

No. 10-0223

IN THE
SUPREME COURT OF TEXAS
AUSTIN, TEXAS

CENTOCOR, INC.,

Petitioner,

v.

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

Respondents.

On Petition for Review from the
Thirteenth Court of Appeals, Corpus Christi, Texas
No. 13-07-00301-CV

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INTEREST OF AMICUS CURIAE AND SUMMARY OF ARGUMENT

IADC is an organization of corporate and insurance attorneys whose practice is concentrated on the defense of civil lawsuits. Since 1920, the IADC has been dedicated to the just and efficient administration of civil justice and continual improvement of the civil justice system. The IADC regularly files briefs in pending cases throughout the United States to support a wide variety of civil justice issues of broad application. The IADC supports a justice system in which plaintiffs are fairly compensated for genuine injuries and responsible defendants are held liable only for appropriate damages. Because the decision below erroneously creates a direct-to-consumer advertising exception to the learned intermediary doctrine—a rule that is well-established and almost uniformly applied throughout the United States—IADC has a strong interest in a prompt review of the case and its reversal. The source of any fee paid for the preparation of this brief is IADC.

STATEMENT OF FACTS

IADC adopts Petitioner’s Statement of Facts in its Brief on the Merits but also provides a short rendition of the facts relevant to IADC’s arguments.

Patricia Hamilton (“Hamilton”) has suffered from Crohn’s disease for approximately thirty years. *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 484 (Tex. App.—Corpus Christi 2010, pet. granted). In December 2001, Dr. Ronald Hauptman (“Dr. Hauptman”), Hamilton’s physician, offered Hamilton two treatment options after she experienced a flare-up of the disease: steroids or Remicade®, the drug manufactured and marketed by Centocor. *Id.* at 482, 485. At the time Dr. Hauptman determined

Hamilton’s treatment options, Dr. Hauptman knew of the risks associated with the use of Remicade®, including the risk of lupus-like syndrome. *Id.* at 485. In fact, the risk of this potential side-effect was expressly stated on the drug’s package insert. *Id.* at 482. Knowing that Hamilton did not like steroids, Dr. Hauptman chose to prescribe Remicade®. *Id.* at 485-86.

Dr. Hauptman referred Hamilton to an infusion clinic to receive the Remicade® infusions. *Id.* at 486. While at this facility, Hamilton was shown a Centocor video about Remicade®. *Id.* Although the video did not specifically warn of the potential side effects of which Hamilton complains, it specifically informed Hamilton that the “video should not be used as a substitute for talking with your doctor” and that she should “see the accompanying Full Prescribing Information.” *Id.* at 488-89.

Following a series of treatments under Dr. Hauptman’s care, and later, after additional Remicade® infusions prescribed by her rheumatologist, Dr. Adriana Pop-Moody, Hamilton began to experience symptoms consistent with lupus-like syndrome—specifically joint pain. *Id.* at 497. Hamilton thereafter filed suit against Centocor based on an alleged failure to warn her of the risk of developing this specific complication. *Id.* at 498 & n.11.

The jury returned a verdict in favor of Hamilton, and Centocor appealed, asserting that Hamilton’s claims were precluded by the learned intermediary doctrine because its warnings to Hamilton’s physicians were adequate as a matter of law. *Id.* at 499. The Corpus Christi Court of Appeals affirmed the trial court’s judgment, creating a novel exception to Texas’ long-standing learned intermediary doctrine. *Id.*

ARGUMENT

I. The Court of Appeals Has Improperly Eradicated Years of Texas Precedent.

The fact that pharmaceutical companies engage in direct-to-consumer advertising is not a new concept; pharmaceutical companies have advertised directly to consumers for well over 100 years. However, unlike advertising decades ago, modern pharmaceutical advertisements are subject to stringent federal regulations restricting their content. Furthermore, federal laws require prescription medications to be accompanied by detailed warnings addressing any potential risks involved with their use. The treating physician, as the individual who maintains the relationship with the patient, assumes the responsibility of decision-maker and “gatekeeper” in prescribing medications and weighing the relative risks and benefits to the patient; in essence, he becomes the learned intermediary.

Because of this unique system, the learned intermediary doctrine has developed under the law to protect manufacturers from liability and relieve them of their duty to warn the consumer directly when the warning is provided to the physician. *See Stewart v. Janssen Pharmaceutica, Inc.*, 780 S.W.2d 910, 911 (Tex. App.—El Paso 1989, writ denied). The learned intermediary doctrine ensures harmonious operation of state product liability law with the “unique system used to distribute prescription [products].” *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 429 (Tenn. 1994). And yet, the Corpus Christi Court of Appeals in this case has jettisoned decades of Texas precedent based on its unsupported belief that changes in advertising techniques and “managed healthcare” have altered the physician-patient relationship. *See Centocor*, 310 S.W.3d at 508. The Court

of Appeals' creation of an unnecessary and unfounded "advertising" exception to the learned intermediary doctrine should be reversed by this Court. *Id.* at 481, 508.

A. The Learned Intermediary Doctrine Is Well Established In Texas Law.

The "learned intermediary" doctrine is well engrafted in Texas jurisprudence. *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588, 591 (Tex. 1986) ("We agree that a manufacturer or supplier may, in certain situations, depend on an intermediary to communicate a warning to the ultimate user of the product."); *Bean v. Baxter Healthcare Corp.*, 965 S.W.2d 656, 661-62 (Tex. App.—Houston [14th Dist.] 1998, no pet.) (applying doctrine in medical device case); *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App.—Corpus Christi 1973, writ ref'd n.r.e.). Texas courts have long recognized that drug manufacturers fulfill their duty to warn by providing warnings about their products to prescribing physicians. *See Stewart*, 780 S.W.2d at 911; *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App.—Waco 1993, writ denied).

Texas courts acknowledge that it is "unreasonable to suppose that a drug manufacturer must go beyond the physician and give actual warnings to the patient." *Gravis*, 502 S.W.2d at 870. Prescription drugs are "manufactured for administration only by a physician or other authorized person." *Id.* As the court in *Gravis* held,

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.

Id. “[O]nce the physician is warned, the choice of which drugs to use and the duty to explain the risks become that of the physician.” *Stewart*, 780 S.W.2d at 911. Any other result would undermine the very foundations of our system for dispensing prescription medication.

B. Centocor Satisfied Any Duties It Owed To Hamilton By Providing The Necessary Warnings Concerning Remicade® To Her Physician.

It is undisputed that Hamilton was treated for her Crohn’s disease by a physician. She received a prescription for Remicade® in the context of a physician-patient relationship. It is also undisputed that the package insert for Remicade® specifically warned of the dangers of lupus-like syndrome—the alleged injury about which Hamilton complains.

In Texas, a warning provided to a physician is deemed adequate as a matter of law if it “specifically mentions the circumstances” of which a plaintiff complains. *Rolen*, 856 S.W.2d at 609; *see also Brumley v. Pfizer, Inc.*, 149 F. Supp. 2d 305, 312 (S.D. Tex. 2001) (granting summary judgment on failure-to-warn claim because the warning “addressed the specific circumstances in which [plaintiff] suffered a fatal heart attack”). Because Centocor provided adequate warnings to Hamilton’s prescribing physician, regarding the possibility of lupus-like syndrome, there can be no liability here premised on a failure to warn. *See, e.g., Wyeth-Ayerst Labs. Co. v. Medrano*, 28 S.W.3d 87, 92 (Tex. App.—Texarkana 2000, no pet.); *see also Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 740 (N.D. Tex. 2000).

In fact, any other result would directly contravene well developed Texas jurisprudence. Unlike the manufacturer, the physician is in the best position to assess the patient, the patient's health history, and weigh risks and benefits of any medication with regard to that patient. The manufacturer, who has no direct contact with the patient, cannot possibly conduct such an analysis. Further, the vast majority of patients are not in a position to understand the complex scientific principles included in warnings about prescription medications intended primarily for physicians. The trained health care provider is in the best position to understand and explain to the patient the medical implications of a laundry list of potential side effects associated with a particular medication. Allowing the Court of Appeals' decision to remain intact will irrevocably harm the important relationship between the physician and patient.

II. A Direct-To-Consumer Advertising Exception To The Learned Intermediary Doctrine Should Be Rejected.

The Court of Appeals' recognition of an advertising exception to the learned intermediary doctrine is not only inconsistent with established Texas law, but also the law of almost every other jurisdiction. *Centocor*, 310 S.W.3d at 499-502. In support of its opinion, the Court of Appeals relies heavily on two cases from outside Texas: *Perez v. Wyeth Laboratories Inc.*, 161 N.J. 1, 734 A.2d 1245 (1999), and *State ex rel. Johnson & Johnson v. Karl*, 220 W. Va. 463, 647 S.E.2d 899 (2007). However, these cases have been rejected by other courts and certainly do not reflect the majority view.

A. The Court of Appeals' Reliance on *Perez* and *Karl* Is In Error.

The Court of Appeals' heavy reliance on *Perez* and *Karl* in creating an advertising exception to the learned intermediary doctrine is misdirected. In *Perez*, the New Jersey Supreme Court considered whether a pharmaceutical manufacturer who engaged in direct advertising to consumers had a duty to directly warn individual consumers of the alleged dangers of Norplant. 734 A.2d at 1247. Ignoring New Jersey's own legislation that, like Texas, created a rebuttable presumption that the warnings were adequate, the Court concluded that when a pharmaceutical manufacturer engages in "mass marketing" of prescription drugs, the manufacturer is not relieved of the duty to provide proper warnings to the consumer. *Id.* As the sole basis for its decision, the *Perez* court simply decided, without empirical evidence, that "medical-legal jurisprudence is based on images of health care that no longer exist." *Id.* at 1246.

Perez is incorrectly decided because it is based on a false premise—namely, that that "managed care," purchase of medication in "pharmacy departments of supermarkets," and increased spending on advertising that puts "pressure on consumers" have upset the balance in the physician-patient relationship. *Id.* at 1247, 1251. The *Perez* court's conclusion that the policies underlying the learned intermediary doctrine—such as concern about interfering with the doctor-patient relationship—do not exist with direct-to-consumer advertising is wrong. *Id.* at 1255. As the dissenting Justices noted, "the majority has created a phantom record to support the creation of its exception to the learned intermediary doctrine." *Id.* at 1268.

Following *Perez's* lead, the *Karl* court also found the “justifications for the learned intermediary doctrine to be largely outdated and unpersuasive.” 647 S.E.2d at 906. Like *Perez*, the *Karl* court claimed that “direct-to-consumer prescription drug advertising has been a fairly recent development.” *Id.* at 908. However, the *Karl* court even went a step further, rejecting the learned intermediary doctrine outright and finding that “manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers.” *Id.* at 914. Relying heavily on perceived “[s]ignificant changes in the drug industry” and “intense proliferation of direct-to-consumer advertising,” the court concluded that it could “ascertain no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized.”¹ *Id.* at 907, 913.

As in *Perez*, the majority in *Karl* was also criticized by the dissenting justices in failing to “analyze[] whether any of the rationales which underlie the doctrine remain valid today.” *Id.* at 914. “Notwithstanding the widespread use of marketing efforts by pharmaceutical companies aimed at the consumer, the need for a physician’s involvement in the decision to choose a specific drug remains.” *Id.* at 916.

¹ Oddly, the *Karl* court declined to acknowledge the acceptance of the learned intermediary doctrine in states where the doctrine had not been addressed by that state’s highest court. *Id.* at 904. The court also found it insignificant that the doctrine had been adopted by twenty-two state supreme courts, and that four state supreme courts had adopted the learned intermediary doctrine after 1997 when the alleged “proliferation of drug advertising” began. *Id.* at 908-09.

The main problem with *Perez* and *Karl* is that they have created overlapping liability for the drug manufacturer and the physician. Under their scheme, both the drug manufacturer and the physician would be charged with warning the patient of the potential dangers of the drug, but only the physician would have the knowledge of the individual patient and could determine the suitability of the medication. *See Rolan*, 856 S.W.2d at 609. Furthermore, “only a physician would understand the propensities and dangers involved” for a particular patient. *Gravis*, 502 S.W.2d at 870. The patient, however, receiving warnings about a drug not particularized to the patient’s situation, would be forced to choose between the physician’s recommended treatment and foregoing the treatment due to the patient’s fear of the manufacturer’s extensive list of potential side effects. Such a result not only raises serious public health concerns, but would irreparably interfere with the physician-patient relationship; the very relationship the learned intermediary doctrine was designed to protect.

1. The Learned Intermediary Doctrine Has Been Adopted In Most Jurisdictions.

The highest courts in over 30 states have adopted or recognized the learned intermediary rule. *See, e.g., Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 761 (Ky. 2004); *McCombs v. Synthes (U.S.A.)*, 587 S.E.2d 594, 595 (Ga. 2003); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 836-38 (Conn. 2001); *Coyle v. Richardson-Merrell, Inc.*, 584 A.2d 1383, 1385 (Pa. 1991). In fact, the doctrine has been applied or at least recognized in 48 states, the District of Columbia and Puerto Rico. *See In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 806-809 (E.D. Tex. 2002) (listing cases in each jurisdiction);

Diane Schmauder Kane, Annotation, *Construction and Application of Learned-Intermediary Doctrine*, 57 A.L.R. 5th 1 (1998); also see Appendix Tab 1.

Several other states have even codified the learned intermediary rule. States such as Ohio, North Carolina, and Mississippi have enacted such a statute. See OHIO REV. CODE ANN. § 2307.76(C); N.C. GEN. STAT. ANN. § 99B-5(c); MISS. CODE ANN. § 11-1-63(c)(ii). Like Texas, New Jersey also has adopted a statutory scheme creating a presumption of an adequate warning in the case of drugs that have been approved by the FDA. See N.J. STAT. ANN. § 2A:58C-4.

The Court of Appeals' decision certainly removes Texas from the mainstream of the law on the issue. The recognition of a direct-to-consumer advertising exception by this Court would be short-sighted, as well as contrary to decisions of other state supreme courts. Such an exception would undoubtedly undermine the physician-patient relationship, and unduly burden drug manufacturers by requiring them to directly warn patients of any inherent risk associated with their products, when doctors are in the best position to understand these warnings and convey them to the patient in layman's terms.

2. *Perez* and *Karl* Have Been Rejected in Other Jurisdictions.

Since the decisions in *Perez* and *Karl*, several states have declined to follow the lead of New Jersey and West Virginia and create a direct-to-consumer advertising exception. In fact, these courts have recognized that in the 12 years since *Perez* was decided, several states have expressly rejected any direct-to-consumer advertising exception. See *Beale v. Biomet, Inc.*, 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) (“Since *Perez* was decided, no court—including any Florida court—has recognized the

DTC exception to the learned intermediary doctrine, and several courts have expressly rejected the DTC exception.”); *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 547 n.30 (E.D. Pa. 2006), *aff’d*, 521 F.3d 253 (3d Cir. 2008), *vacated on other grounds*, 129 S. Ct. 1578 (2009); *Cowley v. Abbott Labs., Inc.*, 476 F. Supp. 2d 1053, 1060 n.4 (W.D. Wis. 2007); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004). Before *Karl* was decided, one Texas federal court noted that New Jersey’s advertising exception “is in direct conflict with the law of every other jurisdiction in the United States.” *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d at 812; *see also Larkin*, 153 S.W.3d at 767 (listing the states that have specifically adopted the learned intermediary rule by common law decision).

The Fifth Circuit, applying Texas law, has flatly rejected an advertising exception to the learned intermediary doctrine. *See In re Norplant Contraceptive Prod. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999) (applying Texas law). In that case, the Court considered whether the Texas learned intermediary doctrine applied to bar plaintiffs’ failure to warn claims, where a manufacturer had allegedly “aggressively” marketed its products. *Id.* at 379. The Fifth Circuit held that “as long as a physician-patient relationship exists, the learned intermediary doctrine applies.” *Id.* The Court also rejected the argument that exposure to video promotions and other material created by the manufacturer to explain the product expanded any duty. *Id.* at 379 n.4. The court found that those materials were “entirely within the control of the physician.” *Id.*

As in these cases, this Court should also decline to create such an exception. Any other result would suggest that physicians are powerless in their decisions of what and

when to prescribe and that consumers can buy prescription products at their own discretion as if they are over-the-counter products. With good reason, that simply is not the case.

B. Exceptions To The Learned Intermediary Doctrine Have Previously Been Rejected or Restricted in Texas.

Texas courts have been reluctant to recognize exceptions that would erode or undermine the learned intermediary doctrine. Exceptions to the learned intermediary doctrine have been recognized in only limited situations. And, when a Texas court has been called upon to address whether any exception to the doctrine is appropriate, it has been rejected or qualified.

For example, courts in other jurisdictions have recognized a limited exception in the case of contraceptives based on the argument that a physician usually has a limited role in a patient's choice of contraception. *See, e.g., MacDonald v. Ortho Pharm. Corp.*, 475 N.E.2d 65, 68 (Mass. 1985). However, Texas has declined to recognize an exception to the learned intermediary doctrine for contraceptives. *Medrano*, 28 S.W.3d at 92 (“Since prescription contraceptives, such as Norplant, can reach a patient only by way of a learned intermediary, we see no reason why the doctrine should not apply to contraceptives.”); *In re Norplant Contraceptives Prod. Liab. Litig.*, 955 F. Supp. 700, 708 (E.D. Tex. 1997) (addressing exception to doctrine for contraceptives (Norplant) and declining to find exception), *aff'd*, 165 F.3d 374 (5th Cir. 1999).

Texas courts have also limited the exception recognized in other jurisdictions in the context of mass immunizations. The learned intermediary doctrine has been found to

be inapplicable “where no individualized medical judgment intervenes between the manufacturer of a prescription drug and the ultimate consumer,” such as in the case of mass immunizations. *See Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968) (holding learned intermediary doctrine did not apply in context of polio vaccine provided at immunization clinics with no physician present). However, the Fifth Circuit has subsequently limited the scope of that exception finding that the learned intermediary doctrine continues to apply to situations involving immunizations if a physician is involved in the process. *See Hurley v. Lederle Labs.*, 863 F.2d 1173, 1179 (5th Cir. 1988); *Swayze v. McNeil Labs., Inc.*, 807 F.2d 464, 471-72 (5th Cir. 1987).

Not only have Texas courts previously sought to avoid erosion of the learned intermediary doctrine, but those courts have taken an expansive view of the doctrine, and even extended it to nurses who are certified to prescribe drugs, *Medrano*, 28 S.W.3d at 93, and to pharmacists. *See Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 469 (Tex. App.—Austin 2000, pet. denied) (applying the learned intermediary doctrine to pharmacist). Courts applying Texas law have also extended the doctrine to include not only prescription medications, but also medical devices. *See Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 468 (5th Cir. 1999); *Dyer*, 115 F. Supp. 2d at 740 (applying the learned intermediary doctrine to spinal fixation devices). The Court of Appeals’ opinion here is simply at odds with long standing Texas precedent and should be rejected.

C. The Court of Appeals' Decision Is Contrary To This Court's Recognition And Application of Restatement Provisions.

This Court has long recognized and applied the American Law Institute's Second and Third Restatements of the Law of Torts. *See, e.g., Bostrom Seating, Inc. v. Crane Carrier Co.*, 140 S.W.3d 681, 683 (Tex. 2004); *Gen. Motors Corp. v. Sanchez*, 997 S.W.2d 584, 592, 594 (Tex. 1999). In particular, section 402A, adopted by this Court, reflects the inherent understanding that pharmaceutical products are "unavoidably unsafe." *See* RESTATEMENT (SECOND) OF TORTS: PRODUCTS LIABILITY §402A, cmt. k (1965). The Restatement acknowledges that "[m]any products cannot possibly be made entirely safe for all consumption, and any . . . drug necessarily involves some risk of harm . . ." *Id.* cmt. i.

Several federal courts applying Texas law have expressly adopted comment k of Section 402A in relation to pharmaceutical products. Comment k provides:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drug. . . . Such a product, properly prepared and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. . . . 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 strictly liable 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.

See id. cmt. k. Comment k provides an exception to the rule that manufacturers must warn ultimate users because all prescription drugs pose risks; however, it is left to the individual physician to decide whether the benefits to the patient outweigh those risks.

Id.; see *Gerber v. Hoffman-La Roche Inc.*, 392 F. Supp. 2d 907, 922 (S.D. Tex. 2005) (recognizing application of comment k); *Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (noting that Texas courts apply comment k in the context of prescription drugs and that it precludes liability when a product is properly prepared and accompanied by proper directions and warnings).

Although the Second Restatement has no specific prescription drug provision, § 6 of the RESTATEMENT (THIRD) was especially drafted with prescription drugs in mind. See § 6 cmt. b (noting “special nature of prescription drugs” and unsuitability of analyzing claims involving same under general products liability provision). The Third Restatement specifically adopts the learned intermediary doctrine. Section 6(d) of the Third Restatement provides:

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 or 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) (1998). Comment e to this provision recognizes that “a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider.” *Id.* cmt. e. Moreover, § 6 of the RESTATEMENT (THIRD) largely conforms to Texas’s preexisting law of products liability relating to medical products. These restatement provisions reflect the majority

view that all prescription drugs may cause some side effects in patients—however, it is the physician’s role to assess the potential risks and benefits of the patient. Any other result would remove the doctor from this key role of advising a patient as to whether risks outweigh benefits.

D. Advertising Techniques Have Not Changed The Physician’s Role.

The Court of Appeals’ opinion is founded on the faulty premise that when the “doctrine was first developed, drug manufacturers did not advertise to the general public.” *Centocor*, 310 S.W.3d at 506. The court concludes that an exception is warranted because of manufacturers’ engagement in direct marketing through which they can directly communicate with consumers. *Id.* at 507-08. The court also blames its creation of an exception to the general rule on “managed care” that has reduced time patients spend with their doctors. *Id.* The fundamental policies underlying the doctrine and realities of the physician-patient relationship demonstrate the deficiencies in the Court of Appeals’ analysis.

First, physicians are, and still remain, in the best position to warn patients. The doctor stands in the best position to evaluate a patient’s needs and assess risks and benefits of a particular medication. The physician then chooses the “type and quantity of drug to be prescribed,” using “his comprehensive training and experience in conjunction with knowledge of the individual patient in determining the suitability of a medication.” *Rolen*, 856 S.W.2d at 609. Through the physician-patient relationship, variations in needs and characteristics of patients can be accurately assessed. *See Reyes*, 498 F.2d at

1276 (applying Texas law). Warnings directly to patients will most certainly interfere with this important physician-patient relationship.

Second, an accurate description of the risks and benefits of prescription medical products requires precise medical terminology not easily understood by patients. *See Gravis*, 502 S.W.2d at 870. Most medications are complex, making it difficult for the average consumer to understand the warnings. *Brumley*, 149 F. Supp. 2d at 312 (health care providers “understand[] the propensities and dangers involved in the use of a given drug”). Warning labels on prescription medication are designed to be read by health care practitioners, not lay persons—the inherent and important distinction between prescription products and over-the-counter products. A physician with specialized training is in the best position to convey warnings in light of technical information in the warnings. Imposing a duty on the physician to counsel patients on the benefits and risks of medication ensures scientific precision.

Third, imposing a duty to warn the patient on the physician rather than the manufacturer is also reflective of how the medication is distributed. Prescription medication is only available after a doctor has decided on the appropriate treatment and allowed the patient to obtain the medication. If a manufacturer was required to assume a duty to warn consumers individually, “[t]he physician’s professional knowledge and judgment in prescribing a medication would cease to be relevant.” *Rolen*, 856 S.W.2d at 609-10. “This is plainly against clear logic, the public’s interest, and holdings of Texas courts for decades.” *Id.* at 610.

Fourth, given the nature of the physician-patient relationship, patients give greater deference to physicians. Patients typically rely on doctors in deciding whether to take a particular medicine—not package inserts. The Court of Appeals simply concludes that “[p]hysicians no longer make the final decision as to whether a patient will take a drug.” *Centocor*, 310 S.W.3d at 507. To the contrary, it has always been the patient who makes the decision whether to take a particular medication. Even if a patient “may have a voice in the choice” of the medication, “even if it is in fact the deciding voice,” this is not enough “to exempt [the] prescription drug from the learned intermediary doctrine.” *Medrano*, 28 S.W.3d at 92. In fact, it would be dangerous to require a drug manufacturer to change its product information and direct it to lay persons. This would most certainly disrupt the physician patient relationship by almost requiring the patient to second-guess the physician’s recommendation.

Finally, having the duty to warn the patient remain with the physician also makes sense to the extent that manufacturers cannot reach all consumers in any meaningful way. Manufacturers will not be able to reach all consumers through one medium. Some consumers will view television ads and others print ads; whereas others will only hear about a particular drug from their physicians. Moreover, not all consumers will understand the same language. Any warning would have to be translated into several languages. Notwithstanding, even if manufacturers included a warning about the potential side effects of a particular drug, there is no way of ensuring that such warning would be listened to during the television ad, read in the print ad, or even understood by the average consumer. *See Gravis*, 502 S.W.2d at 870 (“Generally speaking, only a

physician would understand the propensities and dangers involved.”). Because these drugs are “manufactured for administration only by a physician or other authorized person” and it is the physician’s “choice of which drugs to use,” the duty to warn should remain solely on the learned intermediary. *See id.*

E. The Court of Appeals’ Decision Is Inconsistent With State and Federal Directives and Legislative Intent.

Federal and state statutory schemes have also been enacted and specifically designed to address patient safety concerns. These statutory schemes limit the distribution of prescription drugs based on their inherent safety risks. If the drug were safe for general use, no prescription would be needed. *Rolen*, 856 S.W.2d at 610. These schemes also regulate product marketing and warnings. The fact that both federal and state laws address these issues further weighs against the Court of Appeals’ decision.

1. The Pharmaceutical Industry Remain Highly Regulated.

The pharmaceutical industry is highly regulated by both state and federal laws. For example, Texas statutes prevent a pharmacist or pharmacy from dispensing medication without a valid prescription. *See* TEX. OCC. CODE ANN. §§ 562.056(a), 562.111; TEX. HEALTH & SAFETY CODE ANN. § 481.074(a)(3). Dispensing a controlled substance without a prescription is a violation of both state and federal laws. *See* TEX. HEALTH & SAFETY CODE ANN. § 481.074(a)(1) (“Texas Controlled Substances Act”) (“[a] pharmacist may not: dispense or deliver a controlled substance or cause a controlled substance to be dispensed or delivered under the pharmacist’s direction or supervision except under a valid prescription and in the course of professional practice”); *see also* 21

U.S.C. § 829(a) (“Federal Comprehensive Drug Abuse Prevention and Control Act”) (“Except when dispensed directly by a practitioner, other than a pharmacist, to an ultimate user, no controlled substance . . . which is a prescription drug as determined under the Federal Food, Drug & Cosmetic Act, may be dispensed without the written prescription of a practitioner”). These statutory safeguards serve to ensure that prescription medication is prescribed by a licensed health care provider who can properly advise patients of any inherent risks associated with use of the medication.

Federal law also provides strong incentives for drug manufacturers to ensure that they have the requisite clinical data, and that their products are properly tested and approved by the FDA before marketing those products. Drug manufacturers that fail to comply with federal laws regulating their products can face potential liability if they perform incomplete product testing, or even provide incomplete or inaccurate clinical data to the FDA. *See, e.g.*, TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(b) (addressing liability for misrepresentations to or withholding of information from the FDA). The Food, Drug and Cosmetic Act (FDCA) contains a broad detailed provision on sanctions, including criminal fines and imprisonment as well as civil penalties, for any company violating its provisions. 21 U.S.C. § 333, 335b.

The FDCA also grants the FDA the authority to regulate prescription drug advertisements. *See* 21 U.S.C. § 352(n); 21 C.F.R. § 202.1. The FDA regulates advertisements and promotional materials, including materials placed in circulation by product sponsors directed to consumers. 21 C.F.R. § 202.1(e). Advertisements stating a drug’s benefits must contain a “fair balance” of the drug’s risks and limitations of

efficacy. *Id.* at § 202.1(e)(3)(i), (iii).² It is not only illogical—but also violative of public policy—to impute liability upon a drug manufacturer for advertisements already approved by the FDA. Federal law is already in place for the purpose of ensuring that patients receive proper warnings through their health care providers. Any finding of liability against Centocor here would simply undermine federal objectives in enacting this legislation.

2. Texas’s Statutory Presumption That A Pharmaceutical Product’s Warnings Are Adequate Militates Against An Exception To The Learned Intermediary Doctrine.

Under Texas law, an FDA approved warning on a pharmaceutical product is presumed to be adequate unless the plaintiff can satisfy certain very narrow exceptions. Section 82.007(a) of the Texas Civil Practice & Remedies Code establishes a “rebuttable presumption” that a defendant is “not liable” for failure to provide adequate warnings or information in connection with a pharmaceutical product if the product was accompanied by warnings or information that were approved by the FDA. *See* TEX. CIV. PRAC. & REM. CODE ANN. § 82.007(a).

Section 82.007 of the Texas Civil Practice & Remedies Code provides:

- (a) In a products liability action alleging that an injury was caused by a failure to provide adequate warnings or information with regard to a pharmaceutical product, there is a rebuttable presumption that the defendant or defendants, including a health care provider,

² *See also* Corey Schaecher, *Comment: “Ask Your Doctor If This Product Is Right for You”: Perez v. Wyeth Laboratories, Inc., Direct-To-Consumer Advertising And The Future Of The Learned Intermediary Doctrine In The Face Of The Flood Of Vioxx(R) Claims*, 26 ST. LOUIS U. PUB. L. REV. 421 (2007).

manufacturer, distributor, and prescriber, are not liable with respect to the allegations involving failure to provide adequate warnings or information if:

- (1) the warnings or information that accompanied the product in its distribution were those approved by the United States Food and Drug Administration for a product approved under the Federal Food, Drug and Cosmetic Act (21 U.S.C. Section 301, et seq.), as amended, or Section 351, Public Health Service Act (42 U.S.C. Section 262), as amended[.]

Id. The Texas Legislature enacted this provision as part of House Bill 4 to ensure that state courts do not second guess the extensive FDA review process.

As the Legislature recognized, sound public policy supports application of these principles in pharmaceutical cases:

a manufacturer of a pharmaceutical actually is . . . on trial twice. They're on trial with—as they go through the process and try to prove or determine if they have a safe product and then once that's determined, there's a determination made as to exactly what type of warnings should be given Once they go through that very, very rigorous, --very, very rigorous process, which is far more rigorous than a jury would . . . then we're simply saying that it is poor public policy for them to have to go through and each and every time in litigation prove up again that those warnings were the proper warnings given the—the nature of the product.

See Debate on House Bill 4 on the Floor of the Texas House of Representatives (Second Reading) 78th Leg., R.S. 76 (March 27, 2003). Section 82.007 clearly evidences the Texas Legislature's intent that “if a pharmaceutical product has gone through the rigorous—as the Supreme Court has held—the rigorous review and approval process, and that approval process establishes a certain set of warnings that need be given with that product, and if the manufacturer or a retailer uses that exact warning that was approved

through that rigorous process, then they cannot be held liable for the – for a marketing defect for failure to give the proper warning.” *Id.* at 74-75.

Here, all of the warnings accompanying Remicade® were approved by the FDA following the FDA’s rigorous approval process. Although section 82.007(b) provides several narrow exceptions to the presumption of an adequate warning, none of those apply here. TEX. CIV. PRAC. & REM. CODE § 82.007(b); T. Sales and S. Mitby, *The New Presumption of Adequate Warnings in Texas Pharmaceutical Litigation*, 69 TEX. B.J. 612, 614 (2006) (noting that “the exception found in § 82.007(b)(1) will likely have little practical effect. The exception is likely to apply only in cases where the FDA withdraws approval for a product or changes the required warnings after a finding that the manufacturer misrepresented information to the agency.”).³ Given the Texas Legislature’s intent to shield pharmaceutical manufacturers from liability when warnings are provided to health care providers, this Court should not create common law liability when those warnings are not also given to consumers.

III. Information Distributed Through A Physician Does Not Constitute “Direct-to-Consumer” Advertising.

The Court of Appeals further compounded its error in concluding that the video shown to Hamilton before her infusion of Remicade® constituted “direct-to-consumer”

³ Additionally, in *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341, 343 (2001), the United States Supreme Court held that federal law preempts fraud-on-FDA claims. See *Ackermann v. Wyeth Pharm.*, No. 4:05CV84, 2006 U.S. Dist. Lexis 64499, at *19 (E.D. Tex. 2006) (“absent some evidence that a drug manufacturer has misled the FDA or failed to disclose critical information, preemption should apply in a failure to warn case”), *opinion adopted*, 2006 Lexis 88456 (E.D. Tex. 2006).

advertising. At the time Hamilton viewed the video, the medication had already been prescribed by her treating physician and she had agreed to this course of treatment. Therefore, the video was not a causal factor in her decision to ingest the drug.

At least one federal district court applying Texas law has previously recognized that a pharmaceutical manufacturer's "direct to consumer advertising could not have somehow vitiated the role of the learned intermediary." *See In re Norplant Contraceptives Liab. Litig.*, 955 F. Supp. at 708 (promotional materials including informational brochures and videotapes are not intended to supplant advice of physician). The court found that informational supplements do not supplant the advice of the physician, but merely facilitate counseling. Instead, these materials are merely an "informational supplement to the physician-patient relationship." *Id.* Likewise, in *Medrano*, the court of appeals found that a patient's review of a booklet and videotape about Norplant provided by a nurse and "gear[ed] directly at the patient" did not create a separate duty to the patient since the information only reached the patient because of a physician-patient relationship. 28 S.W.3d at 90, 93.

Other jurisdictions have also declined to find that pamphlets and other information provided to physicians for their patients create additional obligations for the manufacturer. *See Spsychala v. G.D. Searle & Co.*, 705 F. Supp. 1024, 1033 (D.N.J. 1988) (patient brochures do not establish a voluntary undertaking by the drug manufacturer of a voluntary duty to warn the patient directly); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 840 (Ohio 1981) (informational pamphlets did not expand drug manufacturers duty to warn). In fact, one New Jersey Court has cautioned that *Perez*

should not be read so broadly as to encompass information provided through a physician such as office brochures. *See Banner v. Hoffman-LaRoche Inc.*, 891 A.2d 1229, 1236 (N.J. Super. Ct. App. Div. 2006).

In short, not only should a direct-to-consumer advertising exception to the learned intermediary doctrine be rejected, but the facts here do not warrant such an exception. The uncontested evidence in this case demonstrates that the video shown to the Hamiltons was not direct-to-consumer advertising. Instead, the video was shown to the Hamiltons at an infusion clinic by a nurse after the treatment had already been prescribed. This is not a situation where Hamilton saw an advertisement and sought out a prescription by her physician. Any “advertisement” viewed by Hamilton was in the context of the physician-patient relationship. The Court of Appeals’ decision creating a direct-to-consumer advertisement exception should be reversed. Such an exception, even if justified, cannot be predicated on these facts.

PRAYER

Amicus Curiae International Association of Defense Counsel respectfully requests that the Court reject any direct-to-consumer advertising exception to the learned intermediary doctrine in Texas.

Respectfully submitted,

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APPENDIX 1

COURTS REJECTING EXCEPTION TO LEARNED INTERMEDIARY DOCTRINE

STATES	CASES
Florida	<i>Beale v. Biomet, Inc.</i> , 492 F. Supp. 2d 1360, 1376 (S.D. Fla. 2007) (“Since <i>Perez</i> was decided, no court—including any Florida court—has recognized the DTC exception to the learned intermediary doctrine, and several courts have expressly rejected the DTC exception.”).
Ohio	<i>In re Meridia Prods. Liab. Litig.</i> , 328 F. Supp. 2d 791, 812 n.19 (N.D. Ohio 2004).
Pennsylvania	<i>Colacicco v. Apotex, Inc.</i> , 432 F. Supp. 2d 514, 547 n.30 (E.D. Pa. 2006), <i>aff’d</i> , 521 F.3d 253 (3d Cir. 2008), <i>vacated on other grounds</i> , 129 S. Ct. 1578 (2009); <i>also see Heindel v. Pfizer, Inc.</i> , 381 F. Supp. 2d 364, 384 (D.N.J. 2004) (applying Pennsylvania law) (concluding that Plaintiffs’ direct-to-consumer advertising claims were barred by the learned intermediary doctrine).
Wisconsin	<i>Cowley v. Abbott Labs., Inc.</i> , 476 F. Supp. 2d 1053, 1060 n.4 (W.D. Wis. 2007).

COURTS ADOPTING LEARNED INTERMEDIARY DOCTRINE:

STATES AND OTHER U.S. TERRITORIES	CASES
Alabama	<i>Walls v. Alpharma USPD</i> , 887 So. 2d 881, 883 (Ala. 2004); <i>Stone v. Smith, Kline & French Labs.</i> , 447 So. 2d 1301, 1304-05 (Ala. 1984).
Alaska	<i>Shanks v. Upjohn Co.</i> , 835 P.2d 1189, 1200 (Alaska 1992).
Arizona	<i>Gaston v. Hunter</i> , 121 Ariz. 33, 588 P.2d 326, 340 (1978).
Arkansas	<i>West v. Searle & Co.</i> , 305 Ark. 33, 806 S.W.2d 608, 613-15 (1991); <i>Rush v. Wyeth (In re Prempro Prods. Liab. Litig.)</i> , 514 F.3d 825, 830 (8 th Cir. 2008) (applying Arkansas law).
California	<i>Carlin v. Superior Court</i> , 13 Cal. 4 th 1104, 920 P.2d 1347, 1354 (1996); <i>Brown v. Superior Court</i> , 44 Cal. 3d 1049, 751 P.2d 470, 477-78 (1988); <i>see also, Motus v. Pfizer, Inc.</i> , 358 F.3d 659, 661 (9 th Cir. 2004) (applying California law).
Connecticut	<i>Vitanza v. Upjohn Co.</i> , 257 Conn. 365, 778 A.2d 829, 836-39 (2001); <i>Montagnon v. Pfizer, Inc.</i> , 584 F. Supp. 2d 459, 462-63 (D. Conn. 2008).
Delaware	<i>Lacy v. G.D. Searle & Co.</i> , 567 A.2d 398, 399 (Del. 1989) (“The learned intermediary doctrine provides for an exception to the general

	rule that the manufacturer of a drug owes a duty to warn the consumer directly concerning risks associated with the drug.”).
District of Columbia	<i>Mampe v. Ayerst Labs.</i> , 548 A.2d 798, 801-02 & n.6 (D.C. 1988).
Florida	<i>E.R. Squibb & Sons, Inc. v. Farnes</i> , 697 So. 2d 825, 827 (Fla. 1997); <i>Felix v. Hoffmann-LaRoche, Inc.</i> , 540 So. 2d 102, 104 (Fla. 1989); also see <i>Hoffmann-LaRoche Inc. v. Mason</i> , 27 So. 3d 75, 77 (Fla. Dis. Ct. App. 2009) (“the duty of a drug manufacturer to warn of the dangers involved in the use of a drug is satisfied if it gives an adequate warning to the physician who prescribes the drug”); <i>Buckner v. Allergan Pharm., Inc.</i> , 400 So. 2d 820, 822 (Fla. Dis. Ct. App. 1981).
Georgia	<i>Dietz v. Smithkline Beecham Corp.</i> , 598 F.3d 812, 816 n.2 (11 th Cir. 2010) (noting that “Georgia’s long-recognized, unwavering use of the learned intermediary doctrine has cast no ‘substantial doubt’ on the doctrine’s continued validity under Georgia law”); <i>McCombs v. Synthes (U.S.A.)</i> , 277 Ga. 252, 587 S.E.2d 594, 595 (2003); <i>Hawkins v. Richardson-Merrell, Inc.</i> , 147 Ga. App. 481, 249 S.E.2d 286, 288 (1978).
Hawaii	<i>Craft v. Peebles</i> , 78 Haw. 287, 893 P.2d 138, 155-56 (1995).
Illinois	<i>Hansen v. Baxter Healthcare Corp.</i> , 198 Ill. 2d 420, 764 N.E.2d 35, 42 (2002); <i>Kirk v. Michael Reese Hosp. & Med. Ctr.</i> , 117 Ill. 2d 507, 513 N.E.2d 387, 393 (1987).
Indiana	<i>Ortho Pharm. Corp. v. Chapman</i> , 180 Ind. App. 33, 388 N.E.2d 541, 548-49 (1979).
Kansas	<i>Savina v. Sterling Drug, Inc.</i> , 247 Kan. 105, 795 P.2d 915, 928 (1990); <i>Wooderson v. Ortho Pharm. Corp.</i> , 235 Kan. 387, 681 P.2d 1038, 1049-51 (1984).
Kentucky	<i>Larkin v. Pfizer, Inc.</i> , 153 S.W.3d 758, 764 (Ky. 2004).
Louisiana	<i>Cobb v. Syntex Labs., Inc.</i> , 444 So. 2d 203, 205 (La. Ct. App. 1983); see also <i>Stahl v. Novartis Pharms. Corp.</i> , 283 F.3d 254, 265 (5 th Cir. 2002) (applying Louisiana law).
Maryland	<i>Ames v. Apothecan, Inc.</i> , 431 F. Supp. 2d 566, 572 (D. Md. 2006) (“Maryland law recognizes the ‘learned intermediary’ doctrine, which provides that manufacturers need only warn the prescribing physician and not the patient directly.”); <i>Nolan v. Dillon</i> , 261 Md. 516, 276 A.2d 36, 40 (1971).
Massachusetts	<i>MacDonald v. Ortho Pharm. Corp.</i> , 394 Mass. 131, 475 N.E.2d 65, 68-69 (1985).
Michigan	<i>Smith v. E.R. Squibb & Sons</i> , 405 Mich. 79, 273 N.W.2d 476, 479 (1979).
Minnesota	<i>Mulder v. Parke Davis & Co.</i> , 288 Minn. 332, 181 N.W.2d 882, 885

	n.1 (1970); <i>Mozes v. Medtronic, Inc.</i> , 14 F. Supp. 2d 1124, 1130 (D. Minn. 1998).
Mississippi	MISS. CODE ANN. § 11-1-63(c)(ii) (“An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates sufficient information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to an ordinary consumer who purchases the product; or in the case of a prescription drug, medical device or other product that is intended to be used only under the supervision of a physician or other licensed professional person, taking into account the characteristics of, and the ordinary knowledge common to, a physician or other licensed professional who prescribes the drug, device or other product.”); <i>Janssen Pharmaceutica, Inc. v. Bailey</i> , 878 So. 2d 31, 57 (Miss. 2004); <i>Wyeth Labs., Inc. v. Fortenberry</i> , 530 So. 2d 688, 691 (Miss. 1988).
Missouri	<i>Krug v. Sterling Drug, Inc.</i> , 416 S.W.2d 143, 146-47 (Mo. 1967).
Montana	<i>Hill v. Squibb & Sons</i> , 181 Mont. 199, 592 P.2d 1383, 1387-88 (1979).
Nebraska	<i>Freeman v. Hoffman-LaRoche, Inc.</i> , 260 Neb. 552, 618 N.W.2d 827, 841-42 (2000).
Nevada	<i>Allison v. Merck & Co.</i> , 110 Nev. 762, 878 P.2d 948, 958 n.16 (1994).
New Jersey	N.J. STAT. ANN. § 2A:58C-4 (“In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the “Federal Food, Drug, and Cosmetic Act,” 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the “Public Health Service Act,” 58 Stat. 682, 42 U.S.C. §. 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes of this section, the terms “drug,” “device,”

	“food,” and “food additive” have the meanings defined in the “Federal Food, Drug, and Cosmetic Act.”).
New Mexico	<i>Perfetti v. McGhan Med.</i> , 99 N.M. 645, 662 P.2d 646, 649 (1983).
New York	<i>Alston v. Caraco Pharm., Inc.</i> , 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009) (for prescription medications, “the duty to warn is met by providing information to the prescribing physician, not to the patient directly”); <i>Martin v. Hacker</i> , 83 N.Y.2d 1, 628 N.E.2d 1308, 1311 (1993); <i>also see Lindsay v. Ortho Pharm. Corp.</i> , 637 F.2d 87, 91 (2d Cir. 1980).
North Carolina	N.C. GEN. STAT. ANN. § 99B-5(c) (“Notwithstanding subsection (a) of this section, no manufacturer or seller of a prescription drug shall be liable in a products liability action for failing to provide a warning or instruction directly to a consumer if an adequate warning or instruction has been provided to the physician or other legally authorized person who prescribes or dispenses that prescription drug for the claimant unless the United States Food and Drug Administration requires such direct consumer warning or instruction to accompany the product”); <i>also see Cowley v. Abbott Labs.</i> , 476 F. Supp. 2d 1053, 1060 n.4 (W.D. Wis. 2007) (noting that North Carolina has not adopted a direct-to-consumer advertising exception to the learned intermediary doctrine).
Ohio	OHIO REV. CODE ANN. § 2307.76(C) (“An ethical drug is not defective due to inadequate warning or instruction if its manufacturer provides otherwise adequate warning and instruction to the physician or other legally authorized person who prescribes or dispenses that ethical drug for a claimant in question and if the federal food and drug administration has not provided that warning or instruction relative to that ethical drug is to be given directly to the ultimate user of it”); <i>Howland v. Purdue Pharma L.P.</i> , 104 Ohio St. 3d 584, 821 N.E.2d 141, 146 (2004); <i>Seley v. G.D. Searle & Co.</i> , 67 Ohio St. 2d 192, 423 N.E.2d 831, 936-37 (1981); <i>In re Meridia Prods. Liab. Litig.</i> , 328 F. Supp. 2d 791, 811-12 & n.19 (N.D. Ohio 2004).
Oklahoma	<i>Edwards v. Basel Pharm.</i> , 933 P.2d 298, 300-01 (Okla. 1997); <i>Cunningham v. Charles Pfizer & Co.</i> , 532 P.2d 1377, 1381 (Okla. 1974).
Oregon	<i>Oksenholt v. Lederle Labs.</i> , 294 Or. 213, 656 P.2d 293, 296-97 (1982); <i>Vaughn v. G.D. Searle & Co.</i> , 272 Or. 367, 536 P.2d 1247, 1248 (1975).
Pennsylvania	<i>Coyle v. Richardson-Merrell, Inc.</i> , 526 Pa. 208, 584 A.2d 1383, 1385 (1991); <i>Lineberger v. Wyeth</i> , 894 A.2d 141, 149-50 (Pa. Super. Ct. 2006).
Tennessee	<i>Pittman v. Upjohn Co.</i> , 890 S.W.2d 425, 429-30 (Tenn. 1994) (“makers of unavoidably unsafe products who have a duty to give

	warnings may reasonably rely on intermediaries to transmit their warnings and instructions”).
Texas	<i>Gravis v. Parke-Davis & Co.</i> , 502 S.W.2d 863, 870 (Tex. Civ. App.—Corpus Christi 1973, writ ref’d n.r.e.); <i>Ackermann v. Wyeth Pharm.</i> , 526 F.3d 203, 207 (5 th Cir. 2008); <i>Porterfield v. Ethicon, Inc.</i> , 183 F.3d 464, 468 (5 th Cir. 1999); <i>Reyes v. Wyeth Lab.</i> , 498 F.2d 1264, 1276 (5 th Cir. 1974).
Utah	<i>Barson v. E.R. Squibb & Sons, Inc.</i> , 682 P.2d 832, 835 (Utah 1984).
Virginia	<i>Pfizer, Inc. v. Jones</i> , 221 Va. 681, 272 S.E.2d 43, 44 (1980).
Washington	<i>Terhune v. A.H. Robins Co.</i> , 90 Wash.2d 9, 577 P.2d 975, 977 (1978).
Wyoming	<i>Rohde v. Smiths Medical</i> , 165 P.3d 433, 438, 441-42 (Wyo. 2007).
Puerto Rico	<i>Mendez Montes de Oca v. Aventis Pharma.</i> , 579 F. Supp. 2d 222, 227 (D.P.R. 2008) (noting that the learned intermediary doctrine has been applied in Puerto Rico).