No. 10-0223

IN THE SUPREME COURT OF TEXAS

CENTOCOR, INC.,

Petitioner,

v.

PATRICIA HAMILTON, *et al.*,

Respondents.

BRIEF OF AMICUS CURIAE WASHINGTON LEGAL FOUNDATION IN SUPPORT OF PETITIONER

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Pursuant to Rule 11 of the Texas Rules of Appellate Procedure, Washington Legal Foundation (WLF) respectfully submits this brief as amicus curiae in support of Centocor, Inc. urging adoption of the learned intermediary rule, and reversal of the court of appeals' and trial court's judgments.

IDENTITY AND INTEREST OF *AMICUS CURIAE*

WLF is a nonpartisan, nonprofit public interest law and policy center with supporters nationwide, including the State of Texas. WLF engages in litigation and in other advocacy to defend economic liberty and free-market principles. To that end, WLF has appeared in this Court as well as other state and federal courts as amicus curiae to oppose the unwarranted expansion of tort liability that fosters excessive litigation and impedes economic development.

If affirmed by this Court, the appeals court's decision would result in the rejection or severe curtailment of the near universally adopted learned intermediary rule and in its place create a new failure-to-warn cause of action against prescription drug manufacturers that have adequately warned prescribing physicians. Such novel precedent will have adverse social, economic and judicial consequences. Because this litigation strikes at the heart of free enterprise and fosters excessive litigation, it is of particular concern to WLF.

WLF does not have a direct interest in the outcome of this litigation. It seeks merely to assist the Court in understanding the legal and policy implications of a rejection of the learned intermediary rule.

INTRODUCTION AND SUMMARY OF ARGUMENT

It is well established by numerous courts and the American Law Institute that prescription medications hold a unique place in product liability law. Unlike ordinary chattel, prescription drugs are complex medicines, esoteric in formula and varied in effect, which are available only to a consumer from a medical expert who can take into account the propensities of the drug, as well as the susceptibilities of the patient. As such, unlike manufacturers of ordinary chattel, pharmaceutical manufacturers have a duty to warn the ***prescribing physician*** of the risks of the prescription medication, rather than the ultimate user or patient. This is the learned intermediary rule.

Breaking with this framework in the case at bar, the Court of Appeals for the Thirteenth District created what it termed "an exception" to this uniform rule. According to the appeals court, prescription drug companies engaging in direct-to-consumer advertising have a duty to warn consumers directly of potential risks associated with their products. *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476 (Tex. App. – Corpus Christi 2010, pet. granted).

In an attempt to depart even further from the mainstream, amici Texas Medical Association, Texas Medical Liability Trust and Texas Alliance for Patient Access (TMA) ask this Court for a wholesale rejection of the learned intermediary rule.[1] TMA contends such radical variance is warranted because the policy basis for the rule no longer exists, and because the analysis used in *Humble Sand & Gravel, Inc. v. Gomez*, 146 S.W.3d 170

[1] TMA's brief is hereinafter cited as "Br."

(Tex. 2004), supports imposition of a new cause of action. As explained herein, neither of these arguments have merit. The underlying premise for the learned intermediary rule is that prescription drugs are complex and vary in effect depending upon the circumstances of an individual user, and as such, patients can only obtain them from a physician. This bedrock foundation has not changed. It also is what sets prescription drugs apart from the sorts of ordinary chattel at issue in cases such as *Humble Sand.* Moreover, even if the *Humble Sand* analysis is applied here, such analysis counsels rejection of a duty to warn users directly. Indeed, as explained herein, rejecting the learned intermediary rule would create negative social, economic, and judicial consequences. Accordingly, this Court should reject TMA's request and adopt the learned intermediary doctrine.[2]

STATEMENT OF FACTS

Appellant Centocor manufactures the prescription drug Remicade, which the FDA has approved to treat Crohn's disease and rheumatoid arthritis. *Centocor*, 310 S.W.3d at 482. The FDA's approved package insert warns doctors that Remicade may in rare cases cause the development of a lupus-like syndrome. *Id.* All the testifying doctors in the case at bar agreed that "diagnosis of lupus-like syndrome can be difficult." *Id.* at 484. The package insert also instructs physicians that such syndrome dissipates as soon as the drug is discontinued. *Id.* There has been no claim in the instant case that Centocor's warnings to physicians about Remicade were inadequate.

[2] WLF also concurs with Centocor that no advertising exception is warranted.

In December 2001, Respondent Patricia Hamilton's gastroenterologist, Ronald Hauptman, M.D., prescribed three doses of Remicade to be administered at an infusion clinic over a six week period to treat a "moderate flare" of her Crohn's disease. *Id.* at 485-486. Respondent disputed Dr. Hauptman's testimony that he discussed the risks of using Remicade, including the risk of developing lupus-like syndrome. *Id.*

Respondent received her first infusion at Dr. Michael G. Bullen's clinic. Except to provide them with information about reactions that may occur during the infusion process, Dr. Bullen testified that he does not typically warn patients of a medication's side effects because the decision to take a prescription drug has already been made by the time individuals come to his clinic. *Id.* at 486. The clinic merely administers a drug that has been prescribed previously by another physician.

While receiving her first treatment, Respondent watched a videotape produced by Centocor that contained information about Remicade, including a disclaimer stating that if "you have any questions after watching this video, talk to your healthcare provider," and "[t]his video should not be used as a substitute for talking with your doctor." *Id.* at 488. While the disclaimer did not list lupus-like syndrome as a potential side effect, it did state that for Crohn's disease "[t]he safety and efficacy of therapy continued beyond a single dose have not been established." *Id.* It further stated that "[t]he safety and efficacy of therapy continued beyond three doses have not been studied." *Id.*

After the first infusion Respondent felt better, and after the second, Dr. Hauptmann performed a colonoscopy that showed her Crohn's disease was in remission.

Id. at 490. Respondent Hamilton reported feeling "much better" after the third infusion, and it is undisputed that her Crohn's disease is still in remission. *Id.*

In addition to her Crohn's disease, Respondent also suffered from rheumatoid arthritis. *Id.* at 485. In April 2002, rheumatologist Adriana Pop-Moody, M.D. prescribed Respondent the steroid prednisone and further infusions of Remicade for her arthritis. *Id.* at 491. While Dr. Pop-Moody instructed Respondent to slowly taper off her prednisone, "she stopped the medication too early" and suffered a severe arthritis flare. *Id.*

Overall, Dr. Pop-Moody prescribed, and Respondent took, fourteen more (for a total of seventeen) infusions of Remicade. *Id.* at 491-95. It was during Dr. Pop-Moody's treatment that Respondent began suffering symptoms of lupus-like syndrome. *Id.* As with Dr. Hauptmann, Respondent denied Dr. Pop-Moody's testimony that she advised Hamilton that Remicade could cause drug-induced lupus. *Id.* at 494.

ARGUMENT

I. Prescription Drugs Are Unique: Manufacturers Have A Duty To Warn The Physician

Product liability litigation arises only when a person is injured by a defective product. As a matter of general product liability law, the injured user or consumer may bring a claim against the manufacturer of the defective product that caused the injury. *See* Restatement (Second) of Torts § 402A (strict liability), § 388 (negligence).

Either a defect in the manufacturing or design, or inadequate warnings of the dangers attending its use can give rise to a defective product claim. *See* Restatement (Third) of Torts: Product Liability § 6 (b)(1-3) (manufacturing, design, inadequate

instructions or warnings). But, this framework generally has not been applied to certain products. Prescription drugs are the prime example.[3]

Prescription medicines are so complex and potentially dangerous that only a licensed physician, who can understand how such a drug may affect an individual, is permitted to dispense them. Accordingly, prescription drugs have traditionally been subject to different product liability standards:

> 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 drugs. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of ***many*** other ***drugs***, vaccines, and the like, many of which for this very reason ***cannot legally be sold except to physicians, or under the prescription of a physician***. . . . ***The seller of such products***, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, ***is not to be held to strict liability for unfortunate consequences attending their use***, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

Restatement (Second) of Torts § 402A, cmt. k (emphasis added). *See Centocor*, 310 S.W.3d at 516 ("Comment k to section 402A may provide a defense to a design defect

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[3] TMA inaccurately applies the general product liability principle to prescription drug consumers in its "General Rule" argument. Br. at 5 ("if the drug manufacturer knows or should know of potential harm to a user because of the nature of its product, the manufacturer must give an adequate warning"). Tellingly, both of the cases cited for this alleged conclusion concerned drug manufacturer communications directed to a ***prescribing physician*** – not the consumer. *See Bristol-Myers Co. v. Gonzales*, 561 S.W.2d 801, 804 (Tex. 1978) (inadequate warning to doctor), *Crocker v. Winthrop Labs.*, 514 S.W.2d 429, 433 (Tex. 1974) (doctor relied on statements to him by corporation).

claim").[4] *See also Hackett v. G.D. Searle & Co.*, 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (applying comment k).

Concomitantly, a manufacturer's duty to warn of foreseeable product risks runs to the prescribing physician, not the patient. Restatement (Third) of Torts: Product Liability § 6(d)(1). This legal principle is known as the learned intermediary rule. As aptly set forth by the American Law Institute,

> [t]he rationale supporting this "learned intermediary" rule is that ***only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative advantages and disadvantages of a given form of prescription-based therapy***. The duty then devolves on the health-care provider to supply to the patient such information as is deemed appropriate under the circumstances so that the patient can make an informed choice as to therapy.

Id. cmt. b. *See id.* ("prescribing health-care providers, when adequately informed by drug manufacturers, are able to assure that the right drugs . . . reach the right patients"); cmt. d ("When prescribing health-care providers are adequately informed of the relevant benefits and risks associated with various prescription drugs . . . they can reach appropriate decisions regarding which drug . . . is best for specific patients").

Both state and federal courts in Texas recognize this principle as the foundation for the learned intermediary rule. *See, e.g., Morgan v. Wal-Mart Stores, Inc.*, 30 S.W.3d 455, 462 (Tex. App. – Austin 2000, pet. denied) ("physician, relying on his medical

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[4] The court of appeals' recognition that prescription drugs may not be subject to ordinary strict liability conflicts with its rejection of the learned intermediary rule as both legal principles are based upon the same premise—only doctors prescribe such drugs because only they have the expertise and position to understand the drugs and the potential individual user.

training, experience, and knowledge of the individual patient, then chooses the type and quantity of drug to be prescribed."); *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607, 609 (Tex. App. – Waco 1993, writ denied) ("physician must use his comprehensive training and experience in conjunction with his knowledge of the individual patient in determining the suitability of a medication"); *see also Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974) (prescription drugs are "complex medicines, esoteric in formula and varied in effect"; "As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of the patient"); *Ebel v. Eli Lilly & Co.*, 536 F. Supp. 2d 767, 772 (S.D. Tex. 2008) ("In the case of prescription drugs, a patient does not have access to the medication absent a prescription from a physician, therefore a manufacturer need only warn the physician."), *aff'd in pertinent part*, 321 F. App'x. 350 (5th Cir. 2009). Indeed, in *Alm v. Aluminum Co. of America*, 717 S.W.2d 588, 592 (Tex. 1986), this Court recognized the learned intermediary rule and stated this premise: "only the doctor could understand the propensities and dangers involved in the use of a given drug [to an individual patient]," (citing *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863, 870 (Tex. Civ. App.- Corpus Christi 1973, writ ref'd n.r.e.)).

Naturally, in the absence of a prescribing physician this underlying principle does not apply; thus, the traditional duty framework governs and a drug manufacturer must directly warn the consumer. Restatement (Third) of Torts: Product Liability, § 6(d)(2). *See id.*, cmt. e ("Subsection (d)(2) recognizes that direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the

personal intervention or evaluation of a health-care provider."). Mass vaccine inoculation is the uniformly recognized example where a direct consumer warning is required. *Id. See, e.g., Reyes*, 498 F.2d at 1277 (drug manufacturer has duty to warn consumer where it knew or had reason to know oral polio vaccine would not be administered as prescription drug, but by mass vaccination)

The Court of Appeals recognized the foundation for the learned intermediary rule by citing *Gravis*, and it went on to "glean several rationales for applying 'the learned intermediary doctrine'": (1) "choice of which drugs to prescribe properly belongs to the doctor because prescription drugs are manufactured for administration only by a physician or other authorized person"; (2) "only a physician would understand the propensities and dangers involved"; (3) reluctance to interfere with the doctor-patient relationship because direct consumer warnings may contradict the physician's advice or disturb the patient in a way that hinders treatment; and (4) doctors are in a better position to warn patients than drug manufacturers. *Centocor*, 310 S.W.3d at 502-03. TMA contends that times have changed and these four rationales no longer apply; thus, TMA requests this Court to reject the learned intermediary rule. As shown below, TMA is wrong.

II. As Prescription Drugs Are Only Obtainable From A Physician, The Foundation Of The Learned Intermediary Rule Has Not Changed

TMA asks this Court to impose a new duty upon prescription drug manufacturers, requiring them to directly warn patients of the risks and benefits of their prescription drugs, thus establishing a new cause of action on behalf of patients for a manufacturer's

failure to warn. Br. at 4. In support of its novel claim, TMA argues that the Court should reject the learned intermediary rule because it is "an anachronistic legal doctrine," as the circumstances that allegedly informed its creation and supported its application no longer exist. Br. at 3-4 (alleging in the past "citizens were largely unsophisticated," doctors were the "exclusive source of health care information," and drug delivery system "depended solely" on the doctor to provide patient warnings).

Specifically, TMA argues that these changed circumstances undermine the four policy bases identified by the Court of Appeals. Not only are most of TMA's arguments inapposite, but the policy foundation underlying the learned intermediary rule has not changed from when it was adopted years ago. Accordingly, TMA's request that the Court impose a new duty on drug manufacturers should be denied.

A. Any Increase In Publicly Available Information About Prescription Drugs Does Not Change The Fact That Prescription Drugs Are Only Available From A Physician

As noted above, the Court of Appeals' first rationale for the learned intermediary rule is that the "choice of which drugs to prescribe properly belongs to the doctor because prescription drugs are manufactured for administration only by a physician or other person." *Centocor*, 310 S.W.3d at 502. To undermine this rationale, TMA contends that when the learned intermediary rule first arose both drugs and their information and/or warnings were conveyed to the patient only by the prescribing physician. Br. at 12-13. TMA argues that this is no longer true, because consumers today receive such information from "many different sources," including package inserts, the internet, medication guides, consumer medical information sheets and miscellaneous commercial

sources. Br. at 14-19. Therefore, TMA contends, applying the learned intermediary rule today would fail to hold manufacturers responsible for the information they provide outside the doctor-patient relationship. Br. at 12 ("the manner in which a drug is marketed may give rise to legal responsibilities is lost through application of the learned intermediary doctrine"); *id.* at 19 (learned intermediary rule "excuses the entire pharmaceutical industry from exercising ordinary prudence in the manner in which it provides drug information to the public"). This argument should be rejected for at least three reasons.

First, manufacturers have always advertised their prescription drugs directly to consumers. Victor E. Schwartz, et. al., Marketing Pharmaceutical Products in the Twenty-First Century: An Analysis of the Continued Viability of Traditional Principles of Law In the Age of Direct-to-Consumer Advertising, 32 Harvard J. of Law & Pub. Policy 333, 336-337, 349 (2009) (direct-to-consumer advertising "predates regulation of pharmaceuticals").

Second, ***public*** information about prescription drugs (as opposed to information obtained ***solely*** from a physician) is irrelevant to the learned intermediary rule because publication does not alter the principle that prescription drugs are manufactured for distribution only by physicians. *See In re Norplant Contraceptive Prods. Liab. Litig.*, 165 F.3d 374, 379 (5th Cir. 1999) (aggressive drug marketing did not create direct warning liability because "as long as a physician-patient relationship exists, the learned intermediary doctrine exists.").

Third, contrary to TMA's allegation, the learned intermediary rule does not permit manufacturers to escape liability for their product marketing. If a manufacturer provides inadequate information to a physician and causes him/her to prescribe a drug that injures a patient, the learned intermediary rule allows a finding of liability. *See, e.g., Crocker v. Winthrop Labs*, 514 S.W.2d 429, 433 (Tex. 1974) (liability for representation by company to doctor, reliance by doctor upon company representation, and harm results). *See also Alm*, 717 S.W.2d at 592 (inadequate or misleading warning to physician may create liability upon manufacturer for injuries sustained by consumer).

Further, TMA's argument casts too broad a net. It attempts to merge liability for marketing with general products liability. Specifically, a plaintiff must demonstrate an inadequate drug warning caused her injuries. *Pustejovsky v. Pliva, Inc.*, 623 F.3d 271, 276 (5th Cir. 2010) (plaintiff must show inadequate warning caused her doctor to prescribe drug); *Rolen*, 856 S.W.2d at 609 (plaintiff must show warning was defective and this failure to warn was producing cause of injury); *Cooper v. Bowser*, 610 S.W.2d 825, 831 (Tex. Civ. App. – Tyler 1980, no writ) (plaintiff must prove failure to warn was a producing cause of injuries). Thus the relevant drug information is limited to information that causes an injury-inducing drug to be prescribed that would not have been prescribed but for a deficiency in the information. Other statements made by a manufacturer are simply irrelevant to product liability litigation if they have no effect on prescribing practices. This is the case because a patient can only obtain prescription drugs from a licensed physician. In contrast, if a consumer is harmed after ingesting a non-prescription drug that a manufacturer's misleading advertisement caused him to

purchase and consume, the learned intermediary rule would not apply and the consumer has a cause of action directly against the manufacturer. *See* Restatement (Third) of Torts, § 6(d)(2) (manufacturer has duty to directly warn in absence of health-care provider). Accordingly, TMA's initial argument should be rejected.

B. An Allegedly More Educated Consumer Does Not Negate The Fact That Prescription Drugs Are Only Obtainable From A Physician

The second rationale identified by the Court of Appeals as supporting the learned intermediary rule is that "only a physician would understand the propensities and dangers involved." *Centocor*, 310 S.W.3d at 508. To attack this principle, TMA shifts its focus away from an alleged change in prescription drug marketing to a supposed change in the patient of today.

In particular, TMA claims that unlike the patients of the era when the rule was created, today's patients are no longer "too ignorant to understand the risks of drugs that are prescribed for their use" (Br. at 26); rather, they are now capable of "understanding their own healthcare needs and the drugs that are used to assist in treatment." Br. at 24. To support its patient-centered argument, TMA cites (i) federal action to provide patients with accurate general drug information when they obtain their medication, along with federal regulation of drug advertisements; and (ii) increased direct-to-consumer advertising by drug companies-"it is the height of hypocrisy [after spending on ads] to now allege that patients are either too ignorant or too dependent on their physician to discern and act on product safety information that is directed at them." Br. at 21-29. As with its first argument, this contention is in err and the Court should reject it.

Even assuming arguendo that TMA's factual contentions are correct,[5] these contentions are irrelevant because they mistakenly focus upon the knowledge of the patient rather than the knowledge of the doctor. The appeals court's second rationale underlying the learned intermediary rule is that only a physician can understand the propensities and dangers involved in the use of prescription drugs for a specific individual. The focus is thus the doctor, not the patient. *See In re Norplant*, 165 F.3d at 379 (possible increased role of patients in selecting drugs does not negate applying learned intermediary rule for a prescription drug—"Norplant is nevertheless a prescription drug").

Even assuming that patient education has increased since the adoption of the rule, this increase in knowledge is more than counteracted by the exponential progress in medical and pharmaceutical sciences during the same time period. Not only the type of prescription drugs available today, but also the potential side-effects of those drugs on a particular patient are vastly more complex than at any time in the past. In the case at bar, for example, all of the doctors testified that even determining whether the Plaintiff suffered from lupus-like syndrome was difficult. *See Centocor*, 310 S.W.3d at 484. Moreover, the facts here show that many patients either still do not understand drug-related information or simply choose to ignore it. Here, the Plaintiff failed to follow her doctor's instructions to slowly taper-off her prescription prednisone; rather, she just

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[5] Later in its brief, TMA states that "[n]umerous studies and empirical data support the conclusion that a substantial portion of the U.S. population has deficiencies in reading or computation skills, which impacts health literacy." Br. at 42.

stopped taking it at once. *Id.* at 491. Accordingly, the premise of the rule is as valid today as it was when created.

TMA's corporate hypocrisy argument is also inapposite. While manufacturers expend capital to advertise products to consumers, at best such ads can only prompt the consumer ***to request a drug from a physician***. In turn, the physician has the legal and medical obligation to use his expertise to evaluate a patient's drug inquiry in light of the complexities of the specific requested drug and the individual's health. Only if the doctor decides that such a drug is beneficial to a patient should he prescribe it. In other words, there is no hypocrisy because direct-to-consumer advertising does not purport to provide consumers with a full understanding of the complexities of the drug or individual health status; it merely prompts a conversation with ***a professional*** who can prescribe the drug if appropriate—***to whom the law currently requires full disclosure by the manufacturer***. The consumer cannot obtain the drug without a prescription.

TMA's reliance upon federal action to provide patients with accurate general drug information when they obtain their medication, along with regulation of drug advertisements to support repeal of the learned intermediary rule is likewise misplaced. In fact, courts recognize that limiting warning duties to physicians in accordance with the learned intermediary rule conforms the common law to the warning duties imposed by the FDA. *See Ellis v. C.R. Bard, Inc,* 311 F.3d 1272, 1287 (11th Cir. 2002) (per curiam); *Fane v. Zimmer, Inc.*, 927 F.2d 124, 129 (2d Cir. 1991); *Phelps v. Sherwood Med. Indus.*, 836 F.2d 296, 298-99 (7th Cir. 1987).

The federal government has determined that some medicines are so complex and their risks so acute that only a licensed physician can prescribe them. *See* 21 U.S.C. §353(b). For these medicines, in accord with the learned intermediary rule, federal law requires manufacturers to provide detailed and complex scientific data to prescribing physicians. *See* 21 C.F.R. § 201.57(c). Indeed, the FDA has recognized that this complex data is of "questionable" value to patients because it is "relatively inaccessible to consumers." 60 Fed. Reg. 42,581, 42,583 (Aug. 16, 1995).

Recently, the Texas Legislature recognized this congruity when it insulated drug manufacturers from failure-to-warn claims by creating a rebuttable presumption that a drug manufacturer is not liable for failure to warn if the physician warnings that accompanied a product were FDA-approved. *See* Tex. Civ. Prac. & Rem. Code §82.007(a). Therefore, acceptance, not rejection, of the learned intermediary rule would actually foster conformity with both federal and Texas policy.

C. The Kernel Of The Doctor-Patient Relationship Remains Unchanged

Thirdly, TMA argues that the doctor-patient relationship of today is no longer as insulated from outside interferences as it was when the learned intermediary rule was fashioned. Br. at 33 ("The citadel that once was the physician-patient relationship no longer exists."). TMA contends that managed care, increased regulation, and manufacturers' ads all interfere with the doctor-patient relationship. Br. at 30-34. This argument is in err, and this Court should reject it.

While it may be true that there have been changes on the periphery of the doctor-patient relationship, such as increased spending on ads by companies or differences in

how doctors are paid, the kernel of the physician-patient relationship remains unchanged. That is, a physician still retains the vital role of prescribing a drug to a patient based upon the doctor's scientific and medical expertise, and the knowledge of the individual patient's circumstances. Neither managed care, nor antitrust regulations, nor even manufacturer advertisements change this. TMA's only response is to bemoan that manufacturers' advertising causes doctors to prescribe drugs "often despite physician ambivalence about treatment choice." Br. at 32. Yet again, this argument is misplaced. It assumes a physician does not independently weigh the individual risks and benefits before prescribing a requested drug. That is simply not the case. Or, at the very least, it never should be. The physician has both a moral and legal duty to make such an evaluation. *See* Tex. Civ. Prac. & Rem. Code § 74.104; *see also In re Norplant*, 165 F.3d at 379 (possible increased role of patients in selecting drugs does not negate applying learned intermediary rule for a prescription drug—"Norplant is nevertheless a prescription drug").

D. Doctor's Remain In The Best Position To Warn Patients

TMA's final policy argument is that doctors are no longer in a better position than drug manufacturers to warn patients of the side effects of prescription medications. Br. at 34-37. TMA alleges that manufacturers today spend large sums to communicate with patients, while doctors both lack the training for drug "safety issues," and are "overwhelmed by the mass of information to which they are exposed regarding the benefits and risks of proposed treatments." Br. at 35. The premise of this argument is simply false, and as such should be rejected.

As when the learned intermediary rule was created, doctors remain in the best position to warn their patients of a drug's potential side effects. The Court recognized this in *Humble Sand*:

> The rationale for this "learned intermediary" rule is not that a direct warning from manufacturers to patients is infeasible, in the practical, physical sense of that word, but that ***it is better for the patient for the warning to come from his or her physician***.

146 S.W.3d at 190. (emphasis added). A doctor knows a patient's medical history and uses his expertise to prescribe a drug appropriate for each individual. Increased direct-to-consumer advertising can never serve as a substitute because it does not purport to be based on that knowledge/expertise.

If, as TMA alleges, doctors today are not up to the task of prescribing drugs because of a lack of training regarding those drugs, it is the medical academy, not the manufacturer, that is deficient. As aptly stated by the Chief Judge Schell, "if any physician allowed himself to become a mere conduit for Wyeth's materials, then it is the physician who is responsible." *In re Norplant Contraceptives Prods. Liab. Litig.*, 955 F. Supp. 700, 706 (E.D. Tex. 1997), *aff'd* 165 F.3d 374 (5th Cir. 1999).

If doctors are truly overwhelmed by the amount of drug data they receive and lack the training to understand it, then patients would be even more disadvantaged if the Court were to shift to them the burden of trying to absorb the increased data. This would be the result of eliminating the learned intermediary doctrine: To protect themselves from litigation, drug companies would provide patients with the same information that they currently provide to doctors. If a professional with eight years of college and medical

school, and multiple years of internships and residencies cannot properly analyze the risks and benefits of today's prescription drugs, the prospects are dim that an ordinary person with no medical training can ever hope to deal with these complexities. TMA should not be allowed to shift a physician's burden to his patients.

III. *Humble Sand* Factors Are Not Applicable, But If They Were They Support A Duty To The Prescribing Physician, Not The Patient

For its final contention, TMA attempts to confuse traditional product liability law with the unique circumstances of prescription drugs by arguing that the factors set forth in *Humble Sand*-for determining whether to recognize a duty to warn- should be applied here and counsel creation of a new duty for drug manufacturers to provide warnings directly to consumers. Br. at 37-44. The weakness of this argument is betrayed by its brevity. These factors are inapplicable to prescription drugs. Moreover, even if they were applicable, they do not counsel creation of a new duty.

A. Prescription Drugs are Unique: Chattel Factors do not apply

As explained above, it is true that "generally" a product manufacturer has a duty to warn a user or consumer. *See* Br. at 37-38. TMA also correctly notes that *Humble Sand* identified six policy factors for use in determining whether a manufacturer owes a duty to warn an ultimate user when an intermediary is present. Br. at 38. TMA's request to apply these factors here should be rejected because this is not a general chattel case like *Humble Sand*; rather, this litigation concerns prescription drugs and unique doctor-patient relationships.

Humble Sand concerned whether a supplier of flint for abrasive blasting had a duty to warn its customers' employees that inhalation of silica dust could be fatal and that they should wear protective hoods when using the flint. *Humble Sand*, 146 S.W.3d at 172-73. The companies that purchased the flint for their employees' use were well aware of the dangers but chose not to share that knowledge with their employees. The Court identified six factors as relevant to determining whether, despite the existence of an intermediary between the supplier and the employees, a duty should be imposed on the supplier to provide a warning directly to the employees: (1) the likelihood of serious injury from the lack of warning; (2) the burden on the supplier to provide the warning; (3) the feasibility and effectiveness of a warning; (4) the existence and effectiveness of other protections; (5) whether the purchasing employers could be relied upon to warn their own employees; and (6) the social utility of requiring suppliers to provide warnings directly to end users. *Id.* at 192-94.

The Court derived these factors from two sources. *Id.* at 191. First, the Court cited the traditional considerations used to evaluate any decision whether to recognize a common law duty. *Id.* at 182. And, second, the Court consulted the American Law Institute's provisions and comments concerning the potential existence of a chattel manufacturer's duty to an end user in the presence of an intermediary. *Id.* at 186-91 (citing Restatement (Second) of Torts § 388 and cmt. n, along with Restatement (Third) of Torts § 2(c) and cmt. i).

Unfortunately for TMA, as explained by the American Law Institute, these factors do not apply to prescription drugs because they are a special product category that is not subject to the same liability structure as ordinary chattel such as flint:

> The rules set forth in this Section establish separate standards of liability for manufacturing defects, design defects, and defects based on inadequate instructions or warnings. They are generally applicable to most products. Standards of liability applicable to special product categories such as prescription drugs and used products are set forth in separate sections in Topic 2 of this Chapter.

Restatement (Third) of Torts, § 2: Product Liability, cmt. a; *see id.* cmt. k ("Prescription drugs and medical devices are also capable of causing allergic reactions, but they are governed by § 6"); *id.* § 6 (liability for seller of prescription drugs); *see also* Restatement (Second) § 402A, cmt. k (prescription drugs are subject to different liability standards than ordinary chattel). *Accord Vitanza v. Upjohn Co.*, 778 A.2d 829, 845 (Conn. 2001) (refusing to apply ordinary duty factors to prescription drugs because "the two doctrines are not analogous"—sophisticated user doctrine "may be applied to any type of product," whereas the learned intermediary doctrine is limited to "the medical field" (citing Restatement (Second) of Torts, § 402A, cmt. k)).

In congruity with the American Law Institute, Texas precedent recognizes that the physician-patient relationship involving prescription drugs is unique and thereby sets it apart from general product liability principles. *See, e.g.*, *Rolen*, 856 S.W.2d at 609 ("unique nature of this relationship prevents application [of learned intermediary doctrine] to other areas"). Even the Court of Appeals recognized this fact. *Centocor*, 310 S.W.3d

at 516 ("Comment k to section 402A may provide a defense to a design defect claim [for prescription drugs]").

Because the safeguards in place in the prescription drug process--namely the individual doctor-patient relationship and the fact that the product is only available from a licensed physician-do not exist in the ordinary chattel context (such as the flint at issue in *Humble Sand*), the Court should not apply the general intermediary duty factors to the case at bar.

B. *Humble Sand* Factors Do Not Counsel Creation Of Duty To Consumer

Even if the Court were to apply the *Humble Sand* factors, those factors do not counsel creation of a duty upon drug companies to provide warnings directly to consumers. In making this determination, it is important to note that "these factors must be applied to the [drug manufacturing] industry as a whole, not merely to [the parties in the case at bar]." *Humble Sand*, 146 S.W.3d at 192.

1. There is not a significant likelihood that serious injury could be avoided if the Court creates a new manufacturer's duty to warn consumers

TMA contends this factor supports creation of a duty to warn because, it alleges, the current "system already relies to a considerable extent on the drug industry to provide direct information to consumers." Br. at 39. TMA asserts that serious adverse drug events could be reduced if companies were required to warn users. *Id.* TMA is wrong; this factor does not counsel creation of a new duty.

TMA's premise is flawed. Today's health care system does not rely upon drug manufacturers to provide information to consumers; rather, it relies upon them to provide

information to physicians. Moreover, TMA cites no evidence to support its assertion that serious adverse drug events "would be further reduced" if companies were required to warn users directly. Instead, as Texas courts have recognized, requiring manufacturers to provide warnings to consumers would do nothing to decrease injuries (because users would fail to comprehend the warnings) or might actually harm the patients by scaring them from taking a drug that is medically indicated. *See, e.g., Gravis,* 502 S.W.2d at 870 ("some disclosures may so disturb the patient that they serve as a hindrance to needed treatment"); *cf. Wilson v. Scott*, 412 S.W.2d 299, 301 (Tex. 1967) (physicians are granted some discretion in deciding what to disclose because "some disclosures may so disturb the patient that they serve as hindrances to needed treatment"); *Morgan*, 30 S.W.3d at 467 (imposing duty to warn upon pharmacist would unnecessarily interfere with doctor-patient relationship; patient would be overwhelmed by warning and might not take medication).

As noted above, that even a doctor's warning can prove ineffective was demonstrated in the case at bar, where the plaintiff failed to follow her doctor's instructions to slowly taper-off her prescription prednisone and simply stopped taking it. *Centocor*, 310 S.W.3d at 491. If a patient misunderstands or ignores a warning conveyed directly by the doctor with whom she maintains a professional relationship, it is likely that a complex written warning from a distant drug company would be even less effective. Accordingly, there is no evidence that serious injuries would be avoided if a drug manufacturer were required to provide patients with direct warnings of all potential side

effects of its products. *See Humble Sand*, 146 S.W.3d at 192 (evaluating factor and noting "there is some suggestion at least that the warnings would have been ineffectual").

"[A] prerequisite to imposing a duty to warn is a significant likelihood that serious injury be avoided." *Id.* at 196. That has not been shown here. As such, this factor counsels rejection of a new duty for drug manufacturers.

2. Imposing upon manufacturers a duty to warn consumers directly would place a substantial burden upon the prescription drug distribution network

TMA alleges that a new duty is not burdensome because federal law currently requires manufacturers to provide correct information in its labels, medication guides and advertisements. Br. at 40. This argument is misplaced because it focuses on general federal requirements for all patients rather than individual patients.

Under current federal and state law, drug companies supply prescription drugs and their complex scientific data to physicians. A doctor then evaluates each patient and uses his expertise to determine an appropriate drug for the patient's medical condition. Accordingly, a drug company does not know the identity of each individual consumer of its prescription medication. If this Court were to create a new duty, manufacturers would be burdened with inventing new structures to determine each type of patient who receives its drugs so it could then provide them with a warning. *Cf. Isovolta Inc. v. Protrans Int'l, Inc.*, 780 F. Supp. 2d 776, 780 (S.D. Ind. 2011) (*Humble Sand* counsels against recognizing a sprinkler manufacturer's duty to warn consumers where most products sold through distributors and installed by professionals; manufacturers "should not have a

duty to create a 'placement division' whose function is to ensure proper use of its product").

Depending upon the particular drug, the burden of identifying users and providing them with warnings could be onerous. Moreover, it would accomplish little to impose upon manufacturers the duty to ensure that consumers, when they receive their prescriptions, are given written materials that spell out all warnings in detail. Evidence suggests that consumers are incapable of comprehending most such material, and it would be of little value unless tailored to the specific needs and medical condition of each patient.

3. A manufacturer's warning would be neither feasible nor effective

For this factor, TMA contends that direct written company warnings to users would be "very effective" because consumers currently find the information they get with their medication useful. Br. at 41-42. TMA is wrong. As noted above, requiring detailed manufacturer warnings would provide no benefit because users would fail to comprehend them, and might actually harm the patients by scaring them from taking the drugs. *See Gravis*, 502 S.W.2d at 870; *cf. Wilson*, 412 S.W.2d at 301; *Morgan*, 30 S.W.3d at 467. Also, TMA admits that "[n]umerous studies and empirical data support the conclusion that a substantial portion of the U.S. population has deficiencies in reading or computation skills, which impacts health literacy." Br. at 42. Accordingly, complex written disclosures about a drug would not be "very effective."

This factor also counsels rejection of a new duty to warn because the feasibility of a direct drug company warning to consumers is questionable at best. As explained above,

the manufacturer does not know the identity of an individual consumer of its prescription medication. And, even if the identity of the patient were known, the appropriate warning regarding potential risks would be different for each person due to variances in medical history. TMA has failed to suggest any feasible means by which manufacturers could meet directly with patients and thereby attempt to replicate the individualized medical advice that is the hallmark of the doctor-patient relationship.

4. Physicians reliably warn their patients about drug side effects

This factor strongly favors the current system. Reliability is firmly established here: a physician has both a moral and legal duty to warn patients of the potential effects of a drug he prescribes. *Wilson*, 412 S.W.2d at 301; *Gravis*, 502 S.W.2d at 870; *see In re Norplant*, 955 F. Supp. at 705. Indeed, this Court has recognized that "[i]n this situation, it is reasonable for the manufacturer to rely on the intermediary to pass on its warnings." *Alm*, 717 S.W.2d at 592. The reliability of doctors in conveying warnings to their patients stands in sharp contrast to the facts of *Humble Sand*, where the abrasive blasting operators "routinely neglected safety measures and did not warn employees." *Humble Sand*, 146 S.W.3d at 193.

TMA implicitly recognizes the reliability of a doctor's warning by failing to discuss it. Instead, TMA focuses on the print material patients receive when they pick up their drugs from the pharmacy. In particular, TMA alleges that because "[n]umerous studies and empirical data support the conclusion that a substantial portion of the U.S. population has deficiencies in reading or computation skills, which impact health literacy," the current system of warning is imperfect. Br. at 42. Besides being irrelevant, this

allegation actually supports the current system. If TMA is correct that people today have deficient reading skills, then having a professional explain the side effects of a drug in person is more important than ever. A new manufacturer's duty to warn would merely barrage consumers with complex information they would have difficulty understanding.

5. Existence and efficacy of other protections

With respect to this factor TMA merely asserts that it warrants "very little elaboration" and that the best warning system would include drug company warnings. Br. at 43-44. TMA is wrong; this factor counsels retention of the current system.

In discussing this factor, *Humble Sand* noted that the "existence of a comprehensive regulatory scheme to protect against harm weighs against imposing a common law duty to accomplish the same result if the scheme affords significant protections." *Humble Sand*, 146 S.W.3d at 193-94. This is precisely the case here. As discussed above, current federal and state law require drug companies to provide doctors with detailed information about prescription drugs. In turn, physicians select the appropriate drugs for their patients and provide warnings of potential side effects. Indeed, *Gravis* explicitly relied upon this structure when it adopted the learned intermediary rule:

> The entire system of drug distribution in America is set up so as to place the responsibility 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.

502 S.W.2d at 870. As a result, this factor warrants maintaining the current system.

6. There is little social utility in requiring drug companies to provide warnings to end users

For the last of the six factors set out in *Humble Sand*, TMA merely re-argues its tired contention that a drug manufacturer must be held responsible for the marketing material it produces. Br. at 44 (as Centocor created the videotape in this case it must be held responsible for its substance). As explained above, drug manufacturers are already held responsible, under the learned intermediary rule, to provide doctors with detailed information about the risks and benefits of all prescription drugs. There is little social utility in requiring manufacturers to do an end-run around treating physicians by providing the same information to patients as well. Imposing a new duty to warn on manufacturers fails to take into account the unique nature of the doctor-patient relationship.

In reality, this factor strongly counsels adherence to the learned intermediary rule because rejecting it would have severe negative consequences. In addition to the ramifications discussed previously (e.g., burdens on patients who likely will not comprehend the new warnings; burdens on manufacturers who must supply the warnings; and burdens on doctors whose relationships with patients may be undermined) creation of a new duty would necessarily result in a burden on the judicial system. In light of the pharmaceutical industry's perceived deep pockets the position espoused by TMA would open the floodgates to a sea of litigation. Courts would also have to address numerous new legal issues, including the appropriate contents of warnings. The medical community would face considerable uncertainty while courts sorted out such issues as

which risks must be included in a manufacturer warning and the level of specificity required for each such risk.

Finally, it is important to note that imposing a new duty here would shift liability from the doctor to the manufacturer, which would "effectively become the insurer for every patient to whom the drug is prescribed, regardless of the actions of the prescribing physician." *Rolen*, 856 S.W.2d at 609. This negative consequence can be avoided by maintaining the learned intermediary rule, which still imposes a substantial duty on manufacturers to warn of risks but does so by requiring that warnings be provided to doctors-thereby ensuring that patients are informed of potential risks in the manner best calculated to promote patient understanding.

CONCLUSION

For the reasons stated herein, Washington Legal Foundation respectfully asks this Court to adopt the learned intermediary rule in the State of Texas. WLF further joins Centocor in requesting a reversal of the Court of Appeals and trial court's judgments, and asks the Court to reject any alleged direct-to-consumer advertising exception to the learned intermediary rule.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 2d day of December, 2011, I caused true and correct copies of the forgoing BRIEF OF AMICUS CURIAE WASHINGTON LEGAL FOUNDATION IN SUPPORT OF PETITIONER to be served on the following parties by electronic service:

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