to a plaintiff no matter what he or she may plead, no matter what the facts underlying the case happen to be? You talk a lot about how the plaintiff's attempting to kind of recast artfully this claim as a fraud claim, but is failure to warn the one and only avenue for relief that a plaintiff has no matter what the underlying facts may be?

ATTORNEY ROBERT M. ROACH: Yes, assuming that the underlying fact is I didn't get the information I think I should have gotten. That is a failure to warn claim and it is nothing but a failure to warn claim. The most important part of that, I believe, Justice Willett is that the learned intermediary doctrine is there precisely in that situation because patients need somebody, not themselves, to evaluate the appropriateness of that drug given their own medical situation and an educated understanding of what the medical dangers are for that drug.

JUSTICE DEBRA H. LEHRMANN: Let me just ask you something real quickly before you run out of time. What do drug companies base their warnings on as far as developing what they are going to warn the physician about? Are those based upon control studies? What are those based on?

ATTORNEY ROBERT M. ROACH: Yes, it's a whole panoply of things, certainly it includes studies that they do, but also reports that they get from the field from doctors who are using the products. They are obligated to look at all the information that's available just like to the Federal Drug Administration or to doctors and scientists so that they can and they want to do that, they want to have appropriate warnings to make drugs that are by definition because they're prescription dangerous to people as safe as they can possibly be.

CHIEF JUSTICE WALLACE B. JEFFERSON: Any further questions? Thank you, Mr. Roach.

ATTORNEY ROBERT M. ROACH: Thank you, Your Honor.

CHIEF JUSTICE WALLACE B. JEFFERSON: The Court is ready to hear argument from the Cross-Petitioner's Respondents.

MARSHAL: May it please the Court, Mr. Enoch will present argument for Cross-Petitioner Respondents.

ORAL ARGUMENT OF CRAIG T. ENOCH ON BEHALF OF THE RESPONDENT

ATTORNEY CRAIG T. ENOCH: May it please the Court, I guess I need to start learning about PowerPoint over here. Let me address a couple of things. I think there's a couple points to be made. This is a misrepresentation case. I disagree with Mr. Roach that the only way we can present this case is a failure to warn. Even the

restatement 402(b) recognizes there's a distinct cause of action in products' liability for misrepresentation. This is not a case that was brought based on a manufacturer not knowing about their product, failing to warn about a circumstance that later arises and we claim that they could have produced a better warning with the information they had available. We don't have to prove that they knew it. All we have to do is prove there could have been a better warning and a conversation should have occurred and we should have been warned. That's not this case. This case is a straight-up misrepresentation case. They knew the information. They did not convey the accurate information, but they conveyed the information and it is not a case of commercial advertising. It is a case of a misrepresentation to the learned intermediary who they claim they had no burden to raise that defense. That's this case. The court of appeals looked at it. They said, this is the perfect opportunity to talk about an advertising exception to the learned intermediary doctrine and they wrote that opinion on there. You've been provided by a very recent case by a Federal District Judge Keith Ellison, who does a very marvelous job of writing out why an advertising exception ought to exist and you can look at that case and evaluate these issues, but that's really not this case. This case is about a misrepresentation. They represented in the material about Remicade that in a clinical study only three people showed up showing lupus-like syndrome. Next sentence, over the follow-up, three years, there were no other reported incidences. Their own email from their own doctor says, actually there were 175 reported incidences of which we confirmed eight were lupus-like syndrome. We had 16 that probably were.

JUSTICE DAVID M. MEDINA: Is there a difference, excuse me, sorry to interrupt you. Is there a difference between what you're saying was given to the patient and what was given to the doctors?

ATTORNEY CRAIG T. ENOCH: Yes, sir, but the patient was given no warnings about lupus-like syndrome, none at the time she was getting the infusion with the lame go ask the doctor and we have the doctor doing the infusion says, it's not my responsibility, but she was giving no warning.

JUSTICE DALE WAINWRIGHT: Your claim is your client would not have taken it if she had known about the side effects?

ATTORNEY CRAIG T. ENOCH: Your Honor, our claim is that she would not have continued taking it if she knew that what she was suffering from lupus-like syndrome that could be caused by that drug and that goes to the misrepresentation to the doctors.

JUSTICE DALE WAINWRIGHT: The problem that I have with that position is at least according to the CA opinion, I haven't read the entire record yet that Patricia continued to take the drug through September, 2003 and that was several months after this lawsuit was filed.

ATTORNEY CRAIG T. ENOCH: Yes, sir.

JUSTICE DALE WAINWRIGHT: Presumably she had complaints about the warning at the time the lawsuit was filed in March of 2003, but continued to take the drug for several more months until September of that same year.

ATTORNEY CRAIG T. ENOCH: Yes, Your Honor. Her original claim was over her not understanding the necessity to continue taking this drug to address her Crohn's disease. It was prescribed to her for three times. She was getting relief, but the relief would disappear so then she had to have another series of infusions four times and her relief would be there, but then it would disappear and then pretty soon, the relief would disappear more rapidly, more rapidly. Her original complaint was these were thousands of dollars of cost of treatment and the drug seemed to be ineffective, not related at all to the fact that simultaneously she's getting sick, not because the Crohn's disease isn't being healed, but because she's developing lupus-like syndrome.

JUSTICE PAUL W. GREEN: But wouldn't you have to have some medical expert tie in the fact that had she known that she was told that first day that this is what can happen to you and she would think, well, I've been prescribed three times so maybe that will be the end of it, but she continued to take the drug and wouldn't there

have to be some way of explaining medically that the continuation of the drug would cause this, but if she had stopped after three times, it wouldn't have happened. Why is there a missing causation link here?

ATTORNEY CRAIG T. ENOCH: Your Honor, I don't believe there's a missing causation link. The Wyeth case coming out of the Fifth Circuit has a good example. The problem is that you take drugs to meet a chronic illness and you continue taking the drug. The question is, the drug in the first three may not cause a problem. It may not cause a problem in the first seven, but maybe in the eighth it does if you're not warned about that incidence.

JUSTICE PAUL W. GREEN: That's my point, wouldn't you have to have a doctor say that?

ATTORNEY CRAIG T. ENOCH: Your Honor, in this case, we have Centocor's brief, page one. It was a success in treating Crohn's disease, but she developed lupus-like syndromes. The University of Texas Health Science Center over the course of time eventually diagnosed lupus-like syndrome. The syndrome was produced positive on the medical tests and then they stopped the treatment and she got better. Wyeth says, and including in the Pfizer case that this Court decided, that's evidence of causation to get to the jury that the infusion of this drug caused lupus-like syndrome and in fact, it's evidence that had she known she was suffering from lupus-like syndrome, she would have stopped the treatment. This is not a situation where I incurred well let me go to the next point, Your Honor, in addressing this. The learned intermediary doctrine is not a doctrine that says that, the manufacturer discharges their duty by the doctor regurgitating the warning. The learned intermediary doctrine presumes as the Pacific Legal Foundation writes, presumes that you go through the learned intermediary doctrine because the intermediary processes the warning. It's technical. It's complex. We presume that the consumer doesn't know what it means, but we send it to the doctor. This goes right to the point, the Wyeth case in McNeil and the Fifth Circuit was addressing, the doctor is evaluating the risk that she will get lupus-like syndrome and based on that evaluation, the patient takes the medication because the doctor says, the risk is not significant. Centocor's doctor looks at the 175 reports and looks at the 15% positive response rate on lupus like and he says, well, it's not as bad as I thought it would be, but I'd surely discuss the details and make sure my patient knows what that risk is, but I'd probably recommend it anyway. The point is not that. The point is horses versus zebras. You start with a patient presenting a lot of symptoms. You treat the horse. If the horse doesn't do it, you start moving to the zebra. In this case, they could not identify lupus-like syndrome until they discounted, disregarded all the other things that could have presented these symptoms and they concluded through the number of tests finally positive on the lupus that she had lupus. In fact, all they could tell you from the testing was she's got lupus. Others say well it might be lupus-like syndrome. Well, what do you do to treat lupus-like syndrome? Stop the treatment and she gets better. You cannot discharge your duty to warn by just asking the doctor to regurgitate. The doctor processes it. In McNeil v. Wyeth the court struggled with this point does she have to prove she would have never taken the drug? No. What they have to prove is that she took the drug without a proper assessment of the risk, the chances that she would get it. Here you have a multiple difference in what the drug company knew was a risk of lupus-like syndrome over what they reported to the doctor and both the treating physicians, Pop-Moody and Hauptman said, we never knew what the real risk was. We thought the risk was very low based on the report. Centocor's doctor said I've looked at these other reports. I might still recommend taking the drug, that's not the issue, continuation is, but I sure would have discussed the details with my patient and really knew if they knew what they were doing.

JUSTICE DEBRA H. LEHRMANN: Are you saying that the duty to warn the doctor is the same or different than the duty to warn the patient when we're dealing with this direct advertising and what's the difference there?

ATTORNEY CRAIG T. ENOCH: Your Honor, in direct answer to your question, there is no difference in the duty, but it is an affirmative defense.

JUSTICE DEBRA H. LEHRMANN: I don't mean the duty. I mean as to what would be warned.

ATTORNEY CRAIG T. ENOCH: Your Honor, yes.

JUSTICE DEBRA H. LEHRMANN: The substance.

ATTORNEY CRAIG T. ENOCH: There is a difference. The duty is the same. The duty is to warn the con sumer. That never changes. One of the arguments that's going on here is who has the burden. The manufacturer has the defensive burden to come forward and say I adequately warned the doctor. What is contained in the warning to the doctor may be different in what's in the warning to the consumer. To the consumer, you might say you didn't get lupus-like syndrome. To the doctor you would say, we have recorded only three instances of lupus-like syndrome in our clinical studies and three years afterwards in following up on reports, we have no other reports of lupus-like syndrome and the doctor goes to the patient and said, lupus? Very rare, I think we ought to start treatment and the customer says, yes, but it's an affirmative defense. The manufacturer comes up and says, I gave the information to the doctor that the doctor could process and convey accurate information to the consumer. That's a defensive issue and the reason you get this kind of unclear discussions about whether it's an affirmative defense is because you don't get to the learned intermediary doctrine unless you first show or it's conceded that the warning to the consumer was not adequate, infeasible, impossible to give. Learned intermediary doctrine is a lot like let's say you got a car wreck. I'm driving down the street. I get slammed in by somebody else and I assume for the car wreck, they want to come in and say it was an unavoidable accident. No question, affirmative defense. I as the plaintiff don't have to prove it was not unavoidable. I'm entitled to the warning. In this case, I got no warning. They never told me about lupus like. They say, ah, but you got it through a doctor. Fine, what did you tell the doctor and what did the doctor convey from that. They say we have no burden to show that our warning to the doctor was adequate and we have no burden to show that we were reasonably assured that the doctor would convey the information. Every case that deals with learned intermediary talks about the manufacturer gets no benefit from the learned intermediary doctrine if they mislead the intermediary. In Wyeth v. McNeil, the question was once they told the doctor what the incidence of risk was, they had a duty to convey accurately that risk. In Wyeth, that's a failure to warn case. That's an issue where they didn't convey some information. This one they conveyed the number and the doctor said, why, that's insignificant. But Centocor's doctor, this exhibit that's E and F that's in your appendix, Centocor's doctor looked at different numbers and he said that's significant. And as far as causation is concerned, it was undisputed. It was lupus-like syndrome; that was never an issue in this case. It was undisputed that it was diagnosed by the doctors, that it was lupus-like syndrome. It was treated by the doctors as lupus-like syndrome and the treatment was effective.

JUSTICE NATHAN L. HECHT: Let me ask you, the court of appeals this sort of started out by saying today we recognize an exception to the learned intermediary doctrine when a drug manufacturer directly advertises to its consumers in a fraudulent manner. And as I understand your argument today, you're saying that the exception's not necessary because they didn't, Centocor didn't establish the applicability of the doctrine in the first place.

ATTORNEY CRAIG T. ENOCH: That's correct, Your Honor, but I am happy to try and address this issue.

JUSTICE NATHAN L. HECHT: But you're also arguing for the exception or--

ATTORNEY CRAIG T. ENOCH: No, Your Honor, I think the exception, just in my opinion, I think the exception really is a restatement of how the rules would otherwise operate. I get a commercial that may be a direct misrepresentation to me, but in the prescription drug context, the doctor still has a shared responsibility and not prescribe something they think that is not good for me and so you have a collaborative effort. And so in the prescription drug case, what you have is not the exception. You have in the commercial environment was the warning that was given to the doctor adequate. You start with a process. I get a commercial warning. Is the warning adequate to me as the consumer? Well, the manufacturer could say yes. On the TV, it was accurate for the consumer and then they win because it was accurate. You don't get to the learned intermediary until you determine that the warning that I was given was inaccurate. Commercial-wise, it's inaccurate. Now can the manufacturer rely on the doctor? Only if they show that the information they gave to the doctor was accurate and it may not be the same thing. It could be gobbledygook to the consumer, but the doctor is trained. We all say this interme-

diary has got to be trained. We all say it's got to be adequate what the doctor gets and we all say that there has to be a reasonable assurance that the manufacturer can rely on the doctor's convey the warning.

JUSTICE DAVID M. MEDINA: What about a non-prescribing doctor? Does it apply to that doctor?

ATTORNEY CRAIG T. ENOCH: Your Honor, that is a difficult argument for us to make, but I don't. They gave the doctor the video, they, the manufacturer. They gave the doctor the authority to do the infusion and the doctor goes and plugs them in. I'm not sure the doctor didn't stand there and say well I've got no duty to make all of the warning, but I can understand Dr. Bullen's concern about it, but it is a false statement for the manufacturer when this is a first time and only time that Ms. Hamilton hears anything about it. She's already plugged up to the machine and they say oh by the way, look at all these smiling folks and be comfortable. This is really a good thing that's happening and don't worry about it and look at these people have all been healed. And oh by the way, there are some problems with it, but go talk to your doctor.

CHIEF JUSTICE WALLACE B. JEFFERSON: What did the warning say about lupus-like syndrome, the actual warning not the video?

ATTORNEY CRAIG T. ENOCH: It said, Your Honor, it is exhibit, I believe it's E in the packet. And--

CHIEF JUSTICE WALLACE B. JEFFERSON: Did it talk about rates as the video did or not?

ATTORNEY CRAIG T. ENOCH: Not on the video. The video there was no warning at all about lupus-like syndrome, none. There were warnings about other risks, but none about lupus like in the video. And the warning in the insert was in clinical studies, four parties developed clinical symptoms consistent with lupus-like syndrome, three with rheumatoid arthritis and one with Crohn's disease.

JUSTICE DALE WAINWRIGHT: Is it exhibit E?

ATTORNEY CRAIG T. ENOCH: It may be exhibit D.

JUSTICE NATHAN L. HECHT: Plaintiff's trial exhibit 160.

ATTORNEY CRAIG T. ENOCH: Yes, that's correct and it shows up.

JUSTICE NATHAN L. HECHT: So I take it your position is that argument now that if that were correct, there was nothing wrong with the video. I mean the video could not possibly have replicated these four pages of very dense type. I mean that would be a two-hour video just to read it.

ATTORNEY CRAIG T. ENOCH: Your Honor, I think if the video was the only warning that she received, you might be in a position of talking about a failure to warn because this was not an affirmative misrepresentation. It was an omission and we'd have a much more difficult time on the [inaudible].

JUSTICE NATHAN L. HECHT: But you seem to, your concern is that the paragraph, which you referred in the insert, misstates the facts.

ATTORNEY CRAIG T. ENOCH: Yes, Your Honor, it clearly does, I'm sorry it was exhibit B is that statement. Exhibit D, I believe, is the exhibit where it's the internal documentation that shows what the reports were at that period of time and that doctor who's evaluating that report, the Centocor doctor who says that, that in his mind is significant.

JUSTICE DEBRA H. LEHRMANN: Can I ask you, is it your position that there was evidence to indicate that the video was meant to encourage the patient to use the drug?

ATTORNEY CRAIG T. ENOCH: Your Honor, we have some business records that indicate that concern of the business on how it can get consumers to request the brand name Remicade for its use and one of the processes was how do they step up direct marketing to the consumer. This is not a video that was you watch on late night TV or even during the middle of the day. This is a video specifically designed to catch the consumer who is using the drug on the infusion process.

CHIEF JUSTICE WALLACE B. JEFFERSON: Are there any further questions? Thank you, Mr. Enoch.

ATTORNEY CRAIG T. ENOCH: We believe the judgment of the trial court can be affirmed on the grounds that they failed to bring their defense of learned intermediary and doesn't rely on the exception.

CHIEF JUSTICE WALLACE B. JEFFERSON: Thank you, Mr. Enoch. The Court is ready to hear argument from the Cross-Respondent.

MARSHAL: May it please the Court? Mr. Nye and Mr. Cooper will split ten minutes of time for argument. Mr. Nye will present argument for Cross-Respondent and Mr. Cooper will present argument for Amici.

ATTORNEY THOMAS F. NYE: May it please the Court? My name is Tom Nye and I represent Dr. Michael Bullen. I'm going to be focusing on the issue pertaining to the non-prescribing doctor, Dr. Bullen. Mr. Cooper's going to focus on the issues pertaining to prescribing doctors as raised in his brief from the TMA and others. Dr. Bullen owns the infusion center where Mrs. Hamilton received the first three infusions of the drug Remicade. The issue before this Court as to Dr. Bullen, the non-prescribing physician, is as follows. Did Dr. Bullen, a non-prescribing physician, have a duty to warn about the risks associated with Remicade for the treatment of Mrs. Hamilton's Crohn's disease? Clearly, the answer is no for two reasons. One, Dr. Bullen did not prescribe Remicade and two, Dr. Bullen was not the treating physician for her Crohn's disease. The law in Texas is very clear; the physician's duty to obtain informed consent requires the treating doctor disclose the risk and hazards involved in the medical care rendered by that physician.

JUSTICE NATHAN L. HECHT: If Ms. Hamilton walked in and said, oh, incidentally, my cousin has tuberculosis, would he have any duty to tell her that that's a problem?

ATTORNEY THOMAS F. NYE: No. No not at all.

JUSTICE NATHAN L. HECHT: He doesn't have, no matter what she says, or what her high risk factors are?

ATTORNEY THOMAS F. NYE: Well, he might have a responsibility to inform her of things that he obviously knows about, but I think--.

JUSTICE NATHAN L. HECHT: He surely knows about that. Doesn't he have a duty to say did you talk to your treating doctor about tuberculosis?

ATTORNEY THOMAS F. NYE: Does he have a legal duty, no. The legal duty is limited to the doctor-patient relationship between Dr. Hauptman and Mrs. Hamilton who was treating her for the Crohn's disease. That is where the duty lies. The courts--

JUSTICE NATHAN L. HECHT: It seems like a doctor before he stuck the needle in your arm and he knew that there might be a problem ought to say something or sound the alarm or call the other doctor or do something.

ATTORNEY THOMAS F. NYE: It's not his responsibility. The court of appeals in Johnson v. Whitehurst said, it would be unreasonable to place the burden of full and complete disclosure upon each and every specialist. Dr. Bullen was the specialist involved about the infusion process. He did have a duty. His duty was to warn about

the risk and hazards associated with the infusion process. The fact that she could get an infection, that there could be a fever, chills. It's undisputed in this case that that was properly done, but that is the limit of his legal duty. Now if he is aware of other potential risk factors, certainly he can warn her, but that's not his legal duty. In this case, Dr. Hauptman, on the other hand, was treating Mrs. Hamilton for her Crohn's disease. He is a board-certified gastroenterologist and at trial, he had readily accepted the duty to obtain informed consent because he was the prescribing doctor for the Remicade. He testified that he obtained a complete medical history. He did a diagnosis. He weighed the risk and benefits of three different medical options. He recommended Remicade and she agreed to take it. Now that's important because that all occurred even before Mrs. Hamilton even arrived at Dr. Bullen's clinic. The decision to prescribe Remicade had already been made. Dr. Bullen's duty is very limited. He was merely overseeing the infusion process, any potential risk and adverse reactions he was not responsible for the Crohn's disease or the treatment of the Crohn's disease.

JUSTICE PAUL W. GREEN: But he did agree to play the video.

ATTORNEY THOMAS F. NYE: He did play the video, yes.

JUSTICE PAUL W. GREEN: Right and he agreed to do that with an agreement with the manufacturer and so does he, he bears no responsibility whatsoever in connection with what might happen in connection with that video?

ATTORNEY THOMAS F. NYE: I believe that is correct. That video is produced and distributed by Centocor. It's directed at patients like Mrs. Hamilton. When this Court looks at the video, it'll see that it's not a video for Dr. Bullen and information for him. It is a video designed to inform the patient. Dr. Bullen was--.

JUSTICE PAUL W. GREEN: But what if it misinforms the patient and your Dr. Bullen is showing this video to a patient that is now misinformed?

ATTORNEY THOMAS F. NYE: That is the responsibility of Centocor. If they have misinformation, they have the resources, they have the statistics, they have the responsibility to appropriately disseminate accurate information [inaudible] --

JUSTICE PAUL W. GREEN: But it's a but-for cause isn't it? I mean if he didn't show the video, the patient wouldn't be misinformed, but having shown it she was.

ATTORNEY THOMAS F. NYE: Here's the problem with that, if doctors like Dr. Bullen are required to review all of the information, videotape and brochure and then determine if a warning was omitted, that's not his responsibility. He's never prescribed the drug Remicade before. He's not treating her for lupus. He's not treating her for her Crohn's disease. That's not the type of responsibility that we should place on infusion doctors like Dr. Bullen. That's just not his responsibility. Now Dr. Hauptman went over those factors with Mrs. Hamilton and went over the risk and the benefits, but clearly as to the non-prescribing doctor, he had no duty, no legal duty.

JUSTICE DALE WAINWRIGHT: When she showed up and said, I've never heard anything about this drug, the warnings, they just told me to come over here and I'm going to lay down and. What should Dr. Bullen do in that situation?

ATTORNEY THOMAS F. NYE: He should refer her back to Dr. Hauptman.

JUSTICE DALE WAINWRIGHT: Duty in some sense. Maybe not a duty directly related to the liability in this case, but there's some duty.

ATTORNEY THOMAS F. NYE: Yeah, I think there's a responsibility, sure. I think to send him back, to send

her back to Dr. Hauptman and say, look, Dr. Hauptman's prescribing this medication for you. You need to go back and go over the risk and the other potential hazards involved in this medication.

JUSTICE DALE WAINWRIGHT: And if Dr. Bullen has known taking off from Justice Green's question that the video was affirmatively misleading, he shouldn't show it.

ATTORNEY THOMAS F. NYE: Well, yeah if he had knowledge that that is inaccurate, I think that--

JUSTICE DALE WAINWRIGHT: Happened to know, not review everything that comes in his office, all the videos, all the warnings, but if he just knew that one was affirmatively misleading, he shouldn't show it.

ATTORNEY THOMAS F. NYE: I think that's a fair statement, sure.

JUSTICE DAVID M. MEDINA: There's no evidence of that here though.

ATTORNEY THOMAS F. NYE: There's no evidence of that at all here. There's no evidence that Dr. Bullen even reviewed the videotape in question. It was shown after the IV was already hooked up, the medication already been prescribed and she looked at it at that time. I'm going to defer the remainder of my time to Mr. Cooper unless there's any further questions. We respectfully ask that the Court affirm the instructed verdict in favor of Dr. Bullen.

ATTORNEY R. BRENT COOPER: May it please the Court, my name is Brent Cooper. I represent the Amici in this case. You've heard from two sides of the prescribing relationship. I would like to address the view from the third side, that is the physician's. The first two points I want to make. First point is the traditional prescribing relationship that undergirded the learned intermediary doctrine no longer exists. Pharmaceutical companies, such as Centocor, have intentionally inserted themselves into the selection process so as to increase their market share. Their spending billions of dollars each year in order to create their market share. In fact, if you look at the record as far back as 2000, Centocor had a two-pronged marketing strategy. Number one was to refine the definition of the target Remicade patient to physicians and number two, which is most important was to teach patients to demand Remicade. So their advertising was to teach.

JUSTICE NATHAN L. HECHT: It's hard for me to understand how to the doctor is at the mercy of the patient. That seems to be the, sort of the foundation of that argument.

ATTORNEY R. BRENT COOPER: Well, Judge--

JUSTICE NATHAN L. HECHT: When I go in to see my doctor and I say I think you should do this. He said, who made you a doctor?

ATTORNEY R. BRENT COOPER: Some do that, but there are studies that are out there that we reference where it shows that physicians are increasingly facing demands from their patients for specific drugs. The first drug that was advertised was Rogaine and so all the bald men in here may have gone to the doctor and asked. Cross talkingOEcan you help me? Is there something you can do, I've seen this drug advertised on TV and these guys sort of like Justice Medina have a lot of hair and Rogaine is really helping me on that, is there something you can do for me? And that is something that is not uncommon in today's market. Patients do go in. They do ask for drugs. The question though is before this Court is whether drug companies, such as Centocor, should be allowed to spend billions of dollars on their marketing strategies, that is to teach patients to request specific drugs, but push all the liability for the decision to prescribe specific drug on the physician.

JUSTICE DON R. WILLETT: What is your quick take on the Washington Legal Foundation counter brief I guess to the cross talkingOE.

ATTORNEY R. BRENT COOPER: Chapter 82? Chapter 82, again, does not apply to misrepresentation for it to be. In fact, there's a court of appeals noted this is an exception based upon misrepresentation. If you look at chapter 82, it doesn't apply. So I think it's very easily distinguished. But, if you look here, what happens is the drug companies are able to blanket the public with ads and if any of us sit down at night and we turn the TV on no matter, and I won't mention the type of drugs that we're going to see advertised, but there's a lot of drugs, every program you see, many of them that are advertised on how great the benefits are, but yet their position is if we put the bad things, how they can kill you, we bury them deep in the small print on the package inserts that the patients never see that somehow that's all right even though the ads that we put on the TV are some how misleading.

JUSTICE DALE WAINWRIGHT: Counsel, some pharmaceuticals are advertised extensively. Most, maybe the vast majority are never advertised at all that are used out there in the healthcare industry. Should we conduct an industry-by-industry evaluation to determine in which industries LID applies and which one it doesn't?

ATTORNEY R. BRENT COOPER: No, Your Honor, I think the exception that was recognized by the court of appeals and by New Jersey and that is if you are advertising, that is if you are going out, let's put it this way, if you are assuming a duty to communicate directly with the patients in order to increase your market share with that effort, with the benefits come responsibilities. If you don't do that--

JUSTICE DALE WAINWRIGHT: So our evaluation shouldn't be industry by industry, it sounds like your argument is our evaluation should be company by company.

ATTORNEY R. BRENT COOPER: Or advertising exception. That is, if this is Centocor--.

JUSTICE DALE WAINWRIGHT: Do you agree with that or not?

ATTORNEY R. BRENT COOPER: I agree that it should be based upon the advertising that is done by the company. If a company has two drugs, one's being advertised, one's not being advertised, I think this heightened duty, heightened responsibility would follow with the one that's being advertised and would not follow with the one that is not being advertised.

JUSTICE PAUL W. GREEN: That view would put this Court in a very small minority of the country, wouldn't it?

ATTORNEY R. BRENT COOPER: It would, but you know there are always courts that step out to lead the change in, the first court to adopt 402A, California, they were the only court at that point in time. But we have to recognize, I think, that things have changed, that the relationship regarding prescribing medication has changed. The pharmaceutical companies if they want the benefits, they've got to assume the responsibilities.

CHIEF JUSTICE WALLACE B. JEFFERSON: Thank you, Mr. Cooper. The Court is read to hear rebuttal.

REBUTTAL ARGUMENT OF ROBERT M. ROACH, JR. ON BEHALF OF PETITIONER

ATTORNEY ROBERT M. ROACH: Thank you, Your Honor. The learned intermediary doctrine in the prescription drug context is the gold standard for learned intermediary doctrine cases. If you eviscerate, destroy or artfully plead around the learned intermediary doctrine in prescription drug cases, it's gone.

JUSTICE DAVID M. MEDINA: What about the comment by Mr. Enoch that we don't even get there because of the fraud issue? I think, the way I understand his argument would leave that intact because you don't even get there. The only issue we have to address is whether or not there was fraud.

ATTORNEY ROBERT M. ROACH: The problem is you can't get to fraud if the learned intermediary doctrine

is not eviscerated. If the learned intermediary doctrine is in play, just like in the Norplant cases out of the Fifth Circuit, the contraceptive cases where they did the same thing. They tried to plead fraud, negligent misrepresentation, the Fifth Circuit said, nope, you can not plead around a learned intermediary doctrine. It's a failure to warn case if you say you didn't get information that you should have gotten and so because the learned intermediary doctrine is the law, you can't get to fraud, you can't get the negligent misrepresentation. The doctors, I mean, sorry, the manufacturer's liability is extinguished by proving two things, adequate warning and no causation.

JUSTICE DEBRA H. LEHRMANN: What is your response to the argument that the learned intermediary doctrine is based upon antiquated practice?

ATTORNEY ROBERT M. ROACH: Well, isn't that an empirical question that this Court is uniquely situated not to be able to answer? Isn't that a legislative question or a regulatory question?

JUSTICE DEBRA H. LEHRMANN: Well, just answer me. Go ahead and answer it.

ATTORNEY ROBERT M. ROACH: Well, I'll answer it and that is that the legislature has already decided that it hasn't changed enough to eviscerate the learned intermediary doctrine because that's what A2.007 does. It says, it codifies the learned intermediary doctrine by creating, in essence, immunity from liability for drug manufacturers who can show that their warning was approved by the FDA.

JUSTICE DEBRA H. LEHRMANN: What do you say to the argument that these companies are benefitting by the fact that they're advertising, they're getting more business, they're making a lot of money and with that, responsibility attaches.

ATTORNEY ROBERT M. ROACH: They have the responsibility. They have responsibility both for fraudulently advertising, as we discussed before. They also have responsibility if they poorly inadequately warn doctors. They have that responsibility. It's not like they go scot-free, but the federal government and the state are working in tandem. There's comedy here where we want drug manufacturers to be able to make dangerous drugs as long as they, a fair warning, an appropriate warning can make it safe for a particular patient. So everybody's benefitting. Patients more then anybody else can benefit by improved health care, by better drugs, and we as a nation can benefit by having fewer people who are sick and for our litigation system we benefit by not having drug manufacturers in cases where they don't belong where they have adequately warned the doctor and the system is based on doctor prescriptions being in control.

JUSTICE DEBRA H. LEHRMANN: So why don't you limit your advertising to doctors?

ATTORNEY ROBERT M. ROACH: Well, obviously doctors are first and foremost. That's always been the primary source of target for all the information. But again I go back to this DOJFPC study. By telling people that new drugs are out there, it stimulates the conversation. I mean doctors can't go to the patients. The patients have to go to the doctors. So the patient goes to the doctor and says, I saw this ad it's called, for Celebrex. It's describing symptoms that I've got, is that right for me? I have high cholesterol. I went to my doctor and said, are statins right for me? The doctor will not prescribe something that is unsafe, that he can't make safe with a warning, but if he thinks he can make it safe with a warning then he does that.

JUSTICE NATHAN L. HECHT: Respondent seems to argue that the warning to the physician here was inadequate.

ATTORNEY ROBERT M. ROACH: Well, the court of appeals treated it as adequate. There was no evidence from any court that it was inadequate and let's talk about specifically what it was. Okay, this is the warning and the only complaint they have is about the comment that there were only three studies reported. It is a misrepresentation of this report and I ask you to look at it because it starts, the sentence starts in clinical studies, three

patients developed clinical symptoms. So this entire warning, the three number is all about in clinical studies expressly. They're talking about things outside of clinical studies. So this warning is not inaccurate; this warning is accurate.

JUSTICE DALE WAINWRIGHT: That's exhibit B, the document you're holding?

ATTORNEY ROBERT M. ROACH: That's right. Now so let's make it larger, the rarity issue. Is the rarity issue any issue at all? Okay, if, to be a real issue, it would have to be relevant to the doctor's prescription decision, but if the doctor says, it would not have changed my mind if I had known that there were more cases, it was less rare then there's no causation and there's no inadequate warning and that's what happened here. The doctors were never asked by the plaintiff if they would have changed their prescription decision. And most importantly, most importantly, all the doctors, treating doctors testified that they knew that the incident was less than 1% and the three number in that warning is less than 1%. So they were not misled; they said that, they knew the risks and they prescribed because they thought it was the right thing for this lady. The last thing I want to say is that the video, which everyone's talking about, comes in a box and that box has the full warning in it and at the end of the video when you look at it, it tells the patient to do three things. It says, consult your doctor, go to the website, the Remicade website and most importantly it says, look at the full prescribing information in the box. That's this warning. Her testimony is I didn't see it, but her testimony is I didn't look for it. But it was provided by the manufacturer in that box.

JUSTICE DEBRA H. LEHRMANN: How would she see the box if--

ATTORNEY ROBERT M. ROACH: She gets the box. She gets the video and the box and she doesn't deny that she had the box. She also had another box for her sister. She asked for another copy so that her sister also suffering from RA could see it. So she had two copies of this exact warning that the doctors got. My very last point is the doctors, the information goes to the doctors can't be understood by a patient. Let me ask you. Do you know what lupus-like syndrome is? Do you know what the symptoms of lupus-like syndrome is? If the patient had been told that, it would have been meaningless to her without a doctor being involved. Thank you, Your Honors.

CHIEF JUSTICE WALLACE B. JEFFERSON: Any further question? Thank you, Mr. Roach. The cause is submitted and the Court will take a brief recess.

MARSHAL: All rise.

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