IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

January 2007 Term

No. 33211

FILED
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SUPREME COURT OF APPEALS
OF WEST VIRGINIA

**STATE OF WEST VIRGINIA EX REL.
JOHNSON & JOHNSON CORPORATION,
A FOREIGN CORPORATION, AND
JANSSEN PHARMACEUTICA, INC.,
A FOREIGN CORPORATION AND
A WHOLLY-OWNED SUBSIDIARY OF
JOHNSON & JOHNSON, INC.,
Petitioners,**

V.

**THE HONORABLE MARK A. KARL,
JUDGE OF THE CIRCUIT COURT OF MARSHALL COUNTY,
DANIEL W. WILSON, M.D., AND
ESTATE OF NANCY J. GELLNER, BY
GREGORY A. GELLNER, EXECUTOR,
Respondents.**

PETITION FOR WRIT OF PROHIBITION

WRIT DENIED

Submitted: January 23, 2007
Filed: June 27, 2007

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CHIEF JUSTICE DAVIS delivered the Opinion of the Court.

JUSTICES ALBRIGHT AND BENJAMIN dissent and reserve the right to file dissenting opinions.

JUSTICES STARCHER AND MAYNARD concur and reserve the right to file concurring opinions.

SYLLABUS BY THE COURT

1. "'A writ of prohibition will not issue to prevent a simple abuse of discretion by a trial court. It will only issue where the trial court has no jurisdiction or having such jurisdiction exceeds its legitimate powers. W. Va. Code, 53-1-1.' Syllabus point 2, *State ex rel. Peacher v. Sencindiver*, 160 W. Va. 314, 233 S.E.2d 425 (1977)." Syllabus point 1, *State ex rel. Caton v. Sanders*, 215 W. Va. 755, 601 S.E.2d 75 (2004).

2. "'In determining whether to entertain and issue the writ of prohibition for cases not involving an absence of jurisdiction but only where it is claimed that the lower tribunal exceeded its legitimate powers, this Court will examine five factors: (1) whether the party seeking the writ has no other adequate means, such as direct appeal, to obtain the desired relief; (2) whether the petitioner will be damaged or prejudiced in a way that is not correctable on appeal; (3) whether the lower tribunal's order is clearly erroneous as a matter of law; (4) whether the lower tribunal's order is an oft repeated error or manifests persistent disregard for either procedural or substantive law; and (5) whether the lower tribunal's order raises new and important problems or issues of law of first impression. These factors are general guidelines that serve as a useful starting point for determining whether a discretionary writ of prohibition should issue. Although all five factors need not be satisfied, it is clear that the third factor, the existence of clear error as a matter of law, should be given substantial weight.' Syllabus point 4, *State ex rel. Hoover v. Berger*, 199 W. Va. 12, 483

S.E.2d 12 (1996)." Syllabus point 2, *State ex rel. Caton v. Sanders*, 215 W. Va. 755, 601 S.E.2d 75 (2004).

3. Under West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. We decline to adopt the learned intermediary exception to this general rule.

Davis, Chief Justice:

In this action invoking the original jurisdiction of this Court in prohibition, a drug manufacturer asks this Court to adopt the learned intermediary doctrine as an exception to the general duty of manufacturers to warn consumers of the dangerous propensities of their products.[1] After thorough consideration of the learned intermediary doctrine in light of the current state of the prescription drug industry and physician/patient relationships, we decline to adopt this doctrine. Accordingly, the requested writ of prohibition is denied.

I.

FACTUAL AND PROCEDURAL HISTORY

This case is before this Court on a petition for writ of prohibition. Accordingly, the facts have not been conclusively determined below. Nevertheless, it appears to be undisputed that on May 19, 1999, Mrs. Nancy J. Gellner was prescribed the drug Propulsid®[2] by her primary care physician, Daniel J. Wilson, M.D., a respondent to this proceeding (hereinafter referred to as "Dr. Wilson"). Petitioner Janssen Pharmaceutica, Inc., is a wholly-owned subsidiary of petitioner Johnson & Johnson, Corporation (hereinafter

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[1]Under the learned intermediary doctrine, "a drug 'manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers.'" *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 803 (E.D. Tex. 2002) (citing *Porterfield v. Ethicon, Inc*., 183 F.3d 464, 467-68 (5th Cir. 1999)) (additional citation omitted).

[2]Propulsid® is the brand name for the drug cisapride.

collectively referred to as "Janssen"). Propulsid® was manufactured and distributed by Janssen. In addition to prescribing Propulsid®, Dr. Wilson also provided Mrs. Gellner with samples of the prescription drug, which samples had been provided to Dr. Wilson by representatives of Janssen. Mrs. Gellner died suddenly on the third day after she began taking Propulsid®.[3]

On May 17, 2001, Mrs. Gellner's estate (hereinafter referred to as "the Estate"), a respondent herein, filed a products liability/medical malpractice action against Janssen and Dr. Wilson in the Circuit Court of Marshall County, West Virginia.[4] On August 26, 2004, Janssen filed a motion for summary judgment asserting that, under the learned intermediary doctrine, it had fulfilled its duty to warn by providing warnings regarding Propulsid® to Dr. Wilson. Apparently, the circuit court orally denied the motion for summary judgment on March 28, 2005, on the ground that disputed questions of fact

[3]Janssen contends that the evidence will show that Propulsid® should not have been prescribed to Mrs. Gellner due to various medical conditions from which she suffered and due to other medications she was taking. Additionally, Janssen avers that it will be able to establish at trial that it provided adequate warnings to Dr. Wilson. Dr. Wilson, on the other hand, expects to establish that Janssen's warnings to physicians, as well as to consumers, were not adequate.

[4]The Estate has asserted various claims against Janssen, which include strict liability, breach of express warranty, breach of implied warranty, a statutory claim of deceptive practices, and negligence, as well as an additional claim of negligence against Dr. Wilson.

remained pending in the case.[5] Thereafter, Janssen, again relying on the learned intermediary doctrine, filed a motion *in limine* to exclude evidence or argument by the Estate suggesting that Janssen had a duty to provide any warnings regarding Propulsid® to Mrs. Gellner personally. Observing that this Court has not recognized the doctrine of the learned intermediary, the circuit court denied Janssen's motion by order entered on June 13, 2006. Janssen filed a petition for writ of prohibition in this Court seeking to prohibit enforcement of the circuit court's June 13, 2006, order. On October 26, 2006, this Court granted a rule to show cause. We now deny the writ.

II.

STANDARD OF REVIEW

This case is before this Court upon Janssen's petition for a writ of prohibition. When asked to prevent a lower court from enforcing an order it has entered, this Court reviews the order to determine whether the lower court has committed error by so ruling. For an award of the extraordinary remedy of prohibition to be proper in a particular case, however, the allegedly improper actions of the lower court must constitute more than a simple abuse of discretion. "'A writ of prohibition will not issue to prevent a simple abuse of discretion by a trial court. It will only issue where the trial court has no jurisdiction or having such jurisdiction exceeds its legitimate powers. W. Va. Code, 53-1-1.' Syllabus

[5]No subsequent written order was filed.

point 2, *State ex rel. Peacher v. Sencindiver*, 160 W. Va. 314, 233 S.E.2d 425 (1977)." Syl. pt. 1, *State ex rel. Caton v. Sanders*, 215 W. Va. 755, 601 S.E.2d 75 (2004).

The parties to this proceeding do not claim that the lower court lacked jurisdiction when it entered its order of June 13, 2006. Rather, Janssen contends that the lower court exceeded its legitimate powers by refusing to apply the learned intermediary doctrine to rule in its favor. When it is claimed that the lower court has acted beyond its legitimate powers, we consider many factors to ascertain whether granting extraordinary relief through prohibition is warranted.

> "In determining whether to entertain and issue the writ of prohibition for cases not involving an absence of jurisdiction but only where it is claimed that the lower tribunal exceeded its legitimate powers, this Court will examine five factors: (1) whether the party seeking the writ has no other adequate means, such as direct appeal, to obtain the desired relief; (2) whether the petitioner will be damaged or prejudiced in a way that is not correctable on appeal; (3) whether the lower tribunal's order is clearly erroneous as a matter of law; (4) whether the lower tribunal's order is an oft repeated error or manifests persistent disregard for either procedural or substantive law; and (5) whether the lower tribunal's order raises new and important problems or issues of law of first impression. These factors are general guidelines that serve as a useful starting point for determining whether a discretionary writ of prohibition should issue. Although all five factors need not be satisfied, it is clear that the third factor, the existence of clear error as a matter of law, should be given substantial weight." Syllabus point 4, *State ex rel. Hoover v. Berger*, 199 W. Va. 12, 483 S.E.2d 12 (1996).

Syl. pt. 2, *State ex rel. Caton v. Sanders*, 215 W. Va. 755, 601 S.E.2d 75. *See also* Syl. pt. 3, *id.*, ("'In determining whether to grant a rule to show cause in prohibition when a court is

not acting in excess of its jurisdiction, this Court will look to the adequacy of other available remedies such as appeal and to the over-all economy of effort and money among litigants, lawyers and courts; however, this Court will use prohibition in this discretionary way to correct only substantial, clear-cut, legal errors plainly in contravention of a clear statutory, constitutional, or common law mandate which may be resolved independently of any disputed facts and only in cases where there is a high probability that the trial will be completely reversed if the error is not corrected in advance.' Syllabus point 1, *Hinkle v. Black,* 164 W. Va. 112, 262 S.E.2d 744 (1979)."). We will now proceed to apply this standard to review the lower court's ruling.

III.

DISCUSSION

The issue raised in this original jurisdiction action is one of first impression. In order to decide whether prohibition should lie in this case to prohibit the circuit court from refusing to apply the learned intermediary doctrine, we must examine that doctrine and determine whether it should be adopted into the common law of West Virginia.

"The learned intermediary doctrine provides an exception to the general rule imposing a duty on manufacturers to warn consumers about the risks of their products." *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795, 803 (E.D. Tex. 2002) (citing *Reyes v. Wyeth Labs.*, 498 F.2d 1264, 1276 (5th Cir. 1974); *Sterling Drug, Inc. v.*

Cornish, 370 F.2d 82, 85 (8th Cir. 1966)).

> The learned intermediary doctrine stands for the proposition that
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> > a drug "manufacturer is excused from warning each patient who receives the product when the manufacturer properly warns the prescribing physician of the product's dangers." *See Porterfield v. Ethicon, Inc.*, 183 F.3d 464, 467-68 (5th Cir. 1999) (citing *Alm v. Aluminum Co. of America*, 717 S.W.2d 588, 591-92 (Tex. 1986)). Hence, a drug manufacturer's duty to warn consumers about the dangers of its prescription drugs extends only to the prescribing physician or healthcare provider, who acts as a "learned intermediary" between the manufacturer and the ultimate consumer and assumes responsibility for advising individual patients of the risks associated with the drug.

In re Norplant, 215 F. Supp. 2d at 803 (additional citation omitted).

Some authorities have suggested that the number of jurisdictions having adopted the doctrine is an overwhelming majority, but those authorities have either included lower court decisions, or have included jurisdictions where federal circuit courts applying state law have concluded that the doctrine would be adopted. *See, e.g.*, *In re Norplant*, 215 F. Supp. 2d at 806-09 (including lower state court and federal circuit court cases to conclude that forty-eight states, District of Columbia and Puerto Rico have either applied or recognized learned intermediary doctrine, and providing chart reflecting the same); *Vitanza v. Upjohn Co.*, 257 Conn. 365, 379 n.11, 778 A.2d 829, 838 n.11 (2001) (finding that forty-four jurisdictions have adopted learned intermediary doctrine, and including lower state courts and federal courts applying state law in that number); *Larkin v. Pfizer, Inc.*, 153

S.W.3d 758, 768 n.4 and accompanying text (Ky. 2004) (observing that thirty-four states have specifically adopted learned intermediary doctrine, but relying on decisions of some lower state courts).

Our own research has yielded a markedly different result. Considering decisions of only the highest state courts, we find that a mere twenty-one states have expressly adopted the learned intermediary doctrine.[6] In one additional state, North Carolina,

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[6]*See Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1303 (Ala. 1984) (answering affirmatively certified question from United States Court of Appeals for Eleventh Circuit asking whether "adequate warning [from drug manufacturer] to the prescribing physician, but not to the ultimate consumer, [was] sufficient as a matter of law"); *Shanks v. Upjohn Co.*, 835 P.2d 1189, 1200 (Alaska 1992) ("In determining the adequacy of the warnings and directions in the context of typical prescription drugs, it is appropriate for the trier of fact to consider that the warnings and directions were directed to the prescribing physician rather than to the patient." (footnote omitted)); *West v. Searle & Co.*, 305 Ark. 33, 44, 806 S.W.2d 608, 614 (1991) (concluding that "application of the learned intermediary rule is appropriate in the case of oral contraceptives"); *Stevens v. Parke, Davis & Co.*, 9 Cal. 3d 51, 65, 507 P.2d 653, 661, 107 Cal. Rptr. 45, 53 (1973) ("In the case of medical prescriptions, 'if adequate warning of potential dangers of a drug has been given to doctors, there is no duty by the drug manufacturer to insure that the warning reaches the doctor's patient for whom the drug is prescribed.'" (citations omitted)); *Vitanza v. Upjohn Co.*, 257 Conn. 365, 373, 778 A.2d 829, 835 (2001) ("We conclude that: . . . the learned intermediary doctrine is part of our state law . . . ."); *Lacy v. G.D. Searle & Co.* 567 A.2d 398, 400 (Del. 1989) (applying LID in prescription *device* context, but plainly stating that it would apply in prescription drug context); *Felix v. Hoffmann-LaRoche, Inc.* 540 So. 2d 102, 104 (Fla. 1989) (acknowledging that "it is clear that the manufacturer's duty to warn of Accutane's dangerous side effects was directed to the physician rather than the patient. . . . This is so because the prescribing physician, acting as a 'learned intermediary' between the manufacturer and the consumer, weighs the potential benefits against the dangers in deciding whether to recommend the drug to meet the patient's needs." (internal citations omitted)); *McCombs v. Synthes*, 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003) (applying the doctrine in a medical *device* context, but stating that "[u]nder the learned intermediary doctrine, the (continued...)

[6](...continued)
manufacturer of a *prescription drug* or medical device does not have a duty to warn the patient of the dangers involved with the product, but instead has a duty to warn the patient's doctor, who acts as a learned intermediary between the patient and the manufacturer" (emphasis added)); *Kirk v. Michael Reese Hosp. & Med. Ctr*., 117 Ill. 2d 507, 519, 111 Ill. Dec. 944, 950, 513 N.E.2d 387, 393 (1987) ("[W]e believe the learned intermediary doctrine is applicable here and that there is no duty on the part of manufacturers of prescription drugs to directly warn patients."); Syl. pt. 5, in part, *Humes v. Clinton*, 246 Kan. 590, 792 P.2d 1032 (1990) ("Manufacturers of prescription drugs have a duty to warn of dangerous side effects and risks associated with the use of such drugs. The learned intermediary rule, however, relieves manufacturers of the duty to warn patients directly. . . ."); *Larkin v. Pfizer, Inc*., 153 S.W.3d 758, 770 (Ky. 2004) (recognizing that "we now adopt Restatement (Third) of Torts: Products Liability § 6(d) (duty to warn of possible side effects satisfied if adequate warning given to patient's health care provider, subject to exceptions)"); *Wyeth Labs., Inc. v. Fortenberry*, 530 So. 2d 688, 691 (Miss. 1988) ("We hold that the drug manufacturer has a duty to adequately warn the prescribing physician of any known adverse effects which might result from use of its prescription drugs. . . . The general rule is 'that where prescription drugs are concerned, a manufacturer's duty to warn only extends to physicians and not to laymen.'" (citation omitted)); *Hill v. Squibb & Sons, E. R*., 181 Mont. 199, 206, 592 P.2d 1383, 1387-88 (1979) ("As a general rule, the duty of a drug manufacturer to warn of the dangers inherent in a prescription drug is satisfied if adequate warning is given to the physician who prescribes it."); *Freeman v. Hoffman-La Roche, Inc*., 260 Neb. 552, 571, 618 N.W.2d 827, 842 (2000) ("We adopt § 6(d) of the Third Restatement. Accordingly, we apply the learned intermediary doctrine to Freeman's case."); *Niemiera by Niemiera v. Schneider*, 114 N.J. 550, 559, 555 A.2d 1112, 1117 (1989) ("In New Jersey, as elsewhere, we accept the proposition that a pharmaceutical manufacturer generally discharges its duty to warn the ultimate user of prescription drugs by supplying physicians with information about the drug's dangerous propensities. . . . This concept is known as the 'learned intermediary' rule because the physician acts as the intermediary between the manufacturer and the consumer." (internal citation omitted)); *Martin v. Hacker*, 83 N.Y.2d 1, 9, 628 N.E.2d 1308, 1311, 607 N.Y.S.2d 598, 601 (1993) ("Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects. The physician acts as an 'informed intermediary'. . . between the manufacturer and the patient; and, thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient . . . ." (citations omitted)); Syl. pt. 5, *Seley v. G. D. Searle & Co.*, 67 Ohio St. 2d 192, 423 N.E.2d 831 (1981) ("A manufacturer of ethical drugs satisfies its duty to warn of risks associated
(continued...)

the doctrine has been adopted by statute. *See* N.C. Gen. Stat. § 99B-5(c) (1995).[7] Thus, the total number of jurisdictions recognizing the learned intermediary doctrine, either by decision of the highest court or by statute, is only twenty-two.

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[6](...continued)
with use of the product by providing adequate warnings to the medical profession and not to the ultimate user."); *McKee v. Moore*, 648 P.2d 21, 25 (Okla. 1982) ("The manufacturer's duty to warn the ultimate consumer of prescription drugs, or devices, as distinguished from those sold directly to the consumer, is limited to advising the prescribing or treating physician of the drug's or device's potential dangers in the absence of contrary FDA regulations. Once the physician is warned, the choice of treatment and the duty to explain the risk is incumbent on the physician." (footnotes omitted)); *Incollingo v. Ewing*, 444 Pa. 263, 288, 282 A.2d 206, 220 (1971) ("Since the drug was available only upon prescription of a duly licensed physician, the warning required is not to the general public or to the patient, but to the prescribing doctor."), *abrogated on other grounds by Kaczkowski v. Bolubasz*, 491 Pa. 561, 566, 421 A.2d 1027, 1029 (1980), *as recognized by Slaseman v. Myers*, 309 Pa. Super. 537, 545 n.3, 455 A.2d 1213, 1218 n.3 (1983); *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 431 (Tenn. 1994) ("The Upjohn Company's warnings and instructions to prescribing physicians were sufficient to discharge its duty to those persons to whom it owed a duty to warn.").

The Supreme Court of Oregon has adopted the learned intermediary doctrine with respect to negligence claims. *See McEwen v. Ortho Pharm. Corp.*, 270 Or. 375, 386-87, 528 P.2d 522, 529 (1974) ("Although the duty of the ethical drug manufacturer is to warn the doctor, rather than the patient, the manufacturer is directly liable to the patient for a breach of such duty."). However, the Oregon Legislature rejected its application in the context of strict liability. *See Griffith v. Blatt*, 334 Or. 456, 467, 51 P.3d 1256, 1262 (2002) ("Neither the text nor the context of those statutes indicates that the legislature intended to relieve a seller from potential strict product liability on the basis of the adequacy of a manufacturer's product warnings to another intermediary (here, the physician). By contrast, section 402A of the Restatement (Second) of Torts, referred to in ORS 30.920(3), indicates that the legislature intended to create no such protection from strict liability.").

[7]Three other jurisdictions have adopted statutes reflecting the learned intermediary doctrine: Mississippi, *see* Miss. Code Ann. § 11-1-63(c)(ii) (2002); New Jersey, *see* N.J. Stat. Ann. § 2A:58C-4 (1987); and Ohio, *see* Ohio Rev. Code Ann. § 2307.76(c) (West 1987). As reflected in the preceding footnote, in these three states the doctrine has also been recognized judicially.

The highest courts of six other states have either referred to the doctrine favorably in dicta, or have adopted it in a context other than prescription drugs; but, they have not expressly adopted it with respect to prescription drugs.[8]

On the other hand, the highest courts of the remaining twenty-two states, Arizona, Colorado, Idaho, Indiana, Iowa, Louisiana, Maine, Maryland, Michigan, Minnesota, Nevada, New Hampshire, New Mexico, North Dakota, Rhode Island, South Carolina, South Dakota, Vermont, Wisconsin, West Virginia, and Wyoming, have not adopted the learned intermediary doctrine. Likewise, the District of Columbia Court of Appeals and the Supreme Court of Puerto Rico have not adopted the learned intermediary doctrine. Thus, while the doctrine is widely applied among lower courts, the number of high courts who have followed suit and expressly adopted the doctrine, while admittedly in the majority, do not make up the *overwhelming majority* that has often been suggested by courts and commentators.

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[8]*See Craft v. Peebles*, 78 Hawai'i 287, 304-05, 893 P.2d 138, 155-56 (1995) (adopting learned intermediary rule for silicone breast implants); *MacDonald v. Ortho Pharm. Corp.*, 394 Mass. 131, 475 N.E.2d 65 (1985) (rejecting learned intermediary doctrine in context of oral contraceptives, but indicating in dicta that it would adopt in general prescription drug context); *Krug v. Sterling Drug, Inc*, 416 S.W.2d 143 (Mo. 1967) (addressing only issue of whether drug manufacturer had properly warned physician, as that was the issue presented, but quoting learned intermediary doctrine favorably in dicta); *Alm v. Aluminum Co. of Am.*, 717 S.W.2d 588 (Tex. 1986) (commenting favorably about learned intermediary doctrine in dicta in case that did not involve prescription drugs); *Pfizer, Inc. v. Jones*, 221 Va. 681, 684, 272 S.E.2d 43, 44 (1980) (addressing issue of whether drug manufacturer's warnings to physician had been adequate, but referring favorably to learned intermediary doctrine in dicta); *Terhune v. A. H. Robins Co.*, 90 Wash. 2d 9, 577 P.2d 975 (1978) (adopting learned intermediary doctrine with respect to medical *device*, but discussion indicates probable adoption in prescription drug context).

Among the primary justifications that have been advanced for the learned intermediary doctrine are (1) the difficulty manufacturers would encounter in attempting to provide warnings to the ultimate users of prescription drugs; (2) patients' reliance on their treating physicians' judgment in selecting appropriate prescription drugs; (3) the fact that it is physicians who exercise their professional judgment in selecting appropriate drugs; (4) the belief that physicians are in the best position to provide appropriate warnings to their patients; and (5) the concern that direct warnings to ultimate users would interfere with doctor/patient relationships. For example, the Supreme Court of Washington has explained that

> [t]he reasons for this rule should be obvious. Where a product is available only on prescription or through the services of a physician, the physician acts as a "learned intermediary" between the manufacturer or seller and the patient. It is his duty to inform himself of the qualities and characteristics of those products which he prescribes for or administers to or uses on his patients, and to exercise an independent judgment, taking into account his knowledge of the patient as well as the product. The patient is expected to and, it can be presumed, does place primary reliance upon that judgment. The physician decides what facts should be told to the patient. Thus, if the product is properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved, the manufacturer may reasonably assume that the physician will exercise the informed judgment thereby gained in conjunction with his own independent learning, in the best interest of the patient. It has also been suggested that the rule is made necessary by the fact that it is ordinarily difficult for the manufacturer to communicate directly with the consumer.

Terhune v. A. H. Robins Co., 90 Wash. 2d 9, 14, 577 P.2d 975, 978 (1978) (footnote

omitted).[9]

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[9]*See also West v. Searle & Co.*, 305 Ark. 33, 42, 806 S.W.2d 608, 613 (1991) ("There are a number of arguments supporting the application of this exception to prescription drug products. They may be summarized as: First, a physician must prescribe the drug, the patient relies upon the physician's judgment in selecting the drug, and the patient relies upon the physician's advice in using the drug. That is to say that there is an independent medical decision by the learned intermediary that the drug is appropriate. Second, it is virtually impossible in many cases for a manufacturer to directly warn each patient. Third, imposition of a duty to warn the user directly would interfere with the relationship between the doctor and the patient." (citations omitted)); *Carmichael v. Reitz*, 17 Cal. App. 3d 958, 989, 95 Cal. Rptr. 381, 400-01 (1971) ("The rationale of the [learned intermediary doctrine] is: '(1) The doctor is intended to be an intervening party in the full sense of the word. Medical ethics as well as medical practice dictate independent judgment, unaffected by the manufacturer's control, on the part of the doctor. (2) Were the patient to be given the complete and highly technical information on the adverse possibility associated with the use of the drug, he would have no way to evaluate it, and in his limited understanding he might actually object to the use of the drug, thereby jeopardizing his life. (3) It would be virtually impossible for a manufacturer to comply with the duty of direct warning, as there is no sure way to reach the patient.' (Rheingold, *Products Liability – The Ethical Drug Manufacturer's Liability* (1964) . . . 18 Rutgers L. Rev. 947, 987.)." (footnote omitted)); *Lacy v. G.D. Searle & Co.*, 567 A.2d 398, 400 (Del. 1989) ("A patient obviously is unable to obtain a prescription drug . . . unless his physician orders it. When a patient consults with a physician seeking a prescription drug or restricted device, the patient also expects the physician to use his informed independent judgment to advise the patient and to prescribe the most appropriate use of the drug or device, based on his professional judgment. In the final analysis it is the physician who ultimately prescribes the drug or device. Thus, if the manufacturer of prescription products provides the physician with the legally appropriate information, it has satisfied its duty to warn."); *McCombs v. Synthes*, 277 Ga. 252, 253, 587 S.E.2d 594, 595 (2003) ("The rationale for the [learned intermediary] doctrine is that the treating physician is in a better position to warn the patient than the manufacturer, in that the '"decision to employ prescription medication [or medical devices] involves professional assessment of medical risks in light of the physician's knowledge of a patient's particular need and susceptibilities."'"); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 763-64 (Ky. 2004) ("Three basic rationales have been articulated to support the rule. The first and best rationale is that the prescribing physician is in a superior position to impart the warning and can provide an independent medical decision as to whether use of the drug is appropriate for treatment of a particular patient. . . . The second rationale for the rule is that manufacturers lack effective means to communicate directly with each patient. . . . The third rationale for

(continued...)

We find these justifications for the learned intermediary doctrine to be largely outdated and unpersuasive. At the outset, we note that the learned intermediary doctrine is not a modern doctrine. Rather, its origins may be traced as far back as 1925.

> One of the first intimations that the manufacturer's duty to the ultimate consumer would be limited in the case of prescription drugs is found in *Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925). The court, while holding that the manufacturer was liable to the consumer despite lack of privity, stated
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> > "The defendant deals with the public to be treated with its preparations and drugs, not on an equal footing, but with the understanding the public will trust to the superior intelligence and general knowledge of defendant, its agents and employees, in the manufacture and preparation of its products; also, when its compounds, drugs, and preparations are placed on the market, that they are safe, harmless and beneficial in use. In other words, the public relies on the truth of such statements employed in advertising by the defendant, *and does not seek expert advice from others regarding the propriety of the use of the commodities defendant has manufactured and placed on the market.*"
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> *Id.* at 538 (emphasis added). . . .

Odgers v. Ortho Pharm. Corp., 609 F. Supp. 867, 873 n.12 (E.D. Mich. 1985).

The first instance in which a court actually concluded that a manufacturer's

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[9](...continued)
the rule is that imposing a duty to warn upon the manufacturer would unduly interfere with the physician-patient relationship." (citations omitted)).

duty to warn was satisfied by providing warnings to a prescribing physician is the 1948 case of *Marcus v. Specific Pharms.*, 191 Misc. 285, 77 N.Y.S.2d 508 (N.Y. Sup. Ct. 1948).[10] *Marcus* involved an action against a pharmaceutical company to recover for the death of a thirteen-month-old child who had been administered a larger-than-recommended dose of a prescription suppository manufactured by the defendant, Specific Pharmaceuticals, Inc. In granting the defendant drug company's motion to dismiss the complaint, the *Marcus* court stated:

> [I]t is difficult to see on what basis this defendant can be liable to plaintiff. It made no representation to plaintiff, nor did it hold out its product to plaintiff as having any properties whatsoever. To physicians it did make representations. And should any of these be false it might be claimed with propriety that they were made for the benefit of the ultimate consumers. But there is no such claim. The sole claim is not misrepresentation or even concealment, but a negligent failure to give adequate information, and in some instances a failure to use adequate means to call attention to the information given. It may be safely conceded that these allegations would be sufficient if the product were sold to the public generally as a drug for which no physician's prescription was necessary. The situation alleged is materially different. There is no reason to believe that a physician would care to disregard his own knowledge of the effects of drugs and hence of the quantity to be administered, and substitute for his own judgment that of a drug manufacturer. Nor is there any reason to expect that if a doctor did choose to rely on the information given by the manufacturer he would prescribe without knowing what that information was. In the

[10] *See Larkin v. Pfizer, Inc.*, 153 S.W.3d 758, 762. ("The [learned intermediary] rule originated in *Marcus v. Specific Pharmaceuticals*."); *Odgers v. Ortho Pharm. Corp.*, 609 F. Supp. 867, 873 n.12 (E.D. Mich. 1985) ("Apparently the earliest reported case which actually held that the manufacturer's duty to warn is fulfilled by adequate warnings given to the prescribing physician is *Marcus v. Specific Pharmaceuticals*.").

> absence of any such grounds for belief there would be no negligence.

191 Misc. at 287, 77 N.Y.S.2d at 509-10.[11] The *Marcus* court clearly found significance in the fact that no representations had been made directly to the plaintiff by the defendant drug manufacturer. To a large degree, in a world where prescription medicine is widely

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[11]The actual term "learned intermediary" was first applied to the doctrine in 1967 in the case of *Sterling Drug v. Cornish*, 370 F.2d 82 (8th Cir. 1966). *Sterling* involved a drug that produced a condition that resulted in blindness in a small percentage of those individuals who used it. 370 F.2d at 83-84. Maxine Cornish was a member of that small percentage, and she sued Sterling Drug alleging that the company knew or should have known of this side effect and negligently failed to warn doctors, including her own doctor, to properly monitor users of the drug. *Id.* at 84. Ms. Cornish prevailed at trial, and Sterling appealed arguing, *inter alia*, that the trial court had improperly instructed the jury that if Sterling "knew or should have known that a group of persons would suffer rare side effects, [Sterling] had a duty to warn the medical profession of the susceptibility of such a hypersensitive or idiosyncratic group." The Court of Appeals ultimately affirmed the verdict in favor of Ms. Cornish, and commented with respect to the notice issue that

> [i]n the instant case there was sufficient evidence for the jury to find that appellant did in fact know, and thus could have foreseen, that some persons would be injured by the drug's side effect. Moreover, in this case we are dealing with a prescription drug rather than a normal consumer item. In such a case the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided. This is particularly true if the injury takes place slowly, as is the case with the injury in question here. Therefore, the reasons given for denying liability in other cases do not exist here. We believe the court's instruction was an accurate statement of the law.

Id. at 85.

advertised, such a situation is becoming increasingly rare.

We note the lengthy history of the learned intermediary doctrine because the very age of the doctrine requires us to pause and engage in a thorough examination, even though the doctrine has been widely accepted. Significant changes in the drug industry have post-dated the adoption of the learned intermediary doctrine in the majority of states in which it is followed. We refer specifically to the initiation and intense proliferation of direct-to-consumer advertising, along with its impact on the physician/patient relationship, and the development of the internet as a common method of dispensing and obtaining prescription drug information.[12]

When the learned intermediary doctrine was developed, direct-to-consumer advertising of prescription drugs was utterly unknown. "Historically, prescription drug advertising in the United States was directed primarily to prescribers, who were once the sole decision-makers when choosing prescription medications." Francis B. Palumbo & C. Daniel Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 Food & Drug L.J., 422, 424 (2002). *See also* Ozlem A. Bordes, *The Learned*

[12]"[O]ne study shows that '43 percent of the 40.6 million adults who regularly use the Internet search for health-related topics.'" Patrick Cohoon, Comment, *An Answer to the Question Why the Time Has Come to Abrogate the Learned Intermediary Rule in the Case of Direct-to-Consumer Advertising of Prescription Drugs*, 42 S. Tex. L. Rev. 1333, 1352 (Fall 2001) (citation omitted).

Intermediary Doctrine and Direct-to-Consumer Advertising: Should the Pharmaceutical Manufacturer Be Shielded from Liability?, 81 U. Det. Mercy L. Rev. 267, 274-75 (Spring 2004) ("Originally, pharmaceutical manufacturers advertised to physicians directly via medical journals or pharmaceutical representatives. The general public was less aware of what name brand drugs were on the market."). As one court has aptly observed,

> [o]ur medical-legal jurisprudence is based on images of health care that no longer exist. At an earlier time, medical advice was received in the doctor's office from a physician who most likely made house calls if needed. The patient usually paid a small sum of money to the doctor. Neighborhood pharmacists compounded prescribed medicines. Without being pejorative, it is safe to say that the prevailing attitude of law and medicine was that the "doctor knows best." *Logan v. Greenwich Hosp. Ass'n*, 191 Conn. 282, [290,] 465 A.2d 294, 299 (1983).
>
> Pharmaceutical manufacturers never advertised their products to patients, but rather directed all sales efforts at physicians. In this comforting setting, the law created an exception to the traditional duty of manufacturers to warn consumers directly of risks associated with the product as long as they warned health-care providers of those risks.
>
> For good or ill, that has all changed. Medical services are in large measure provided by managed care organizations. Medicines are purchased in the pharmacy department of supermarkets and often paid for by third-party providers. Drug manufacturers now directly advertise products to consumers on the radio, television, the Internet, billboards on public transportation, and in magazines.

Perez v. Wyeth Labs. Inc., 161 N.J. 1, 4, 734 A.2d 1245, 1246-47 (1999).

Direct-to-consumer prescription drug advertising has been a fairly recent

development. "The first U.S. prescription drug print advertisement directed to the consumer was issued in 1981." Palumbo & Mullins, *supra*, 57 Food & Drug L.J. at 424. Thereafter,

> [i]n 1997, the [Food & Drug Administration] issued draft guidelines intended to supplement the regulations regarding broadcast advertisements. These guidelines led to a *rapid proliferation* of a newer, more informative broadcast advertisement, allowing the manufacturers to include both the product name and indication. The guidelines recommended that drug manufacturers provide a means for consumers to obtain more information (*e.g.* an Internet Web page address).

Patrick Moore & Michael Newton, *Prescription Drug Advertising on the Internet: A Proposal for Regulation*, 2 W. Va. J. L. & Tech. 1.1, ¶ 3 (Feb. 14, 1998) (emphasis added) (footnote omitted).[13] *See also* Palumbo & Mullins, *supra*, 57 Food & Drug L.J. at 423 ("[R]ecent changes . . . in the Food and Drug Administration's . . . guidance – introduced in 1997 and finalized in 1999 – have *opened the door to a plethora of advertisements*." (emphasis added)).[14] Indeed, it has been observed that "drug manufacturers have spent more

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[13]This article is available on the internet at http://www.wvu.edu/~law/wvjolt/ (last visited June 14, 2007).

[14]The massive increase in direct-to-consumer advertising in recent years is striking. One commentator has provided the following table tracking spending on direct-to-consumer, or DTC, spending from the year 1989 to the year 2001:

Year	DTC Spending
1989	$12 million
1990	$48 million
1991	$56 million
1992	$156 milllion
1993	$166 million

(continued...)

money on direct-to-consumer advertising in the last few years than on advertising to doctors." Bordes, *supra*, 81 U. Det. Mercy L. Rev. at 268 (citing Paula C. Ohliger, *DTC Advertising and the Potential Liability of Manufacturers*, Drug Benefit Trends, 11(8):39-40 (1999)).

Since the 1997 proliferation of drug advertising, only four high courts have adopted the learned intermediary doctrine. *See Vitanza v. Upjohn Co.*, 257 Conn. 365, 778 A.2d 829 (2001); *McCombs v. Synthes*, 277 Ga. 252, 587 S.E.2d 594 (2003); *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (Ky. 2004); *Freeman v. Hoffman-La Roche, Inc.*, 260 Neb. 552, 618 N.W.2d 827 (2000). In deciding to adopt the learned intermediary doctrine, none of those courts gave thorough consideration to the changes that have occurred in the prescription drug industry with respect to direct-to-consumer advertising. We, however, find such changes to be a significant factor in deciding this issue, especially the impact direct-to-consumer advertising has had on the physician/patient relationship. *See Larkin v. Pfizer, Inc.*, 153

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[14](...continued)

1994	$242 million
1995	$313 million
1996	$595 million
1997	$844 million
1998	$1.17 billion
1999	$1.58 billion
2000	$2.24 billion
2001	$2.38 billion

Palumbo & Mullins, *The Development of Direct-to-Consumer Prescription Drug Advertising Regulation*, 57 Food & Drug L.J. at 423 (footnotes omitted).

S.W.3d 758, 770-71 (Wintersheimer, J., dissenting) ("This Court should take notice of the abundantly obvious fact that the development of direct to consumer pharmaceutical advertising has indelibly changed the realities of physician/patient relationships. Anyone who watches television is regularly bombarded with a variety of pharmaceutical products which suggest that the ultimate consumer ask his physician to prescribe a particular advertised product.").

Opponents of direct-to-consumer advertising have made the following arguments regarding the impact of such advertising on the physician/patient relationship:

> [P]hysicians state that they are increasingly asked and pressured by their patients to prescribe drugs that the patient has seen advertised. For example, the diet drug combinations known as fen-phen was prescribed despite little hard scientific evidence of its potential side-effects. Physicians are under attack for prescribing the pills too often and too readily to inappropriate patients. Physicians argue that it is not their fault; rather, they claim pushy patients, prodded by DTC advertisements, pressed, wheedled, begged and berated them for quick treatments. . . . Physicians complain that it is impossible to compete with pharmaceutical companies' massive advertising budgets, and resign themselves to the fact that if consumers make enough noise, they will eventually relent to patient pressure.
>
> Moreover, industry critics of DTC advertisements argue that the advertisements distort doctor-patient relationships and may actually increase the use of prescription drugs. They also believe that drug advertisements are created to sell products and thus are inadequate sources of information and poor substitutes for medical advice. Critics also argue that the advertisements do not discuss other medications, alternative treatments and the wisdom of doing nothing. Furthermore, these advertisements

> are unable to diagnose an ailment. All these factors may create a misinformed patient whom the physician will have to educate.
>
> Studies show that DTC advertising generates an increased patient load and often causes physicians to spend more time reviewing the benefits and risks of a specific brand with each patient and explaining formulary restrictions when patients request a brand that is outside the health plan's drug formulary. This may be a potential waste of time for both the patient and the physician, because their discussion will have little effect on formulary rules. The doctor-patient relationship may suffer when physicians must justify decisions to patients concerning which product they will prescribe. Physicians also believe that superficial and misleading advertisements create unreasonable or inappropriate patient expectations for product effectiveness and often lead patients to request inappropriate products for their medical needs.

Tamar V. Terzian, Note, *Direct-to-Consumer Prescription Drug Advertising*, 25 Am. J. L. & Med. 149, 158 (1999) (footnotes omitted). *See also* Bordes, *supra*, 81 U. Det. Mercy L. Rev. at 280-81 ("Today, doctors still argue that their relationship with patients is undermined by direct-to-consumer advertising. They claim that patients demand a particular drug they saw on television, or in a magazine. Additionally, the advertisements encourage lay people to make self-diagnoses by listing symptoms and suggesting the viewer may have the condition that the drug can treat. . . . [One doctor] says that direct-to-consumer advertising 'has created more conflict between the doctor and the patient where the doctor is seen as a barrier to the drug the patient wants.' . . . [Another] says that if a doctor feels that the requested prescription is not right for the patient, doctors find their credibility at issue, not the manufacturer. She also adds that insurance companies may not cover the prescription drug that the patient wants. The physician must then explain to the patient it is not covered

by the plan. The patient may ask the physician to petition the insurer to get the drug covered, which can waste valuable time." (footnotes omitted)).

In rejecting the application of the learned intermediary doctrine to drugs that had been the subject of direct-to-consumer advertising, the Supreme Court of New Jersey opined, and we agree, that such advertising obviates each of the premises upon which the doctrine rests:

> These premises: (1) reluctance to undermine the doctor patient-relationship; (2) absence in the era of "doctor knows best" of need for the patient's informed consent; (3) inability of drug manufacturer to communicate with patients; and (4) complexity of the subject; are all (with the possible exception of the last) absent in the direct-to-consumer advertising of prescription drugs.
>
> First, with rare and wonderful exceptions, the "'Norman Rockwell' image of the family doctor no longer exists." [Lars Noah, *Advertising Prescription Drugs to Consumers: Assessing the Regulatory and Liability Issues*, 32 Ga. L. Rev. 141, 180 n.78 (1997)] (citing Paul D. Rheingold, *The Expanding Liability of the Drug Manufacturer to the Consumer*, 40 Food Drug Cosm. L.J. 135, 136 (1985)). Informed consent requires a patient-based decision rather than the paternalistic approach of the 1970s. *See Largey v. Rothman*, 110 N.J. 204, 206, 540 A.2d 504 (1988) (discussing *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064, 93 S. Ct. 560, 34 L. Ed. 2d 518 (1972)). The decision to take a drug is "not exclusively a matter for medical judgment." *See* Teresa Moran Schwartz, *Consumer-Directed Prescription Drug Advertising and the Learned Intermediary Rule*, 46 Food Drug Cosm. L.J. 829, 831 (1991) (citing Margaret Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 St. Louis. U. L.J. 633, 652 (1986)).

Second, because managed care has reduced the time allotted per patient, physicians have considerably less time to inform patients of the risks and benefits of a drug. Sheryl Gay Stolberg, *Faulty Warning Labels Add to Risk in Prescription Drugs*, N.Y. Times, June 4, 1999, at A27. "In a 1997 survey of 1,000 patients, the F.D.A. found that only one-third had received information from their doctors about the dangerous side effects of drugs they were taking." *Ibid*.

Third, having spent $1.3 billion on advertising in 1998, *supra* at 12-13, 734 A.2d at 1251-52, drug manufacturers can hardly be said to "lack effective means to communicate directly with patients," Noah, *supra*, 32 *Ga. L. Rev*. at 158, when their advertising campaigns can pay off in close to billions in dividends.

Consumer-directed advertising of pharmaceuticals thus belies each of the premises on which the learned intermediary doctrine rests.

> First, the fact that manufacturers are advertising their drugs and devices to consumers suggests that consumers are active participants in their health care decisions, invalidating the concept that it is the doctor, not the patient, who decides whether a drug or device should be used. Second, it is illogical that requiring manufacturers to provide direct warnings to a consumer will undermine the patient-physician relationship, when, by its very nature, consumer-directed advertising encroaches on that relationship by encouraging consumers to ask for advertised products by name. Finally, consumer-directed advertising rebuts the notion that prescription drugs and devices and their potential adverse effects are too complex to be effectively communicated to lay consumers. Because the FDA requires that prescription drug and device advertising carry warnings, the consumer may reasonably presume that the advertiser guarantees the adequacy of its warnings. Thus, the common law duty to warn

the ultimate consumer should apply.

> [Susan A. Casey, Comment, *Laying an Old Doctrine to Rest: Challenging the Wisdom of the Learned Intermediary Doctrine*, 19 Wm. Mitchell L. Rev. 931, 956 (1993) (footnotes omitted).]

> When all of its premises are absent, as when direct warnings to consumers are mandatory, the learned intermediary doctrine, "itself an exception to the manufacturer's traditional duty to warn consumers directly of the risk associated with any product, simply drops out of the calculus, leaving the duty of the manufacturer to be determined in accordance with general principles of tort law." *Edwards v. Basel Pharms.*, 116 F.3d 1341, 1343 (10th Cir. 1997) (discussing question of adequacy of nicotine patch warning under Texas law certified in *Edwards v. Basel Pharms.*, 933 P.2d 298 (Okla.1997)). . . .

Perez v. Wyeth Labs. Inc., 161 N.J. 1, 18-19, 734 A.2d 1245, 1255-56. *See also* Patrick Cohoon, Comment, *An Answer to the Question Why the Time Has Come to Abrogate the Learned Intermediary Rule in the Case of Direct-to-Consumer Advertising of Prescription Drugs*, 42 S. Tex. L. Rev. 1333, 1356-60 (Fall 2001) (explaining how each of the bases for the learned intermediary doctrine no longer exist in light of direct-to-consumer advertising).

Many jurisdictions have addressed the shortcomings of the learned intermediary doctrine by developing various exceptions.

> [C]ourts have recognized exceptions [to the learned intermediary doctrine] regarding: (1) vaccine inoculations; *Davis v. Wyeth Laboratories, Inc.*, [399 F.2d 121, 131 (9th Cir. 1968)]; (2) oral contraceptives; *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 135-36, 475 N.E.2d 65,

> *cert. denied*, 474 U.S. 920, 106 S. Ct. 250, 88 L. Ed. 2d 258 (1985); (3) contraceptive devices; *Hill v. Searle Laboratories*, [884 F.2d 1064, 1070-71 (8th Cir. 1989)]; (4) drugs advertised directly to consumers; *Perez v. Wyeth Laboratories, Inc.*, [161 N.J. 1, 21, 734 A.2d 1245, 1257 (1999)]; (5) overpromoted drugs; *Proctor v. Davis*, 291 Ill. App. 3d 265, 279-84, 225 Ill. Dec. 126, [136-40,] 682 N.E.2d 1203, [1212-16,] *cert. denied*, 175 Ill. 2d 553, 228 Ill. Dec. 725, 689 N.E.2d 1146 (1997); and (6) drugs withdrawn from the market; *Nichols v. McNeilab, Inc.*, 850 F. Supp. 562, 565 ([E.D.] Mich. 1993).

Vitanza v. Upjohn Co., 257 Conn. at 393, 778 A.2d at 846-47. *See also* Bordes, *supra*, 81 U. Det. Mercy L. Rev. at 270-74 (discussing exceptions to learned intermediary doctrine).

Even the version of the learned intermediary doctrine contained in the Restatement (Third) of Torts incorporates the foregoing exceptions by including a general exception to cover those circumstances where the manufacturer knows or should know that a physician will not be in a position to provide an adequate warning:

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

Restatement (Third) of Torts: Products Liability § 6(d), at 145 (1998).[15] In Comment *e* to

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[15]Section 6 of the Restatement (Third) of Torts: Products Liability states in its entirety,

> (a) A manufacturer of a prescription drug or medical device who sells or otherwise distributes a defective drug or medical device is subject to liability for harm to persons caused by the defect. A prescription drug or medical device is one that may be legally sold or otherwise distributed only pursuant to a health-care provider's prescription.
>
> (b) For purposes of liability under Subsection (a), a prescription drug or medical device is defective if at the time of sale or other distribution the drug or medical device:
>
> > (1) contains a manufacturing defect as defined in § 2(a); or
> >
> > (2) is not reasonably safe due to defective design as defined in Subsection (c); or
> >
> > (3) is not reasonably safe due to inadequate instructions or warnings as defined in Subsection (d).
>
> (c) A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients.
>
> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:

(continued...)

§6, the American Law Institute discusses some circumstances under which direct warnings to patients may be warranted under subsection 6(d)(2).[16] Ultimately, though, the Institute

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[15](...continued)

> (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.
>
> (e) A retail seller or other distributor of a prescription drug or medical device is subject to liability for harm caused by the drug or device if:
>
> (1) at the time of sale or other distribution the drug or medical device contains a manufacturing defect as defined in § 2(a); or
>
> (2) at or before the time of sale or other distribution of the drug or medical device the retail seller or other distributor fails to exercise reasonable care and such failure causes harm to persons.

[16]Comment e states in full:

> *e. Direct warnings to patients*. Warnings and instructions with regard to drugs or medical devices that can be sold legally only pursuant to a prescription are, under the "learned intermediary" rule, directed to health- care providers. Subsection (d)(2) recognizes that direct warnings and instructions to patients are warranted for drugs that are dispensed or administered to patients without the personal

(continued...)

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

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

Those who assert the need for adequate warnings directly to consumers contend that manufacturers that communicate directly with consumers should not escape liability simply because the decision to prescribe the drug was made by the health-care provider. Proponents of the learned intermediary rule argue that, notwithstanding direct communications to the consumer, drugs cannot be dispensed unless a health-care provider makes an individualized decision that a drug is

(continued...)

commented that it "leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized." Restatement (Third) of Torts: Products Liability § 6 cmt. e, at 149. It has been observed that, "[o]ne commentator described the *Restatement's* approach as a 'tepid endorsement' of the learned intermediary doctrine." *Perez v. Wyeth Labs. Inc.*, 161 N.J. at 14-15, 734 A.2d at 1253 (quoting Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 Rutgers L. Rev. 821, 869 (1994)).[17]

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[16](...continued)
appropriate for a particular patient, and that it is for the health-care provider to decide which risks are relevant to the particular patient. The Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.

When the content of the warnings is mandated or approved by a governmental agency regulation and a court finds that compliance with such regulation federally preempts tort liability, then no liability under this Section can attach. For the rules governing compliance with governmental standards generally, see § 4(b).

Restatement (Third) of Torts: Products Liability § 6(d) cmt. e, at 148-49 (1998).

[17]In this context, the *Perez* court commented:

Parallel to the developments in drug marketing, the American Law Institute was in the process of adopting the Restatement (Third) of Torts: Products Liability (1997) . . . . Despite the early effort to provide an exception to the doctrine in the case of direct marketing of pharmaceuticals to consumers, the drafters left the resolution of that issue to "developing case law." *Id.* at § 6d comment e. One

(continued...)

Given the plethora of exceptions to the learned intermediary doctrine, we ascertain no benefit in adopting a doctrine that would require the simultaneous adoption of numerous exceptions in order to be justly utilized. This is particularly so when our existing law of comparative contribution among joint tortfeasors is adequate to address issues of liability among physicians and drug companies in those cases where patients sue for injuries related to the use of prescription drugs.[18]

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[17](...continued)
commentator described the Restatement's approach as a "tepid endorsement" of the learned intermediary doctrine. Charles J. Walsh et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 Rutgers L. Rev. 821, 869 (1994). Thus, under the new Restatement, "warnings may have to be provided to a health-care provider or even to the patient," depending on the circumstances. William A. Dreier, *The Restatement (Third) of Torts: Products Liability and the New Jersey Law-Not Quite Perfect Together*, 50 Rutgers L.J. 2059, 2097 (1998).

161 N.J. at 14-15, 734 A.2d at 1253.

[18]Petitioner Janssen notes that federal courts applying West Virginia law have long speculated that West Virginia would adopt the doctrine. *See Ashworth v. Albers Med., Inc.*, 395 F. Supp. 2d 395, 407 (S.D.W. Va. 2005); *Pumphrey v. C.R. Bard, Inc.*, 906 F. Supp. 334, 338 (N.D.W. Va. 1995); *Rohrbough v. Wyeth Labs., Inc.*, 719 F. Supp. 470, 478 (N.D.W. Va. 1989), *aff'd*, 916 F.2d 970 (4th Cir. 1990). While federal court opinions applying West Virginia law are often viewed persuasively, we are not bound by those opinions. *See Life Ins. Co. of North Am. v. Cichowlas*, 659 So. 2d 1333, 1340 (Fla. Dist. Ct. App. 1995) ("Opinions of federal courts which interpret and apply Florida law are persuasive, but the courts of this state are not bound by such opinions." (citation omitted)); *Jacobsen v. Farmers Union Mut. Ins. Co.*, 320 Mont. 375, 381, 87 P.3d 995, 998 (2004) ("[F]ederal court decisions applying Montana law are not binding on this Court[.]"); *Garrison Contractors, Inc. v. Liberty Mut. Ins. Co.*, 927 S.W.2d 296, 300 (Tex. Ct. App. 1996) ("Decisions of the federal courts of appeals and district courts applying Texas law are (continued...)

Furthermore, we believe that if drug manufacturers are able to adequately provide warnings to consumers under the numerous exceptions to the learned intermediary doctrine, then they should experience no substantial impediment to providing adequate warnings to consumers in general. "There is no question that pharmaceutical manufacturers believe they have very effective methods to communicate directly with consumers." *Larkin v. Pfizer, Inc.*, 153 S.W.3d at 771 (Wintersheimer, J., dissenting).

Finally, because it is the prescription drug manufacturers who benefit financially from the sales of prescription drugs and possess the knowledge regarding potential harms, and the ultimate consumers who bear the significant health risks of using those drugs, it is not unreasonable that prescription drug manufacturers should provide appropriate warnings to the ultimate users of their products.

> Public policy dictates that the manufacturer should warn the ultimate user of the harmful effects of its pharmaceuticals since it involves a person's health. The knowledge of pharmaceutical side effects goes well beyond the scope of the average individual. The benefit in warning the consumer directly is far outweighed by the costs. It is not as though the manufacturer must incur costs to discover the risks as they are already known. It is only a matter of adding the consumer to the list of who to warn. . . .
>
> . . . Since the early 1980's, direct-to-consumer advertising has boomed into a very profitable venture for

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[18](...continued)
not binding on this court. They are, however, received 'with respectful consideration.'" (citation omitted)).

> pharmaceutical manufacturers. Yet, consumers' exposure to harm has increased as a result. They are surrounded by various prescription advertisements in all forms of print and broadcast media. Advertisements directed to consumers, however, often supply partial or incomplete information. Additionally, self-diagnosis by the consumer has resulted from these advertisements, as well as patient-demand for the brand-name drugs. *It is in the best interest of the general public that manufacturers have a duty to warn the ultimate user of side effects and risks.* Courts are increasingly motivated to protect the consumer, and require manufacturers to warn more than just the physician.
>
> . . . .
>
> Pharmaceutical manufacturers spend millions to make millions more. They are pushing their products onto the general public like never before. Consequently, consumers need more protection. As a response to the changing times, courts have diminished the manufacturer's shield of the learned intermediary doctrine. They have imposed a duty to warn the consumer in addition to the physician. In doing so, the goal of product liability to protect the ultimate user from harm, is more attainable. In the end, the burden should be on the one producing health care, not the one consuming it.

Bordes, *supra*, 81 U. Det. Mercy L. Rev. at 286-87 (emphasis added). West Virginia physicians naturally have duties and responsibilities regarding their role in providing prescription medicines to consumers. It would be unreasonable not to require the manufacturers of those medicines to accept similar responsibilities.

Based upon the foregoing, we now hold that, under West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers. We decline to adopt the

learned intermediary exception to this general rule.

IV.

CONCLUSION

In denying Janssen's motion *in limine* and declining to adopt the learned intermediary doctrine, the circuit court concluded that

> [e]xisting West Virginia law permits the full development of the claims and defenses as to the adequacy and method of communicating warnings without adopting the Learned Intermediary Doctrine.
>
> . . . .
>
> West Virginia's law as to comparative contribution among tortfeasors will adequately address the issues of warnings as between the manufacturer and Dr. Wilson, without adopting a legal concept not yet embraced by the West Virginia Supreme Court of Appeals.

We agree with the circuit court's conclusions and find no grounds upon which to grant the requested writ of prohibition. Accordingly, Janssen's petition for writ of prohibition is denied.

Writ denied.