Supreme Court of Tennessee
in Nashville

FREDDIE JONES, LUKE JONES, TRENNA JONES, RALPH JONES, LAVON JONES, and JIMMY FREEMAN, as Surviving Children of ELNORA JONES, Deceased,	)	
Plaintiffs/Petitioners,	)	
v.	)	Case # M2013-00769-SC-R23-CQ
ABBOTT LABORATORIES,	)	
Defendant/Respondent.	)	

On Certified Questions from the United States District Court
for the Western District of Tennessee, Western Division
Case #2:07-cv-02120-WGY

BRIEF OF WASHINGTON LEGAL FOUNDATION AND ALLIED EDUCATIONAL FOUNDATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

INTERESTS OF *AMICI CURIAE*

The interests of *amici curiae* are more fully set forth in the accompanying motion for leave to file this brief. In brief, the Washington Legal Foundation (WLF) is a public interest law and policy center with members and supporters in all 50 States, including Tennessee residents who are involved in the healthcare field. WLF engages in litigation and other advocacy to defend economic liberty and free enterprise principles. To that end, WLF has appeared before state and federal courts throughout the country to oppose the unwarranted expansion of tort liability that fosters excessive litigation and impedes economic development. *See, e.g., Centocor, Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012).

The Allied Educational Foundation (AEF) is a non-profit charitable foundation based in Englewood, New Jersey. Founded in 1964, AEF is dedicated to promoting education in diverse areas of study, such as law and public policy, and has appeared as *amicus curiae* in state and federal courts on a number of occasions.

INTRODUCTION AND SUMMARY OF ARGUMENT

Petitioners request that the Court respond to certified questions submitted to it by the U.S. District Court for the Western District of Tennessee, and in doing so to eliminate Tennessee's longstanding adherence to the learned intermediary doctrine. They make this request despite: (1) the absence of any indication from the Court that it is dissatisfied with the doctrine (to which it has adhered for 20 years) or that the doctrine has led to unjust verdicts in any Tennessee courts; (2) the overwhelming support for the doctrine from courts throughout the nation; and (3) the absence of any evidence that application of the doctrine to Petitioners will prevent them from asserting a failure-to-warn claim in the district court.

Even if the Court were inclined to revisit the leaned intermediary doctrine, Petitioners have not demonstrated that this case presents an appropriate vehicle for doing so. Most importantly, responding to the certified questions – which ask whether Tennessee recognizes a direct-to-consumer-advertising exception to the learned intermediary doctrine and whether Tennessee follows § 6(d)(2) of the Restatement (Third) of Torts – will do little to assist the district court in resolving this case. Although Respondent has engaged in direct-to-consumer advertising for Humira, there is no possible causal relationship between those advertisements (and their allegedly inadequate health warnings) and Elnora Jones's decision to take Humira because there is no evidence that she ever saw or relied upon the advertisements. Moreover, the Restatement (Third) of Torts fully embraces the learned intermediary doctrine and does not recognize any exceptions to the doctrine that are relevant to this case. Accordingly, a decision by this Court to adopt § 6(d)(2) would not cause the district court to reconsider its determination that Tennessee law does not recognize the exceptions to the doctrine asserted by Petitioners.

Should the Court decide to answer the certified questions, *amici* urge the Court to reaffirm its longstanding commitment to the learned intermediary doctrine. Applying that doctrine, the highest courts of at least 36 States (including Tennessee) have held that a prescription drug manufacturer fulfills its duty to warn consumers regarding its product's risks by providing adequate warnings to the treating physician (the "learned intermediary"), whose prescription is necessary before the patient can gain access to the drug. Those courts have recognized that the treating physician is far better positioned than the manufacturer to evaluate a drug's risks and benefits for the patient, because only (s)he has access to the patient's complete medical history. Accordingly, the courts have recognized that patients are best served when they

receive health warnings directly from a well-informed physician (who owes his/her patients an informed consent obligation) rather than from the manufacturer.

Contrary to Petitioners' assertions, the learned intermediary doctrine does not absolve a manufacturer of its responsibility to use reasonable care to prevent injury to consumers of its products. The doctrine requires drug manufacturers to provide adequate safety warnings to the treating physician. Indeed, in this case Petitioners have alleged that Respondent's warnings to the treating physician were inadequate, and the district court held that questions of fact required it to deny Respondent's summary judgment motion on that issue. The doctrine simply operates to ensure that safety warnings are conveyed in the manner (*i.e.*, directly to the doctor) most likely to protect the patient's health.

The doctrine also strengthens the doctor-patient relationship by ensuring that patients look to their doctors for detailed information regarding the pros and cons of prescribing a specific drug. If third parties (such as drug companies or pharmacists) are required by tort law to provide potentially conflicting warning directly to consumers, a consumer may be less willing to accept the advice of his doctor, the person best positioned to evaluate risks and benefits of various treatment options in light of the patient's medical history. Finally, the doctrine takes into account the difficulty manufacturers would face in identifying product users if required to provide warnings directly to those users.

Petitioners ask alternatively that the Court rule that the learned intermediary doctrine does not apply when the drug in question has been marketed directly to consumers. Petitioners argue that the Court should reconsider its adoption of the doctrine in *Pittman v. Upjohn Co.*, 890 S.W.2d 425 (Tenn. 1994), because, they assert, drug companies did not begin advertising

prescription drugs directly to consumers until several years after that decision. The factual premise for that argument is incorrect; widespread direct-to-consumer (DTC) advertising of prescription drugs began in 1985 and was a well-recognized practice by the time that *Pittman* adopted the learned intermediary doctrine in Tennessee. More importantly, the exception urged by Petitioners ignores that patients cannot obtain Humira and similar drugs without a doctor's prescription, and thus a rule ensuring that the doctor is well-informed also ensures that DTC advertising will not cause the drugs to be dispensed to a patient for whom they are not appropriate. Indeed, the form of the DTC exception urged by Petitioners is far broader than the exception recognized by New Jersey, the only State that has recognized such an exception. Petitioners' exception is premised on their belief that causation is conclusively presumed whenever a manufacturer's DTC advertising allegedly fails to provide sufficiently broad warnings – even when, as here, the patient never saw the advertising and does not allege that she relied thereon. Such a presumption is contrary to well-established Tennessee common law and wholly ignores the role that the prescribing physician plays in determining medical treatment. Finally, because all brand-name drug companies use DTC advertising as part of their promotional efforts, a DTC "exception" to the learned intermediary doctrine would eviscerate the doctrine in all cases not involving generic drugs.

Even less appropriate is the other exception requested by Petitioners: that the learned intermediary doctrine be deemed inapplicable whenever the treating physician has received compensation from the manufacturer for conducting clinical trials of the drug in question. That exception has not been recognized by the highest court of *any* State, with good reason. Such compensation is a well-accepted part of sound medical practice, provided only that doctors are

not paid in excess of the fair market value of their services. This case presents no occasion to closely examine payments for clinical trials, because the evidence indicates that Elnora Jones was not enrolled in a Humira "HERO" study and thus that her treating physician received no compensation from Respondent as a result of his decision to prescribe Humira. In any event, current law can adequately address cases in which the evidence demonstrates that the treating physician prescribed a drug in return for a kickback from the manufacturer. In such cases, the patient can seek to demonstrate that the manufacturer's kickback likely clouded the doctor's understanding of the drug's risks and benefits and thus that the manufacturer failed to provide an adequate warning to the doctor.

In urging the Court to adopt § 6(d)(2) of the Restatement (Third) of Torts, Petitioners have inaccurately portrayed that provision. Far from accepting wholesale exceptions to the learned intermediary doctrine, § 6(d) of the Restatement (Third) strongly reaffirms the doctrine as currently accepted by the vast majority of States. The Restatement (Third) was released in 1998 at a time when some ALI members were advocating creation of a DTC advertising exception to the learned intermediary doctrine and just a year before the New Jersey Supreme in 1999 recognized such an exception. The Restatement took note of that position, but Respondents are incorrect in asserting that the Restatement said that DTC advertising "would trigger" an exception to the doctrine under § 6(d)(2). To the contrary, the Restatement said that it "leaves to developing case law" whether, and to what extent, a DTC advertising exception should be recognized. Restatement (Third) of Torts: Products Liability, § 6, cmt. e. In the 14 years since the New Jersey decision was handed down, the verdict of "developing case law" has been loud and clear: no State has followed New Jersey's lead in accepting a DTC advertising

exception, and numerous courts have rejected it.

Under § 6(d)(2), a drug manufacturer does not fulfill its duty to warn even when it provides adequate instructions and warnings to health-care providers, if it "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." A doctor or other health-care provider will, or course, always "be in a position to reduce the risks of harm" if (s)he deals individually with the patient, knows the patient's medical history, and can decline to write a prescription if (s)he determines that the drug in question is not medically indicated. Accordingly, the language of § 6(d)(2) makes clear that that provision does not kick in simply because the drug manufacturer has engaged in DTC advertising or because (unlike in this case) a patient responds to the advertising by requesting that the drug be prescribed to him. In those situations, the doctor would still "be in a position" to warn the patient of all potential risks and to decline to write the prescription if not medically indicated. In sum, should the Court decide to adopt § 6(d) of the Restatement (Third) of Torts, it should make clear that that provision does not entail a modification of Tennessee's longstanding acceptance of the learned intermediary doctrine.

ARGUMENT

I. THE COURT SHOULD DECLINE TO EXERCISE ITS DISCRETION TO ANSWER THE CERTIFIED QUESTIONS

The U.S. District Court for the Western District of Tennessee certified two questions of law to the Court:

1. Does Tennessee law recognize exceptions to the learned intermediary doctrine when prescription drug companies advertise their products directly to consumers or pay physicians to prescribe their drugs?

2. Does Tennessee follow section 6(d)(2) of the Restatement (Third) of Torts:

> Products Liability, which mandates that pharmaceutical companies warn patients directly when healthcare providers are poorly positioned to reduce the risk of harm to patients taking prescription drugs?

The Court's exercise of jurisdiction over questions of law certified by a federal court is discretionary. Tenn. Sup. Ct. R. 23, § 1. The Court should exercise its discretion to decline to answer the two certified questions in this instance. In particular, answering the certified questions is unlikely to provide meaningful assistance to the district court in resolving the case that gave rise to the certified questions.

As explained by the district court in its Order of Certification, Petitioners (the surviving children of Elnora Jones) seek to recover from Respondent Abbott Laboratories all damages allegedly caused by Humira, a drug manufactured by Abbott. Petitioners contend that Abbott breached its duty of care by failing to provide an adequate warning about the risks of lymphoma associated with taking Humira. Petitioners allege that their mother developed lymphoma as a result of the Humira prescribed for her by her doctor to treat the symptoms of severe rheumatoid arthritis. In its motion for summary judgment, Abbott argued that it provided an adequate warning to Jones's rheumatologist, Dr. Adams, and that that warning was sufficient as a matter of law under the learned intermediary doctrine to meet its duty of care. Order at 6-8. Petitioners contended that the learned intermediary doctrine was inapplicable because: (1) Abbott promoted Humira by means of DTC advertising; and (2) Dr. Adams allegedly received payments from Abbott in connection with clinical trials of Humira. *Id.* There was no evidence in the district court that Jones ever saw or relied on DTC advertising for Humira or that Dr. Adams received any compensation from Abbott in connection with his treatment of Jones.

Relying on this Court's *Pittman* decision, the district court held that the learned

intermediary doctrine applied, and it declined to recognize any exceptions to the doctrine under the facts of this case. *Id.* at 10. It nonetheless declined to grant Abbott's summary judgment motion, finding that there were disputed issues of fact regarding the adequacy of Abbott's warning to Dr. Adams. Although the district judge *already decided* (in Abbott's favor) the issues of law that are the subject of the two certified questions, he nonetheless certified the questions. He reasoned that because he would not be trying the case – it had been assigned to him temporarily as a visiting judge who normally sits on the federal bench in Massachusetts – the judge who ends up trying the case might disagree with his resolution of those questions and thus might welcome guidance from this Court. *Id.*

The district court's recitation of the underlying facts makes plain the inadvisability of a response by this Court to the certified questions. In particular, Petitioners' contention that the learned intermediary doctrine is inapplicable due to alleged payments from Abbott to Dr. Adams is heavily dependent on the facts of this case. As the Court has repeatedly explained, "Rule 23 permits consideration of questions of law only, not questions of fact or controversies as a whole." *Seals v. H&F Inc.*, 301 S.W.3d 237, 241 (Tenn. 2010); *Renteria-Villegas v. Metropolitan Gov't of Nashville and Davidson Country*, 382 S.W.3d 318, 320 (Tenn. 2012). Petitioners do not contend that *any* payment from a drug company to a doctor categorically prevents the company from *ever* asserting the learned intermediary doctrine with respect to prescriptions written by that doctor, but rather that the Court should create an exception to the doctrine when, as allegedly occurred in this case, the drug company makes substantial and "pervasive" payments. Pet. Br. 18-21. Accordingly, the first certified question can only be viewed as: (1) an effort to persuade the Court to make findings of fact regarding the extent of

Abbott's payments to physicians (findings that are impermissible under Rule 23); or (2) an effort to persuade the Court to decide the first certified question on the basis of hypothetical facts on which the parties do not agree, a decision that would be too fact-specific to provide meaningful guidance to the federal courts.

It would be equally inappropriate to use this case as a vehicle for considering whether to create a DTC advertising exception to the learned intermediary doctrine. Although Abbott has engaged in DTC advertising for Humira, there is no possible causal relationship between those advertisements (and their allegedly inadequate health warnings) and Jones's decision to take Humira because there is no evidence that she ever saw or relied upon the advertisements. If the Court were inclined to address the issue, it would be far preferable to do so in the context of a case in which a manufacturer's advertising at least arguably played a role in the plaintiff's injury. Anything the Court could say in this case about potential manufacturer liability for inducing a patient to "demand" that her doctor prescribe a specific drug would have little relevance to the district court's ultimate decision in a case in which manufacturer advertising indisputably played no role.

Moreover, there is little reason for the Court to revisit the learned intermediary doctrine. The Court's 1994 *Pittman* decision adopted the doctrine as part of Tennessee law. The Court reaffirmed its commitment to the doctrine just two years ago in *Nye v. Bayer Cropscience, Inc.*, 347 S.W.3d 686 (Tenn. 2011). The Court said that it did not "quarrel with" the proposition that a prescription drug manufacturer's duty to warn "is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use." *Id.* at 703. It deemed the learned intermediary doctrine "an understandable exception" to the general rule

requiring manufacturers to provide warnings directly to ultimate users. *Id.* Petitioners have supplied no reason to conclude that the current tort system is providing inadequate protection for Tennessee citizens who take prescription drugs. For example, they have provided no evidence that physicians are not fulfilling their responsibilities to inform their patients of both benefits and risks before prescribing medications. Nor have federal courts applying Tennessee law had significant difficulty in ascertaining the scope of a drug company's duty to warn. *See, e.g., Jacobs v. E.I. du Pont de Nemours & Co.*, 67 F.3d 1219 (6th Cir. 1995).

The district court is correct that this Court has not yet determined whether Tennessee follows § 6(d) of the Restatement (Third) of Torts. But that issue is of limited importance because the Restatement (Third) of Torts fully embraces the learned intermediary doctrine and does not recognize any exceptions to the doctrine that are relevant to this case. *See* Restatement (Third) of Torts, Product Liability § 6, cmt. b (learned intermediary is retained because "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."). Accordingly, a decision by this Court to adopt § 6(d)(2) would not cause the district court to reconsider its determination that Tennessee law does not recognize the exceptions to the doctrine asserted by Petitioners.

II. THE LEARNED INTERMEDIARY DOCTRINE IS ACCEPTED BY VIRTUALLY ALL STATES AND FURTHERS IMPORTANT HEALTHCARE GOALS

Should the Court decide to answer the certified questions, *amici* urge the Court to reaffirm its longstanding commitment to the learned intermediary doctrine. The doctrine serves numerous beneficial purposes. In particular, it ensures that medical patients are appropriately informed of the risks and benefits of prescription drugs before they agree to take the drugs, and

that the information comes from the individual – the patient's treating physician – best positioned to provide the information. As the Court explained in *Nye*:

> This special standard for prescription drugs is an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products. Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, and individualized medical judgment bottomed on a knowledge of both patient and palliative.

Nye, 347 S.W.3d at 703-04 (quoting *Dooley v. Everett*, 805 S.W.2d 380, 386 (Tenn. App. 1990)).

A. The Doctrine Continues To Receive Virtually Unanimous Support by Courts Across the Nation

Petitioners would have the Court believe that *Pittman* and *Nye* are somehow out of step with a nationwide trend against acceptance of the learned intermediary doctrine. Not true. The "trend" identified by Petitioners consists of a single decision from the West Virginia Supreme Court of Appeals that has been followed in no other State. *Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899 (W. Va. 2007).

Most recently, the Texas Supreme Court unanimously rejected a challenge to the learned intermediary doctrine and declined to recognize any exceptions thereto. *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012). According to the Texas court, "The highest courts of at least thirty-five states [not counting Texas] have adopted some form of the learned intermediary doctrine within the prescription drug products-liability context or cited favorably to its application within this context." *Id.* at 158 n.17 (citing cases). It added, "[W]e note that scores of other intermediate state courts and federal courts applying state law have also recognized the validity of the learned intermediary doctrine within the context of prescription drugs, the

physician-patient relationship, and the drug manufacturer's duty to warn." *Id.* Many of the cited cases were decided within the past five years, well after West Virginia issued its *Karl* decision.

B. The Doctrine Does Not Absolve Drug Manufacturers of Their Duty of Reasonable Care

Central to Petitioners' critique of the learned intermediary doctrine is that it somehow provides drug manufacturers with a unique and unwarranted immunity from paying damages for injuries they cause. Pet. Br. 31-32. They argue that drug manufacturers should be treated "the same as manufacturers of other products" and should not be permitted to foist liability onto "local doctors, who have both limited resources and comparatively low culpability." *Id.* at 31. That critique is based on a misinterpretation of the doctrine, which imposes traditional tort responsibilities on drug manufacturers.

Tennessee law imposes a duty on all individuals "to conform to a reasonable person standard of care in order to protect others against unreasonable risks of harm." *Satterfield v. Breeding Insulation Co.*, 266 S.W.2d 347, 355 (Tenn. 2008). The standard of care required in a given situation is dependent on numerous factors, including the foreseeability and gravity of the potential harm and the importance or social value of the activity being engaged in. *Id.* at 365-66.

In general, a product manufacturer's duty of care includes a duty to ensure that those likely to use or be exposed to the product are warned of non-obvious dangers associated with use of the product. *Nye*, 347 S.W.3d at 693. Thus, in *Satterfield*, a manufacturer whose employees were regularly exposed to asbestos owed a duty of care to employees and to their immediate families to ensure that asbestos-laden work clothes were not taken home from work. *Id.* at 369 (the employer "had a duty to use reasonable care to prevent exposure to asbestos fibers not only to its employees but also to those who came into regular contact with its employees'

contaminated work clothes over an extended period of time."); *see also id*. at 374 (duty to warn does not extend to "all foreseeable persons who might be exposed to asbestos fibers on an employee's work clothes" because that duty "would be too great a burden."). The Court made clear, however, that the duty of care owed to the employees' immediate family members did *not* require that warnings be provided directly to them. Rather, the measures endorsed by the Court as "feasible and efficacious" (and thus mandated by the reasonable care standard) included: (1) providing "basic warnings" to *employees* regarding the dangers of asbestos; (2) requiring employees to change their clothes before leaving the workplace; and (3) laundering its employees' work clothes on site. *Id.* at 368.

A major factor in determining whether the duty of care to an individual includes providing a warning directly to that individual is the ease with which such warnings could be conveyed. Thus, in *Whitehead v. Dycho Co.*, 775 S.W.2d 593 (Tenn. 1989), the Court held that a chemical distributor's duty to warn of the dangers of its product (Naptha) ran to the company to which it sold the product and not to the company's employees, in large measure because the chemical distributor was not in a position to effectively communicate directly with the employees. The Court concluded that the employer "was the only party in a position to issue an effective warning to the Plaintiff" and that the chemical distributor "had no reasonable access to the Plaintiff." *Id.* at 600. Although the chemical distributor owed a duty of reasonable care to the purchaser's employees because it knew that they were likely to come into contact with its dangerous product, that duty did not include a duty to provide warnings directly to them. *Id.*

The learned intermediary doctrine is fully consistent with this duty-of-care case law. It recognizes that drug manufacturers owe a duty of care to users of their products, a duty that

includes taking steps to ensure that the users are warned of relevant product risks. But it also recognizes that such warnings are most effective, and most easily conveyed, if they come from the prescribing physician. As with the defendant in *Whitehead*, drug manufacturers would have great difficulty effectively communicating directly with patients. For one thing, they generally do not have lists of patients who have been prescribed their drugs, and privacy laws make it very difficult to obtain such lists. Print advertisements consisting of detailed product warnings would be incomprehensible to most patients, would likely reach only a small fraction of them, and would be read by even fewer. So for many of the same reasons that motivated the Court's decision in *Whitehead*, the learned intermediary doctrine imposes a duty to warn on drug manufacturers but directs that the warnings be provided to doctors, not to patients.

As *Pittman* and *Nye* pointed out, treating physicians are far better positioned than are drug manufacturers to inform patients of the risks and benefits to them of taking prescription medications. *Pittman*, 890 S.W.2d at 430; *Nye*, 347 S.W.3d at 703 ("As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient."). But the law nonetheless imposes a duty on the manufacturer to take steps to ensure that doctors fulfill their duties to fully inform their patients. As *Pittman* explained, "[P]hysicians can be learned intermediaries only when they have received adequate warnings. Thus, the learned intermediary doctrine does not shield a drug manufacturer from liability for inadequate warnings to the physician." *Pittman*, 890 S.W.2d at 429 (citations omitted). Nor does the learned intermediary doctrine eliminate a manufacturer's responsibility to provide warnings to product "users" because, as *Pittman* explained, doctors – as the only class of individuals permitted to write prescriptions – are "users of prescription drugs." *Id.* at 430.

Petitioners have alleged that Abbott failed to provide adequate warnings to Dr. Adams regarding the risks of lymphoma among Humira users. The district court denied Abbott's motion for summary judgment, finding that there exist disputed issues of fact with respect to the adequacy of Abbott's warnings to Dr. Adams. Petitioners will have an opportunity in the district court to attempt to demonstrate that the warnings were inadequate and were the proximate cause of Jones's lymphoma. Accordingly, Petitioners are mistaken in asserting that the learned intermediary doctrine absolves drug manufacturers of the duty of care that is imposed on other product manufacturers. Like other manufacturers, they are required to disseminate information regarding product risks in the manner best calculated to ensure that users learn of those risks.

C. The Doctrine Protects the Primacy of the Doctor-Patient Relationship

Petitioners repeatedly decry efforts by drug companies to educate consumers regarding the availability of prescription products, asserting that such efforts create "a fundamentally different backdrop for the traditional doctor/patient relationship." Pet. Br. 18. Yet the result they espouse – abolition of the learned intermediary doctrine – would itself cause significant damage to the doctor-patient relationship.

The learned intermediary doctrine strengthens the doctor-patient relationship by ensuring that patients look to their doctors for detailed information regarding the pros and cons of prescribing a specific drug. In the absence of the doctrine, drug companies and pharmacists would be required to inundate patients with detailed safety information in order to protect themselves from potential tort liability. Because such information could not be drafted with the patient's detailed medical history in mind, it could well end up conflicting with the information and/or advice provided by the prescribing physician. At the very least, doctors would be

required to spend substantial time explaining why generic safety information provided by the manufacturer might not be pertinent to someone with the patient's specific medical history. More worrisome is that the additional information might cause a patient to doubt the abilities of his own doctors and to challenge their medical judgments for unfounded reasons. Many courts have adopted the learned intermediary doctrine for the explicit purpose of preventing direct warning obligations from harming the physician-patient relationship. *See, e.g., Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 873 (Ky. 2004); *Vitanza v. Upjohn Co.*, 778 A.2d 829, 846 (Conn. 2001).

The federal Food and Drug Administration (FDA) shares those concerns. It has stated: "FDA agrees that health care providers should be the primary source of information about medications for their patients. The purpose of written information is to reinforce and supplement, *not to interfere with*, the doctor-patient relationship." 63 Fed. Reg. 66378, 66386 (FDA Dec. 1, 1998) (emphasis added).

The Nation's restricted distribution system for prescription medical products is based on the understanding that prescription drugs pose significant health risks and thus should be made available only after consultation with a physician. *See* 21 U.S.C. § 353(a) (FDA is charged with determining what drugs require physician prescriptions due to "toxicity or other potentiality for harmful effects."). The learned intermediary doctrine harmonizes tort law with that distribution system by ensuring that patients learn the individualized risks and benefits of a prescription drug from the same person who has power to authorize the prescription.

III. THE COURT SHOULD NOT RECOGNIZE THE "EXCEPTIONS" TO THE LEARNED INTERMEDIARY DOCTRINE PROPOSED BY PETITIONERS

Petitioners ask alternatively that the Court create two "exceptions" to the learned intermediary doctrine, including a rule that the doctrine does not apply when the drug in question

has been marketed directly to consumers. Petitioners argue that the nature of prescription drug distribution has been altered significantly since the Court's 1994 adoption of the doctrine in *Pittman*; they assert that drug companies did not begin advertising prescription drugs directly to consumers until several years after that decision.

The factual premise for that argument is incorrect; widespread DTC advertising of prescription drugs began in the 1980s and was a well-recognized practice by the time that *Pittman* adopted the learned intermediary doctrine in Tennessee. DTC advertising had become so widespread that FDA in 1983 demanded (and obtained) a "voluntary" moratorium on advertising while FDA studied the impact of such ads. *See* Michael S. Wilkes, *et al.*, "Direct-to-Consumer Prescription Drug Advertising Trends, Input, and Implications," 19 *Health Affairs* 110, 113 (2000). After concluding that DTC advertising would not create any safety concerns and could provide consumers with valuable health-related information, FDA in 1985 permitted DTC advertising to resume, provided that each advertisement included a detailed summary of the drug's contra-indications, side effects, and effectiveness. *See* 56 Fed. Reg. 36677 (Sept. 9, 1985). By the time that *Pittman* was decided in 1994, drug companies were devoting hundreds of millions of dollars to DTC advertising.

Annual DTC advertising expenditures increased considerably after 1997, when FDA relaxed its detailed "summary" requirement for broadcast advertising. That requirement had rendered broadcast advertising unfeasible, because it was impossible to include all required disclosures in a 60-second advertisement. The changes in drug distribution practices between 1994 and today have been relatively modest, however. DTC advertising was widespread when *Pittman* was decided, yet that practice did not cause the Court to qualify its support for the

learned intermediary doctrine. The most salient feature of drug distribution practices in both 1994 and 2013 was/is the prescription system: patients could not obtain a prescription drug in 1994 without a doctor's permission, and that same restriction is still in effect.

Petitioners have provided no evidence that patients are responding to DTC advertisements for Humira by seeking out compliant doctors willing to acquiesce to demands for a Humira prescription without regard to whether they believe that treatment with Humira is medically indicated. There is certainly no such evidence in this case. Indeed, Petitioners do not allege that Jones ever saw a DTC advertisement for Humira, let alone that an advertisement induced her to seek a Humira prescription from Dr. Adams. To the contrary, Dr. Adams's testimony was that it was his suggestion that Jones be treated with Humira, a suggestion he made after evaluating all the known risks of Humira – including lymphoma. The facts of this case provide no support for Petitioners' contention that patients make their own prescription drug decisions on the basis of DTC advertisements, and thus that lengthy warnings of the sort traditionally provided only to doctors (too lengthy to be included in a broadcast advertisement) should be provided directly to consumers by drug manufacturers.

New Jersey adopted a DTC advertising exception to the learned intermediary doctrine in 1999. *Perez v. Wyeth Laboratories Inc.*, 734 A.2d 1245 (N.J. 1999). In the 14 years since *Perez* was handed down, no other State has followed New Jersey's lead.[1] Moreover, a DTC

[1] Moreover, the form of the DTC exception urged by Petitioners is far broader than the exception recognized by *Perez*. In order to prevail under New Jersey law on a failure-to-warn claim against a drug manufacturer, plaintiffs must establish that the DTC advertising contained misinformation and that "the misinformation was a substantial factor contributing to their use of a defective pharmaceutical product." *Id.* at 1263. Petitioners would, of course, lose under that standard; in the absence of evidence that Jones ever heard a Humira advertisement, any "misinformation" in a Humira advertisement could not have been a "substantial factor"

advertising exception wholly ignores the role that the prescribing physician plays in determining medical treatment. What was true when *Pittman* was decided in 1994 is just as true today: a patient cannot gain access to a prescription drug unless a doctor writes a prescription after determining that use of the drug is medically indicated.

Petitioners contend that several jurisdictions have followed New Jersey in adopting a DTC exception to the learned intermediary doctrine. That contention is erroneous. According to Petitioners, *Vitanza v. Upjohn Co.*, 778 A.2d 829, 846-47 (Conn. 2001), identified "six separate common law exceptions" to the doctrine, including two ("drugs advertised directly to consumers" and "overpromoted drugs") that would "apply directly to Humira." Pet. Br. 23. *Vitanza* held no such thing. Instead, it applied the learned intermediary doctrine to bar a failure-to-warn claim against a drug manufacturer, observing that prior decisions adopting the doctrine were "highly persuasive." *Id.* at 838. Far from endorsing a DTC advertising exception, the court explicitly rejected the exception sought by the plaintiff. *Id.* at 846. The court noted that *Perez* had created a DTC advertising exception in New Jersey (which it characterized as being limited

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contributing to her decision to use Humira. So instead of urging adoption of the *Perez* standard, Petitioners' standard is premised on a presumption of causation whenever a manufacturer that has engaged in DTC advertising fails to provide adequate warnings directly to the patient. Petitioners' standard presumes that had the advertisements included adequate warnings, Jones would not have taken Humira. Pet. Br. 16-18. Such a presumption is nonsensical; given the lack of evidence that Jones ever saw a Humira advertisement, there is no reason to suppose that she would have decided against taking Humira had the unseen advertisements included more complete safety warnings. *Perez* imposed on manufacturers that engage in DTC advertising a duty to provide warnings directly to consumers, but it nonetheless made clear that a plaintiff alleging breach of that duty could not recover unless he could demonstrate causation – *i.e.*, that he would not have taken the drug had the advertising included an adequate warning. Accordingly, *amici* respectfully request that whatever the Court ends up saying about a DTC advertising exception, it should include a statement making clear that Tennessee tort rules regarding causation are unaffected. Otherwise, federal court plaintiffs may assert that silence should be interpreted as an indication that this Court does not dispute their view of causation.

to situations "where patients essentially control selection of the product") and then added: "Without deciding whether our law also should recognize any of these exceptions, we see no reason to create an entirely new exception on the facts of the present case, where the traditional doctor-patient relationship existed, there were no communication problems, and adequate warnings were provided to the prescribing physician." *Id.* at 847.

Petitioners have similarly misconstrued the Kentucky Supreme Court's decision in *Larkin v. Pfizer, Inc*., 153 S.W.3d 758 (Ky. 2004). Petitioners contend that *Larkin*'s embrace of § 6(d) of the Restatement (Third) of Torts: Product Liability is an indication that Kentucky embraces a DTC exception to the learned intermediary rule. Pet. Br. 33. To the contrary, the Kentucky Supreme Court – in response to a certified question from the U.S. Court of Appeals for the Sixth Circuit – held unequivocally that, under the learned intermediary doctrine, a drug manufacturer that informed the treating physician of all relevant risks was not also required to inform the patient of those risks. *Id.* at 761.[2] The court went on to adopt § 6(d), which it characterized as providing that the "duty to warn of possible side effects [is] satisfied if adequate warning [is] given to [the] patient's health care provider, subject to exceptions." *Id*. at 770. Far from adopting any of those exceptions, the court stated explicitly, "The posture of this case does not require us to decide which, if any, of the recognized exceptions to this rule should be adopted

[2] The court added, "[W]e reject the argument that adopting the learned intermediary rule would immunize manufacturers of prescription drugs from products liability claims. Manufacturers still have a duty to warn; the rule only identifies the party to be warned, *i.e.*, the health care provider who prescribes the drugs. If the manufacturer fails to adequately warn the prescribing health care provider, the manufacturer is directly liable to the patient for damages resulting from that failure." *Id*. at 770.

in Kentucky." *Id.*[3]

Petitioners have also misconstrued an Oregon Supreme Court decision, *Griffith v. Blatt*, 51 P.3d 1256 (Ore. 2002). According to Petitioners, *Griffith* held that the learned intermediary doctrine "was not a valid limitation on strict liability." Pet. Br. 23. *Griffith* held no such thing. The case involved failure-to-warn claims filed against *the pharmacist* that dispensed an allegedly defectively labeled prescription drug to the plaintiff; the claims against the manufacturer had previously been dismissed on statute of limitations grounds. The Oregon Supreme Court held that the pharmacist could be required, under § 402A of the Restatement (Second) of Torts, to provide warnings directly to the patient regarding dosage limitations. *Id.* at 1262. The decision had nothing to say regarding the right of *manufacturers* to rely on the learned intermediary doctrine.

In sum, the DTC advertising exception proposed by Petitioners has nothing to recommend it and has not been embraced by other jurisdictions. Only one state supreme court (the New Jersey Supreme Court in *Perez*) has adopted any sort of DTC advertising exception, and New Jersey's exception is far more limited in nature than the one espoused by Petitioners. In the 14 years since *Perez* was handed down, no State has followed New Jersey's lead. There is no reason for Tennessee to consider becoming the first to follow New Jersey's lead in the absence of evidence that doctors no longer play the decisive role in selecting which prescription

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[3] Petitioners note that the Nebraska Supreme Court has also adopted § 6(d) of the Restatement (Third) of Torts: Product Liability. Pet. Br. 23 (citing *Freeman v. Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 842 (Neb. 2000)). But *Freeman* provided no indication that it intended to signal thereby its adoption of any exceptions to the learned intermediary rule. To the contrary, it indicated that its adoption of § 6(d) was synonymous with an embrace the learned intermediary doctrine. *Id.* ("We adopt § 6(d) of the Third Restatement. Accordingly, we apply the learned intermediary doctrine to Freeman's case.").

drugs their patients should use.

Even less appropriate is the other exception requested by Petitioners: that the learned intermediary doctrine be deemed inapplicable whenever the treating physician has received compensation from the manufacturer for conducting clinical trials of the drug in question. That exception has not been recognized by the highest court of *any* State, with good reason. Such compensation is a well-accepted part of sound medical practice, provided only that doctors are not paid in excess of the fair market value of their services. This case presents no occasion to closely examine payments for clinical trials, because the evidence indicates that Jones was not enrolled in a Humira "HERO" study and thus that Dr. Adams, her treating physician, received no compensation from Abbott as a result of his decision to prescribe Humira.

Petitioners apparently seek adoption of an exception that would bar use of the learned intermediary doctrine when, as allegedly occurred in this case, the drug company makes substantial and "pervasive" payments that exceed the value of services rendered. Pet. Br. 18-21. *Amici* respectfully suggest that such an exception cannot be meaningfully articulated in connection with a response to a certified question, where no factual findings have been made with respect to the extent of any payments. The Court should postpone any consideration of what effects, if any, manufacturer kickbacks should have on the learned intermediary doctrine, until a live controversy comes before the Court in which there are evidentiary findings regarding the extent of kickbacks.

In any event, current law can adequately address cases in which the evidence demonstrates that the treating physician prescribed a drug in return for a kickback from the manufacturer. In such cases, the patient can seek to demonstrate that the manufacturer's

kickback likely clouded the doctor's understanding of the drug's risks and benefits and thus that the manufacturer failed to provide an adequate warning to the doctor. As *Pittman* explained, "[T]he learned intermediary doctrine does not shield a drug manufacturer from liability for inadequate warnings to the doctor." *Pittman*, 890 S.W.2d at 429.

IV. ADOPTION OF SECTION 6(d)(2) WOULD NOT HAVE ANY IMPACT ON THE LEARNED INTERMEDIARY DOCTRINE AS CURRENTLY RECOGNIZED BY TENNESSEE

The second certified question asks whether Tennessee follows § 6(d)(2) of the Restatement (Third) of Torts: Products Liability. *Amici* believe that § 6(d) provides a well-balanced approach to the learned intermediary rule and thus would welcome a decision by this Court adopting § 6(d).[4] *Amici* do not believe, however, that any such decision is relevant to this case because § 6(d) does not represent a change from the learned intermediary rule as adopted by Tennessee in *Pittman*.

Petitioners are urging adoption of § 6(d)(2) in the mistaken belief that that provision endorses a DTC exception to the learned intermediary doctrine, and might also endorse a payments-to-physicians exception. Petitioners have explained their position as follows:

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[4] Section 6(d) 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 and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; or
> >
> > (2) the patient when the manufacturer knows or has reason to know that health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings.

> Section (d)(2) recognized that warnings may also be required to "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." Comment *e* to this section describes two conditions which would trigger § 6(d)(2), *i.e.*, (1) when "government regulatory agencies have mandated that patients be informed of risks attendant to the use of a drug," and (2) when the "manufacturers have advertised a prescription drug and its indicated use in the mass media." *Id.* Obviously, both apply here.
>
> But this listing is not intended to be complete. Rather, the "Institute leaves to developing case law whether exceptions to the learned intermediary rule in these *or other situations* should be recognized." *Id.* Needless to say, the "situation" in which a patient's doctor is being paid by the drug company to prescribe its medication to his patients would present a fairly compelling circumstance that should also trigger § 6(d)(2).

Pet. Br. 22.

Petitioners have badly misquoted § 6(d) and its accompanying comments. In the first paragraph quoted above, Petitioners claim that Comment *e* to § 6 "describes two conditions which would trigger § 6(d)(2)," and that DTC advertising is one of the two conditions. That claim is false; Comment *e* absolutely does not endorse (or "trigger") a DTC advertising exception to the learned intermediary doctrine. Rather, it merely notes that *some* have argued in support of such an exception: "Although the learned intermediary rule is generally accepted and a drug manufacturer fulfills its legal obligation to warn by providing adequate warnings to the health-care provider, arguments have been advanced that in two other areas courts should consider imposing tort liability on drug manufacturers that fail to provide direct warnings to consumers." Restatement (Third) of Torts: Product Liability, § 6, cmt e. One of the two areas in which "arguments have been advanced" for a learned intermediary exception is DTC advertising. But far from endorsing such an exception, Comment *e* merely states that "[t]he Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized." *Id.*

Section 6(d)(2) provides that manufacturers should provide warnings directly to patients when "health-care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings." The "be in a position" language does not readily call to mind a DTC advertising exception. Regardless whether such advertising takes place, a doctor or other health-care provider will always "be in a position to reduce the risks of harm" if (s)he deals individually with the patient, knows the patient's medical history, and can decline to write a prescription if (s)he determines that the drug in question is not medically indicated. Accordingly, § 6(d)(2)'s "be in a position" language strongly indicates that that provision does not kick in simply because the drug manufacturer has engaged in DTC advertising or because (unlike in this case) a patient responds to the advertising by requesting that the drug be prescribed to him. In those situations, the doctor would still "be in a position" to warn the patient of all potential risks and to decline to write the prescription if not medically indicated.

If the "be in a position" language of § 6(d)(2), along with Comment *e*, leaves any doubt on this issue, it is dispelled by the drafting history of § 6(d)(2). A 1993 preliminary draft of the Restatement (Third) would have recognized several exceptions to the learned intermediary rule, including where "the manufacturer advertised or otherwise promoted the drug or medical device directly to consumers." Restatement (Third) of Torts, Product Liability § 103(a)(3)(iii) (Council Draft No. 1, 1993). After debate, the would-be DTC exception was eliminated due to "concern about creating a wholly new common-law duty to warn when there was no case law to support it." Restatement (Third) of Torts, Product Liability § 4(b)(3), at Preface (Council Draft No. 1A, 1994). Thus, the drafting history conclusively demonstrates that § 6(d)(2) does not create a DTC advertising exception to the learned intermediary doctrine, and does no more than leave open the

possibility that "developing case law" might later recognize such an exception. In the 14 years since the New Jersey Supreme Court handed down its *Perez* decision in 1999, the verdict of "developing case law" has been loud and clear: no State has followed New Jersey's lead in accepting a DTC advertising exception, and numerous courts have rejected it.

Comment *e* makes clear what the drafters had in mind when they referred to instances in which "health care providers will not be in a position to reduce the risks of harm in accordance with the instructions or warnings":

> An example is the administration of a vaccine in clinics where mass inoculations are performed. In many such programs, health-care providers are not in a position to evaluate the risks attendant upon use of the drug or device or to relate them to patients. When a manufacturer supplies prescription drugs for distribution to patients in this type of supervised environment, if a direct warning to patients is feasible and can be effective, the law requires measures to that effect.

Restatement (Third) of Torts: Products Liability § 6, cmt. e.

The example provided is a far cry from the DTC advertising exception espoused by Petitioners. It describes a situation in which doctors truly are not "in a position" to evaluate and discuss risks and benefits with individual patients, both because there are too many patients and because doctors are unlikely to be familiar with the medical histories of those patients. In contrast, even when a patient comes to a doctor after seeing a DTC advertisement and seeks a prescription for the advertised drug, any doctor will still be "in a position" to evaluate the patient, determine whether the requested drug is medically indicated, discuss potential risks and benefits with the patient, and decline to write a prescription if (s)he determines that taking the drug is not in the patient's best interests.

In sum, should the Court decide to adopt § 6(d) of the Restatement (Third) of Torts, it should make clear that that provision does not entail a modification of Tennessee's longstanding

acceptance of the learned intermediary doctrine and does not create a DTC advertising exception to the doctrine.

CONCLUSION

For the foregoing reasons, the Court should decline to answer the questions certified by the federal district court, or in the alternative, should reaffirm its controlling precedent and hold that the learned intermediary doctrine applies in prescription-drug product liability cases in Tennessee and that neither of the "exceptions" identified by the district court are recognized as a matter of Tennessee law.

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Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 31st day of May, 2013, the foregoing brief of *amici curiae* Washington Legal Foundation, *et al.*, was served via electronic mail and first-class U.S. Mail on the following attorneys of record:

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