

The Status of the Learned Intermediary Rule in South Carolina

by Brian A. Comer

One of the most important concepts in drug and medical device litigation is whether or not a state has adopted the "learned intermediary" doctrine. This doctrine provides that manufacturers of prescription drugs and medical devices discharge their duty of care to patients by providing warnings to the prescribing physicians. Restatement (Third) of Torts: Products Liability § 6 cmt. d, reporters' note (1997). The justification for this rule is that consumers cannot buy prescription drugs or medical devices directly from a manufacturer, and therefore the manufacturer discharges its duty to warn by providing the warning to a learned intermediary.

As stated by the Fourth Circuit Court of Appeals in *Talley v. Danek Med., Inc.*, 179 F.3d 154, 163 (4th Cir. 1999):

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, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

The status of the law in South Carolina with regard to the learned intermediary rule is not entirely clear. South Carolina's state courts do not appear to have explicitly adopted the learned intermediary doctrine in the drug and medical device context. In fact, only two state court cases cite to the rule at all: *Bragg v. Hi-Ranger, Inc.*, 319 S.C. 531, 462 S.E.2d 321 (Ct. App. 1995) and *Madison v. American Home Prods. Corp.*, 358 S.C. 449, 595 S.E.2d 493 (1995). *Madison* only mentions the rule in dicta. *Madison*, 358 S.C. at 455, 595 S.E.2d at 496. ("[S]trict liability is inconsistent with the learned intermediary

doctrine, which places the duty to warn on the prescribing physicians, and not pharmacists..."). In *Bragg*, one of the issues on appeal was whether or not the trial court had correctly charged the jury on the "sophisticated user defense." The charge at issue was as follows:

Now, ladies and gentlemen, under South Carolina law, *a manufacturer has no duty to warn of potential risks or dangers inherent in a product if the product is distributed to what we call a learned intermediary or distributed to a sophisticated user who might be in a position to understand and assess the risks involved, and to inform the ultimate user of the risks, and to, thereby, warn the ultimate user of any alleged inherent dangers involved in the product.* Simply stated, the sophisticated user defense is permitted in cases involving an employer who was aware of the inherent dangers of a product which the employer purchased for use in his business. Such an employer has a duty to warn his employees of the dangers of the product.

Bragg, 319 S.C. at 549, 462 S.E.2d at 331-32 (emphasis added). The South Carolina Court of Appeals concluded that the trial court properly charged the jury concerning the sophisticated user defense. *Id.*

However, the federal courts have been more explicit about the issue and have predicted that South Carolina state courts would apply the learned intermediary rule in the drug and medical device context. In *Brooks v. Medtronic, Inc.*, 750 F.2d 1227 (4th Cir. 1984), the Fourth Circuit Court of Appeals heard an appeal of a pacemaker case from the District of South Carolina, and one of the issues on appeal was whether the pacemaker manufacturer had a duty to warn the consumer directly, or whether the warnings to the physician were sufficient. *Id.* at 1230. The court stated that "[a]lthough the South Carolina Supreme Court has not addressed the issue, we conclude it would adopt the [learned intermediary] rule, generally accepted and supported by sound policy, restricting the manufacturer's duty to warn to the prescribing physician."

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Id. at 1231. From reviewing South Carolina strict liability law, the court pointed out that other jurisdictions had adopted the learned intermediary rule, and it believed that South Carolina would as well. *Id.* at 1231. Since *Brooks v. Medtronic*, numerous federal court decisions interpreting South Carolina law have reached this same conclusion. See *Odom v. G.D. Searle Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992); *Tarallo v. Searle Pharmaceutical, Inc.*, 704 F. Supp. 653, 659 n.2 (D.S.C. 1988); *Jones v. Danek Medical, Inc.*, No. 4:96-3323-12, 1999 WL 1133272, at *7 (Oct. 12, 1999, D.S.C.); *Sizemore v. Georgia-Pacific Corporation*, Nos. 6:94-2894 3, 6:94-2895 3, and 6:94-2896 3, 1996 WL 498410, at *6 (Mar. 22, 1996, D.S.C.); *Pleasant v. Dow Corning Corp.*, No. 3:92-3180-17, 1993 WL 1156110, at *6 (Jan. 7, 1993, D.S.C.).

In addition, other practitioners have stated unequivocally that South Carolina has adopted the learned intermediary defense, sometimes citing *Bragg* or *Madison* as support. See, e.g., <http://druganddevicelaw.blogspot.com/2007/07/headcount-whos-adopted-learned.html> (visited January 22, 2010) (citing to *Madison* as support that South Carolina has adopted the rule in the non-prescription medical product case); Lynn H. Gorod, "The Evolving Duty of Pharmacists: To Warn or Not to

Warn?" 16 S. Carolina Lawyer 14, 16 (July 2004) ("The basis for not extending this duty has widely been premised on the 'learned intermediary doctrine.' This doctrine, which has been accepted in many jurisdictions, including South Carolina, provides that manufacturers of prescription drugs have a duty to warn prescribing physicians of a drug's known dangerous propensities.") (Emphasis added).

There is no question that *Bragg* supports that South Carolina has adopted the learned intermediary doctrine (perhaps relabeled as the sophisticated user defense), and South Carolina's federal courts have reached this same conclusion. However, there is very little South Carolina case law in comparison to other states on this issue, and any "adoption" of the doctrine at the state level is likely to be subject to greater argument than in other states, where adoption in the drug and medical device context is often more explicit. See, e.g. *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301 (Ala. 1984); *Hawkins v. Richardson-Merrell, Inc.*, 249 S.E.2d 286 (Ga. Ct. App. 1978); *Pittman v. Upjohn Co.*, 890 S.W.2d 425 (Tenn. 1994) (all explicitly adopting the learned intermediary doctrine in the prescription drug context).

