

No. 33211 – *Johnson & Johnson Corporation, a foreign corporation, and Janssen Pharmaceutica, Inc., a foreign corporation and a wholly-owned subsidiary of Johnson & Johnson, Inc. 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*

FILED

June 27, 2007

released at 3:00 p.m.

RORY L. PERRY II, CLERK
SUPREME COURT OF APPEALS
OF WEST VIRGINIA

Albright, Justice, dissenting:

In wholesale fashion, the majority rejected the adoption of a doctrine that numerous states¹ have seen fit to apply for a number of years. Although I do not believe that a writ of prohibition – due to the limited development of facts – presented the optimal case for a discussion of whether this state should adopt some variant of the learned intermediary doctrine, I think the majority was exceptionally shortsighted in deciding that the doctrine has *completely* outlived its purpose. A careful consideration of the doctrine, as modified by courts and/or the *Restatement (Third) of Torts*, suggests that there still may be a need for its adoption.

¹The majority uses the modifier “mere” to refer to the twenty-three states that it identifies as adopting the learned intermediary doctrine. I find it difficult, if not impossible, to discern how the adoption of the doctrine by twenty-three states, either by court or legislative action, does not constitute a significant figure – a figure that clearly approaches a majority position. And, while I am not attempting to play the “numbers game,” I note that in *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (Ky. 2004), the appellate court identified the number of states that had specifically adopted the learned intermediary doctrine as thirty-four. *Id.* at 767 and n.3.

Rather than trying to enervate the near-majority of jurisdictions that have already adopted the doctrine, the majority should have earnestly analyzed whether any of the rationales which underlie the doctrine remain valid today. What the majority overlooks by emphasizing the direct marketing of drugs to consumers is that the doctrine may still serve a useful purpose for prescription drugs that are not heavily marketed and in those circumstances where a physician's expertise is relied upon to make the all-important selection of which particular drug(s) to prescribe; to interpret contraindicative information; and to interpret the myriad of warning-related information distributed by a pharmaceutical manufacturer.

As the Kentucky Supreme Court recently recognized in *Larkin v. Pfizer, Inc.*, 153 S.W.3d 758 (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 the rule is that imposing a duty to warn upon the manufacturer would unduly interfere with the physician-patient relationship.

Id. at 763-64. After essentially deciding that advertising and communication changes have attenuated or eliminated the second rationale stated above,² the majority rejected any need for the doctrine's adoption

Notwithstanding the widespread use of marketing efforts by pharmaceutical companies aimed at the consumer, the need for a physician's involvement in the decision to choose a specific drug remains. Just because a warning can be printed and advertised as part of the marketing plan for a prescription drug does not mean that a consumer, especially one not educated in medical jargon, can digest or comprehend the significance of that warning in a useful fashion. And, in those cases, where a physician's expertise has been relied upon to select a specific prescription drug, the learned intermediary doctrine, with the exceptions identified by the *Restatement (Third) of Torts*, is a well-recognized and reasoned approach to resolving the issue of the adequacy of the warnings issued by a pharmaceutical company for its product.

Both the northern and southern federal district courts for this state predicted that this Court, when presented with the issue, would choose to adopt the learned intermediary doctrine. *See Ashworth v. Albers Medical, Inc.*, 395 F.Supp.2d 395 (S.D.

²In fact, the majority concluded in conclusory fashion that all three of the rationales for the doctrine were "largely outdated and unpersuasive." *Johnson & Johnson Corp. v. Honorable Mark A. Karl*, __ W.Va. __, __ S.E.2d __, No. 33211 (filed June 27, 2007) at slip op.13.

W.Va. 2005); *Pumphrey v. C.R. Bard, Inc.*, 906 F.Supp. 334 (N.D. W.Va. 1995). In *Ashworth*, the court described the doctrine as an “‘understandable exception’ to the general rule that manufacturers must warn foreseeable end users about the dangers inherent in their products.” 395 F.Supp.2d at 407 (quoting *Walls v. Alpharma USPD, Inc.*, 887 So.2d 881, 883-84 (Ala. 2004)). “[T]he superior role of the physician in servicing the patient’s medical needs” was one of the litany of reasons the court in *Ashworth* relied upon in choosing to extend the doctrine’s reach to a pharmacy. 395 F.Supp.2d at 407. In addition to citing the accepted rationale that “the determination of whether certain medications and medical devices should be utilized in any given case requires an individualized medical judgment which can be made only by the patient’s physician with knowledge of the patient’s characteristics,” the northern district court looked to the fact that “West Virginia generally follows the *Restatement of Law* in appropriate cases.” 906 F.Supp. at 338 (citing draft provision of *Restatement of the Law Third: Torts, Product Liability*).

Finding the position taken by the *Restatement (Third) of Law*³ undeserving of

entirety,³Section 6 of the *Restatement (Third) of Torts: Products Liability* states in its

(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:

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adoption, the majority essentially concludes that the learned intermediary doctrine is unworkable because it would require the need for case-by-case consideration of its application “through developing case law” and would also present a need for recognizing exceptions to the rule. *Johnson & Johnson*, ___ W.Va. at ___, ___ S.E.2d at ___, No. 33211 (filed June 27, 2007) at slip. op 29 (quoting *Restatement (Third) of Torts: Products Liability* § 6 cmt. e, at 149). In my opinion, the *Restatement* position combined with the exceptions

³(...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.

recognized in comment e,⁴ introduce a balanced and fair approach that would allow this state

⁴Comment 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 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.

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both to adopt the doctrine and to develop rules as to its application based on the factual and legal variations of the cases in which the doctrine was applied.

Consistent with comment e to the *Restatement (Third) of Torts*, I would follow the American Institute of Law's proposal that prescription drugs which are marketed via the mass media should be treated as a distinct category. Because government regulations already require that these heavily-marketed drugs must include appropriate risk-related information as part of the advertising materials, there is an established procedure for

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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 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).

requiring that the manufacturers of such drugs disclose pertinent warning-related information concurrent with the marketing of these pharmaceuticals. Where the need for the doctrine's adoption is most clear is where the drugs at issue were not the subject of a massive advertising campaign and/or where the physician did in fact assume the role of a "learned intermediary" in advising and recommending that the plaintiff/patient use a particular drug. And, in the case of a defective drug, the manufacturer should always be required to advise both the pharmacies and all the direct purchasers of the drug at issue as to the nature of the product concerns.

Because I believe that the issue of adequate pharmaceutical warnings is one that will largely depend on the unique circumstances of the case, I think it was unwise to completely cast aside the learned intermediary doctrine. Furthermore, by attaching undue importance to the effects of direct marketing, the majority downplays the continuing and vital role that a physician plays in the decision as to which prescription drugs are appropriate for a given patient based upon that particular individual's specific medical needs. In those circumstances where the physician has received extensive warning material regarding the effects of a specific drug and makes an individualized decision to prescribe that medication based on such information, there is a valid and continuing rationale for permitting the learned intermediary doctrine to operate. Where on the other hand, a physician advises against the use of a specific drug and the consumer insists on a particular medication based

on his or her exposure to a massive advertising campaign for a specific drug, the need for the doctrine's application is arguably reduced. But to presume, as the majority appears to, that the mere presence of pharmaceutical advertising in our society relegates the role of the physician to a mere dispensary of prescriptions is simply not true. In those cases where the medications are prescribed in a traditional fashion with the physician carefully weighing the advantages and disadvantages of a given drug for a patient presenting with specific concerns, to deny on an across-the-board basis the application of the learned intermediary doctrine – a doctrine that has been applied throughout this country for years – seems both precipitous and unwarranted. Accordingly, I dissent.

I am authorized to state that Justice Benjamin joins in this dissenting opinion.