

THE IDC MONOGRAPH:

EVOLUTION OF THE LEARNED INTERMEDIARY DOCTRINE IN ILLINOIS - DOCTOR KNOWS BEST *MOSTLY*

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Introduction

In 1987, Illinois joined the great majority of jurisdictions which recognized the learned intermediary doctrine. *Kirk v. Michael Reese Hospital & Medical Center*, 117 Ill. 2d 507 (1987), *cert. denied* 485 U.S. 905 (1988). That rule applies to insulate pharmaceutical and medical device manufacturers and suppliers from liability in failure to warn cases. Simply stated, with few exceptions which are discussed *infra*, the purveyor of a prescription product has no duty to warn the ultimate user of its potential side effects and risks. The obligation to inform and warn stops with the prescribing physician who, as the “learned intermediary,” decides whether its therapeutic benefits outweigh any potential adverse reactions.

The rule has its genesis in the nature of prescription products, the regulatory process which is required before they are marketed, and the singular knowledge which is possessed by the technically trained physician/intermediary as to *both* the product’s properties and the patient’s physical condition and needs. In these respects the court in *Kirk* adopted the following explanatory language from *Stone v. Smith, Kline & French Laboratories*, 731 F.2d. 1575, 1579-80 (11 Cir. (Ala.) 1984):

We cannot quarrel with the general proposition that where *prescription* drugs are concerned, the 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. 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. See Restatement (Second) of Torts, Section 388, (1965). 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.

By their nature prescription drugs and medical devices are intended to provoke a biologic response. They are prescribed for that purpose to correct a disease or condition which poses a greater risk to the patient's health than the altered state which results. Consequently, only someone who understands the properties of the product can predict its potential therapeutic effects and drawbacks in a specific patient. Thus, if the physician is adequately advised to recommend the product, it becomes his responsibility to inform the patient of any side effects and thereby to obtain the patient's informed consent. *Kirk* 117 Ill. 2d at 519.

As manufacturing defects are rare, most pharmaceutical and medical device cases turn on the adequacy of the information which is provided to the prescribing physician. While the learned intermediary doctrine was recognized before the concept of strict liability in tort gained acceptance, its maturation and growth, with the concomitant barnacled exceptions, commenced apace with the publication of section 402(A) of the Restatement (Second) of Torts. Comment *k* discusses the issue in the context of "unavoidably unsafe products." In doing so the drafters recognized:

k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous.

Kirk v. Michael Reese Hospital adopts the reasoning of the Restatement. Its progeny, of both legitimate and bastard parentage, consider and apply the rule in a number of settings, and in others distinguish and fail to follow it. In addition, the American Law Institute has reformulated the doctrine in its present evolved state. (Restatement (Third) of Torts, Section 6). This monograph discusses the reasons for the rule, its history in Illinois and its anticipated course, given the dialectic effect of the law and the exigencies of an evolving society.

Regulation

The rationale which underpins the issue of warnings generally in product liability cases is found in the objective of consumer comprehension in both the selection and use of the product. *Hammond v. North American Asbestos Corp.*, 97 Ill. 2d 195, 206 (1983) and *Woodhill v. Parke Davis & Co.*, 79 Ill. 2d 26, 29 (1980). In most instances, the purchaser is able to evaluate the potential hazards of a product at the time of purchase. Thereafter, he is equally blessed with sufficient knowledge to decide when and how to use it safely. Thus, a product is not unreasonably dangerous where the user understands and appreciates the risk it poses.¹

Prescription products are materially different in two fundamental respects. First, they are intended to produce a biologic response in the human body. Second, an understanding of that response, as well

as potential injurious side effects, requires knowledge of the physical and human sciences which is beyond the “ken” of the average consumer. *Kirk v. Michael Reese Hospital, supra* at 522-23. Simply stated, if the patient were to read the package insert or PDR regarding a drug, he would likely not understand it and therefore be unable to balance its therapeutic value against its potential harm.

The safety and effectiveness of prescription products lies within the province of the Food & Drug Administration (FDA) 21 USC § 355 and 21 CFR § 5.10(a)(1). Before any such drugs or medical devices can be marketed, they undergo an extensive regulatory screening process pursuant to the Federal Food, Drug, & Cosmetic Act (21 USC §§ 301 *et seq.*) That process consists, *inter alia*, of filing a new drug application (NDA), which includes the results of medical research and extensive clinical tests. 21 USC § 355.

The application also requires submission of the “label” which contains the information upon which a physician can consider whether or not to prescribe the product for his patient. 21 USC § 355(a)(1)(F). In deciding that a product is both “safe and effective,” the FDA also approves the label which then accompanies the product as a package insert, as well as being incorporated into the Physicians Desk Reference (PDR). 21 CFR §§ 601.2, 601.25.

The label tells the medical profession what properties the product has, what conditions have been approved for its use, what side effects have been associated with it, and what contra-indications exist for its use. Once the label has been approved, it can not be changed without subsequent FDA sanction. 21 CFR § 601.12. Thus, prescribing physicians can rely upon the FDA’s approval of the product as “safe and effective” for the conditions and the uses which are set forth in PDR.

The fact that a product has been licensed by the FDA, including approval of its label, does not insulate a manufacturer from potential liability. The adequacy of a warning *vis a vis* the prescribing intermediary is a fact-driven consideration which is generally unaffected by the doctrine of federal preemption. *Medtronic, Inc. v. Lohr*, 518 US 470, 485, 116 S. Ct. 2240, 2250, 135 L.Ed.2d 700 (1996), *Weiland v. Telectronics Pacing Systems, Inc.*, 188 Ill. 2d 415, 418, 721 N.E.2d 1149, 1151, 242 Ill. Dec. 618, 620 (1999); *cf.*, *Mitchell v. Collagen Corp.*, 126 F.3d. 902, 911 (7 Cir. (Ind.) 1997), *cert. denied* 523 U.S. 1020 (1998).

However, where the adequacy of a warning is in dispute, the testimony of the prescribing physician is obviously controlling. If he testifies that he would have prescribed the product without regard to inclusion of the disputed information, not only is the product not defective, the absence of that information is not a cause in fact of the patient’s injury. *Thomas v. Hoffman - La Roche, Inc.*, 949 F.2d. 806, 817 (5th Cir. (Miss.) 1992), *cert. denied* 504 U.S. 956 (1992).

Products to Which the Doctrine Has Been Applied

The learned intermediary doctrine contemplates that the safety and effectiveness of the product, including its label, will have been approved by the FDA before it is marketed. Thereafter the physician, as learned intermediary, will take that information and consider it in the context of the patient’s needs in deciding whether or not to prescribe the product. The prescription evidences the professional’s determination that use of the drug is in the patient’s best interest, taking into account potential side effects and adverse reactions.

Consequently, the doctrine does not apply to “over the counter” drugs and devices which are merely recommended to the patient by his doctor. *Prager v. Allergan, Inc.*, 1990 WL 70875 (N.D.Ill. 1990). There, the plaintiff suffered an eye injury when he used a contact lens solution recommended by his physician. The manufacturer contended that the recommendation was sufficient to invoke the learned intermediary doctrine, thereby leaving any duty to warn with the doctor. In rejecting that contention, the *Prager* court found that the doctrine did not apply to products which the patient could obtain without either a prescription or physician’s recommendation.

Prager v. Allergan is consistent with the general rule in other jurisdictions: *Mitchell v. VLI Corp.*, 786 F. Supp. 966 (M.D.Fla. 1992), and *Torsiello v. Whitehall Laboratories*, 165 N.J.Super. 311, 398 A.2d. 132 (1979).

The learned intermediary doctrine has been applied to a variety of prescriptive drugs.

Type of Medication: Authority applying doctrine:

Antipsychotic	<i>Hatfield v. Sandoz-Wander, Inc.</i> , 124 Ill. App. 3d 780 (1984) <i>Stinson v. Physician's Immediate Care, Ltd.</i> , 269 Ill. App. 3d 659 (2nd Dist. 1995) <i>Kirk v. Michael Reese Hospital</i> , 117 Ill. 2d 507 (1987)
Analgesic	<i>Wooten v. Johnson & Johnson Products, Inc.</i> , 635 F. Supp. 799 (N.D.Ill. 1986) <i>Happel v. Wal-Mart Stores, Inc.</i> , 199 Ill. 2d 179 (2002)
Antibiotic/Antifungal	<i>Koncz v. Burroughs Wellcome Co.</i> , 1994 WL 178320 (N.D.Ill.) <i>Woodbury v. Janssen Pharmaceutical, Inc.</i> , 1997 WL 201571 (N.D.Ill.)
Sleep	<i>Ashman v. SK & F Lab Co.</i> , 702 F. Supp. 1401 (N.D.Ill. 1988)
Uric Acid Suppressant	<i>Grisostomo v. Stanley</i> , 857 F.2d. 1146 (7 Cir. (Ill.) 1988)
Antacid	<i>Ashman v. SK & F Lab Co.</i> , 702 F. Supp. 1401 (N.D.Ill. 1988)
Corticosteroid	<i>Proctor v. Davis</i> , 291 Ill. App. 3d 265 (1st Dist. 1997), <i>appeal denied</i> 175 Ill. 2d 553
Birth Control	<i>Martin v. Ortho Pharmaceuticals</i> , 268 Ill. App. 3d 980 (1st Dist. 1994), <i>reversed</i> 169 Ill. 2d 234 (1996) <i>Mahr v. G.D. Searle & Co.</i> , 72 Ill. App. 3d 540 (1st Dist. 1979)
Osteoarthritis	<i>Leesley v. West</i> , 165 Ill. App. 3d 135 (2nd Dist. 1988), <i>appeal denied</i> 119 Ill. 2d 558
Headache	<i>Frye v. Medicare - Glaser Corp.</i> , 219 Ill. App. 3d 931 (5th Dist. 1991), <i>reversed</i> 153 Ill. 2d 26 (1992)

The rule also applies to vaccines such as that for tetanus. *Tongate v. Wyeth Laboratories*, 220 Ill. App. 3d 952 (1st Dist. 1991), *appeal denied* 143 Ill. 2d 649.

Medical devices also fall within the ambit of the rule. In Illinois, these include IV tubing connections (*Hanson v. Baxter Healthcare Corporation*, 198 Ill. 2d 420, 430-438 (2002), and a topical oxygen chamber for home use (*Friedl v. Airsource, Inc.*, 323 Ill. App. 3d 1039 (1st Dist. 2001)).

As a rule of thumb, the learned intermediary doctrine applies to any product which is ingested by, implanted in, applied to or used by the patient based upon the prescription or order of his doctor.

In some jurisdictions an exception is made for the birth control pill. *MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass 131, 475 N.E.2d 65 (1985), *cert. denied* 474 U.S. 920; *Humes v. Clinton*, 246 Kan 590, 792 P.2d. 1032 (1990). The exception rests upon the FDA's mandate that information, including warnings, must be provided directly to the patient.

In *Martin v. Ortho Pharmaceuticals*, 169 Ill. 2d 234 (1996), the plaintiff's physician prescribed the oral contraceptive Ortho-Novum at a time when neither knew she was pregnant. A child was born with deformities attributed to the contraceptive. Ortho Pharmaceuticals obtained summary judgment based upon the learned intermediary doctrine. The First District reversed (268 Ill. App. 3d 980), finding that an exception exists where a statute or regulation requires direct warnings to the ultimate user.

Thereafter, the Illinois Supreme Court reinstated the judgment in favor of the defendant. In so doing, the court held that the doctrine derives from the physician's expertise in prescribing the product and it therefore is unaffected by warnings that are given directly to the patient. In this regard the opinion states:

We agree with those decisions which have declined to recognize an exception to the learned intermediary doctrine for manufacturers of contraceptive pharmaceuticals. By refusing to abrogate State common law in light of Federal regulation, these courts have recognized the important policy considerations underlying the learned intermediary doctrine. The doctrine rests on the assumption that prescribing physicians, and not pharmaceutical manufacturers, are in the best position to provide direct warnings to patients concerning the dangers associated with prescription drugs.

Martin 169 Ill. 2d at 244.

Persons to Whom the Doctrine Applies

As stated by the court in *Kirk v. Michael Reese Hospital*, 117 Ill. 2d 507 (1987), the doctrine is based upon the prescribing physician's highly technical knowledge regarding both the product and the patient:

The doctor, functioning as a learned intermediary between the prescription drug manufacturer and the patient, decides which available drug best fits the patient's needs and chooses which facts from the various warnings should be conveyed to the patient, and the extent of disclosure is a matter of medical judgment.

Kirk 117 Ill. 2d at 519.

Assuming that the prescribing doctor had adequate information from the manufacturer to order the product for his patient, the rule should insulate everyone in the chain of supply from the manufacturer to the retailer. In *Leesley v. West*, 165 Ill. App. 3d 135 (2nd Dist. 1988), *appeal denied* 119 Ill. 2d 558, the court agreed and refused to hold the pharmacist liable. In so doing, it held that a pharmacist should not have a legal duty which exceeds that of the manufacturer.

However, the Illinois Supreme Court recently reached the opposite result in *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179, 188 (2002). There, it appeared that the pharmacist had actual knowledge of allergies which contraindicated use of the medication prescribed by the plaintiff's physician. He filled the prescription without warning her, and she sued for her resultant injuries. In finding that the pharmacist was not protected by the learned intermediary doctrine, the court carved out an exception for those circumstances where a pharmacist knows that a prescription, if filled, is likely to injure the patient.

That exception is based upon the breach of a duty to exercise ordinary care which Wal-Mart voluntarily assumed in soliciting allergy information from its customers. In this regard the opinion states:

The consequence of accepting Wal-Mart's "chilling effect" argument would be to sanction the status quo, where pharmacies solicit allergy information from their customers but are under no obligation to follow through with a warning, even where the pharmacy knows that the drug being prescribed is contraindicated for the individual customer. The difficulty with this approach is that the status quo is unacceptable. By asking customers about their drug allergies, the pharmacy is engendering reliance in the customer that the pharmacy will take steps to ensure that the customer does not receive a drug to which the customer is allergic. There can be no other reason for a pharmacy's seeking this information regarding drug allergies. Where the pharmacy fails to warn the customer, then the customer is placed at risk of serious injury or death.

Happel 199 Ill. 2d at 178.

The Supreme Court's reasoning in *Happel* is antithetical to that of the appellate court decision in *Leesley v. West, supra*. While the *Happel* decision makes sense on an *ad hoc* basis, it deprives pharmacists of the legal certainty required for them to provide needed medications without fear of liability. It also drives a wedge between the physician and the patient by obligating the pharmacist to second guess the prescribing doctor. Whether a pharmacist should have refused to fill a prescription will become a fact-driven issue based upon the patient's files and the types of medications which had been previously supplied.

Nor are the suppliers of medical products which are prescribed for home use necessarily able to rely upon the physician's order. In *Friedl v. Airsource, Inc.*, 323 Ill. App. 3d 1039 (1st Dist. 2001), a multiple sclerosis patient was given a prescription for a topical oxygen chamber to treat sores and lesions which had developed on her feet. She leased the product from the defendant, Airsource, a medical device rental company. While using the machine she sustained burns on her feet. She sued Airsource claiming that it failed to provide proper operating instructions for the machine. The company asserted the learned intermediary doctrine and was subsequently dismissed.

In reversing, the appellate court distinguished allegations of giving improper "operating instructions" from claims that the product has been improperly prescribed. It concluded that the learned intermediary doctrine applies to the latter but not to the former, stating: "We hold that the learned intermediary doctrine does not apply to bar actions against distributors of prescribed medical devices for failing to properly instruct the consumer about the device's operation." *Friedl*, at 1043.

When a Warning is Inadequate

The learned intermediary doctrine substitutes the prescribing physician for the ultimate user as the person to whom product information is to be provided. Consequently, the adequacy of a warning

depends upon the quality and quantity of the information imparted to the doctor. The fact that the label has been approved by the FDA does not preempt the issue. *Weiland Teletronics Pacing Systems, Inc.*, 188 Ill. 2d 415, 721 N.E.2d 1149 (1999). To the contrary, the pregnant question is commonly whether the adverse consequence suffered by the plaintiff falls within the ambit of the literature provided to the doctor, or was anticipated by him at the time he made the prescription.

Where the prescribing physician professes otherwise, a question of fact exists. This question typically requires the opinion of experts, as there is no need to provide a warning of those risks which are commonly known by the medical community. *Proctor v. Davis*, 291 Ill. App. 3d 265 (1st Dist. 1997), *appeal denied* 175 Ill. 2d 553. While the testimony of engineers who are not medically trained has been received, it is probable that the opinions of a physician will be required. *Hansen v. Baxter Healthcare Corp.* 198 Ill. 2d 420, 428-29, 438 (2002).

The most complex and significant issues regarding the adequacy of information provided to the medical profession involve: (1) whether physicians should be informed of contraindications for off label uses after the product has been approved for marketing, and (2) the sufficiency of warnings which are approved by the FDA, particularly when coupled with actual knowledge of potential problems by the prescribing physicians.

The former area of concern focuses upon the tendency of doctors to prescribe medications and devices for therapeutic reasons which were not initially contemplated by either the manufacturer or the FDA in releasing the product to the market. Those uses do not appear in the package insert or the PDR. However, they are often reported to the manufacturer anecdotally or learned by it through subsequent clinical studies. Drug and device manufacturers have an ongoing obligation to keep their new drug applications (NDAs) up to date. 21 CFR § 310.303. They can also seek licensure for new applications of existing products and amended labels. 21 CFR § 601.12.

However, where approval of the product and its labels are limited to certain uses, can the manufacturer be liable for failing to warn of off label prescriptions? As otherwise expressed, does the learned intermediary doctrine shield the manufacturer for failure to warn of side effects and potential hazards in applications for which the product was not approved? In Illinois the answer turns on what the company and the prescribing doctor knew.

Proctor v. Davis, 291 Ill. App. 3d 265 (1st Dist. 1997), *appeal denied* 175 Ill. 2d 553, involved a corticosteroid, Depo-Medrol manufactured by Upjohn Company. In 1959, Upjohn received FDA approval which was "limited to intramuscular, intra-articular and intralesional injections" for the treatment of various inflammatory disorders. Upjohn did not test or seek approval for the use of Depo-Medrol in intra-ocular or peri-ocular injections.

Following approval, the manufacturer became aware of the drug's use by various physicians who injected it in or near the eye to reduce ocular inflammations. Upjohn had not conducted animal tests for that application. Upjohn also knew that Depo-Medrol was an insoluble toxic material which would remain in affected tissues with an adequate blood supply for six-eight weeks. It was also aware that the eye did not possess "such a blood supply."

Between 1959 and 1983, Upjohn received a number of drug experience reports (DERs) from ophthalmologists regarding the results of their use of Depo-Medrol in peri-ocular injections. Some of these included potential adverse reactions. These were forwarded to the FDA with a letter indicating that the use involved was not recommended. Nonetheless, Upjohn did not conduct animal tests, seek to file a supplemental NDA or inform physicians of potential adverse reactions when the drug is injected into or near the eye.

The prescribing physician was unaware of side effects which had been reported to Upjohn when he commenced a series of peri-ocular injections in the plaintiff. Following an intra-ocular injection, the plaintiff lost vision in the left eye. Suit was prosecuted against Upjohn on a strict liability theory and resulted in a verdict in plaintiff's favor for both compensatory and punitive damages.²

Judgment was affirmed by the appellate court. In doing so the court made a traditional product liability analysis which incorporated the learned intermediary doctrine. Adhering to *Kirk v. Michael Reese Hospital*, 117 Ill. 2d 507 (1987), the court recognized that the drug was “unavoidably unsafe” without a warning. The warning to the ultimate user would be obviated where it was adequately given to the prescribing physician as a “learned intermediary.” However, the “learned intermediary doctrine” would not apply if the physician lacked adequate knowledge to make a risk-benefit analysis. While a product manufacturer is not obligated to warn of risks which are generally known to the medical community, the duty exists as to hazards of which it has knowledge and regarding which the physician population is unaware.

Applying that analysis, the court held that Upjohn knew of the potential hazard of using Depo-Mederol in intra-ocular and peri-ocular injections. It had not conveyed that risk to the medical community and therefore the learned intermediary doctrine did not apply to insulate the manufacturer against the obligation to warn the plaintiff. It is also significant to note that the court reasoned that the duty to warn is “non-delegable,” so that a product supplier cannot rely upon the medical community to do research or otherwise ascertain potential side effects which are known to the manufacturer but not communicated to physicians.

In *Proctor v. Davis*, the court considered the adequacy of warnings in the context of knowledge by the manufacturer of contraindications which it had not communicated to the medical community, and which were not generally known to the profession. Consequently, the rationale and result do not significantly undermine or imperil the fundamental concept that the supplier of a prescriptive drug or device is not obligated to warn the ultimate user of side effects which should be considered by the prescribing physician in considering the risks and benefits of the product.

In *Hansen v. Baxter Healthcare Corp.*, 198 Ill. 2d 420, 430-438 (2002), the application of the doctrine was cast into doubt in design defect cases, *even where the prescribing physician, and the medical community, are aware of the particular risk which cause the plaintiff's injury.* *Hansen v. Baxter Healthcare* is also significant for its analysis of the interrelationship drawn between the learned intermediary doctrine and the “consumer expectation test” which is used in determining whether a product is “unreasonably dangerous.”

In *Hansen v. Baxter Healthcare Corp.*, the plaintiff's decedent, Andrena Hansen, suffered an air embolism because an intravenous (IV) tube became detached from a catheter inserted into her jugular vein. The embolism caused brain damage and paralysis and led to her death four years later. Baxter Healthcare (Baxter) provided the connector used to join the IV tube to the catheter.

Baxter manufactured and marketed two types of connectors: “friction-fit and “Luer-lock.” The friction fit type has two mating tempered fittings which are joined by a medical professional who applies sufficient force to maintain a leak-proof connection. The Luer-lock serves the same purpose but has a threaded collar that screws onto the hub of the catheter. In its patent application Baxter stated that the Luer-lock was “designed to overcome the problem of inadvertent disconnection that occurs with friction-fit connectors.” The additional costs of the Luer-lock versus the friction-fit connector was approximately three to five cents per unit.

After development of the Luer-lock type, Baxter supplied both connectors to hospitals, including Mt. Sinai, where the decedent was admitted for treatment of stomach ulcers. Following successful surgeries, fluids were administered intravenously through decedent's jugular vein, which is known as a “central line” application. The potential for an air embolism with resultant brain damage was a known consequence if a central line IV tube disconnected from the mated catheter. It was also generally known that the friction-fit connector would separate, whereas the Luer-lock did not have that problem.

While the second year surgical resident who placed the catheter in the decedent's jugular vein testified that he was unfamiliar with Luer-lock connectors, the attending general surgeon and the

supervising surgical resident were familiar with both types of connectors. They also knew that friction-fit connectors could unintentionally separate but “Luer-lock connectors were safe to use in central lines.” The decedent’s problems arose when the Baxter friction-fit connector parted, allowing the introduction of air into the catheter.

The plaintiff pursued a strict liability defective design theory against Baxter, contending that the friction-fit connector was defectively designed because it did not have the security against detachment of the Luer-lock. The plaintiff also claimed that the product was defective because Baxter had failed to warn of the problem and that friction-fit connectors were contraindicated for central line applications.

Baxter defended, *inter alia*, on the premise that the medical community and the prescribing physicians knew that friction-fit connectors should not be used in central line applications and that Luer-lock connectors were less likely to fail. Baxter also contended that application of the “consumer expectation test” in determining whether or not the friction-fit connector was “unreasonably dangerous” turned on the expectations of the prescribing physicians, as opposed to what the patient, as ultimate user, anticipated.

At the trial, a number of Baxter employees testified on adverse examination that the company knew of the propensity of friction-fit connectors to separate unintentionally. Those witnesses also generally conceded that friction-fit connectors were inadequate for central line use and therefore medical professionals should use Luer-locks, which were recommend for that application. Baxter representatives also acknowledged that Baxter did not recommend one product over the other.

The plaintiff used a mechanical engineer, Neil Sheehan, as its expert witness. He had worked for several companies which developed and sold IV components and, in some cases, had personally designed and patented medical devices, including IV equipment. He testified regarding the comparative strength of the line union connection between friction-fit connectors and those which had the Luer-lock.

In his opinion the friction-fit connector became obsolete once the Luer-lock became available. Sheehan’s testimony was received without objection, despite the fact that he lacked medical training. The jury was instructed on both failure to warn and defective design theories. It returned a general verdict for the decedent’s estate. No special interrogatories were requested or submitted.

On appeal in *Hansen v. Baxter Healthcare Corp.*, 309 Ill. App. 3d 869 (2000), the First District held that Baxter was not obligated to warn the decedent’s physicians of the risks associated with friction-fit connectors because they already knew of those hazards. The appellate court cited the following language from *Proctor v. Davis, supra*, with approval:

In Illinois, there is no duty to warn of a risk that is already known by those to be warned. In the context of prescription drug litigation, this principle means that a drug manufacturer need not provide a warning of risks known to the medical community.

Proctor 291 Ill. App. 3d at 277.

However, the appellate court affirmed on grounds that the evidence sufficiently supported the general verdict on the theory of defective design.

The Illinois Supreme Court accepted the appeal on both issues. With respect to the former it reversed, holding that Baxter’s superior knowledge of the separation problem with friction-fit connectors, and the benefits of Luer-lock connectors in that regard, overcame the general knowledge of the decedent’s treating physicians. The court held that the issue is whether medical professionals are “sufficiently” warned, which involves a comparative analysis between what the manufacturer knew and the knowledge possessed by the prescribing professionals. Referring to *Proctor v. Davis, supra*, with approval the court held:

In the instant case, Baxter gave the medical community no warning at all about the need to use Luer-locks in central line applications. Thus, this issue was properly submitted to the jury. The jury's general verdict for plaintiff *could have been reasonably based on a finding that Baxter's knowledge with respect to the use of Friction-fit connectors was superior to that of the medical community and thus Baxter breached its duty to warn . . .* (Emphasis supplied).

Hansen 198 Ill. 2d at 432.

Equally troubling from the defense perspective is the court's analysis of the design defect claim in the context of "*the consumer expectation test*" as a defining factor in determining whether the friction-fit connector was unreasonably dangerous. In that analysis the court cited with approval the following language from *Lamkin v. Towner*, 138 Ill. 2d 510, 529 (1990).

A plaintiff may demonstrate that a product is defective in design, so as to subject a retailer and a manufacturer to strict liability for resulting injuries, in one of two ways: (1) by introducing evidence that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner or (2) by introducing evidence that product's design proximately caused his injury and the defendant fails to prove that on balance the benefits of the challenged design outweigh the risk of danger inherent in such designs. See generally *Palmer v. Avco Distributing Corp.* (1980), 82 Ill. 2d 211, 219-20, citing *Barker v. Lull Engineering Co.* 1978), 20 Cal. 3d. 413, 427-28, 573 P.2d. 443, 452, 143 Cal. Rptr. 225, 234-35.

Baxter urged that the "consumer expectation test" in prescription product cases turns on what the prescribing physician or "learned intermediary" would expect. Applying that standard to the friction-fit coupler, it argued that because the general surgeon and senior resident knew of the potential for separation, and therefore that a friction-fit connector should not be used in central line applications, the product was not unreasonably dangerous.

The Supreme Court rejected that contention and applied the "ordinary consumer expectation test." It relied upon its previous decision in *Haudrich v. Howmedica, Inc.*, 169 Ill. 2d 525, 542 (1996), *cert. denied* 519 U.S. 910 (1996). There the court applied the expectations of "*an ordinary person*" in its analysis of whether there was a design defect in a prescribed knee prosthesis.

In the context of the friction-fit versus Luer-lock connectors supplied by Baxter, this analysis means that the product could be considered defective because the *patient* was unaware that a friction-fit connector might separate, whereas a Luer-lock was less likely to do so. Therefore in design defect cases, which presuppose feasible alternatives (*Kerns v. Engelke*, 76 Ill. 2d 154, 162-63 (1979)), the learned intermediary doctrine will be of limited significance. If the standard applicable to prescription product safety is determined by what a lay consumer would expect, the knowledge of the prescribing physician becomes irrelevant.

The Future

The *Hansen* court also reached the same result regarding product design liability by applying the "risk - utility test." As articulated in *Lamkin v. Towner, supra*, a product may be defectively designed, even though it satisfied the consumer expectation test, if the benefits of the challenged design are outweighed by its potential for injury. Applying the risk - utility analysis, the *Hansen* court concluded that the Luer-Lock collar would have prevented unintentional disconnection "at a cost of between three and five cents per unit."

Baxter argued that, in pharmaceutical and medical device cases, the traditional “risk - utility” analysis had been superseded by Section 6(c) of the Restatement (Third) of Torts which provides:

(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.

Under that standard, the plaintiff in *Hansen v. Baxter Healthcare* would have to prove that the risks inherent in the friction-fit coupling were so great that no reasonable doctor would order its use for any patient.³ The Restatement’s use of the term “any class of patients” would also appear to encompass cases such as *Hansen* in which the product was safe for some uses but not for others.

The *Hansen* court refused to apply Section 6 of the Restatement (Third) of Torts on grounds that it had not been raised at the trial court level or before the appellate court until Baxter’s reply brief. However, the court went on to state: “We do not foreclose consideration of the Restatement (Third) of Torts standard in another case where it is raised at trial and is appropriately briefed and argued.”

This statement should be viewed as an invitation to use Section 6 in future design defect cases involving prescription drugs and medical devices. The context in which the suggestion was made also infers that the Restatement (Third) “. . . would apparently require expert medical testimony to establish whether reasonable health-care providers, knowing the foreseeable risks and therapeutic benefits of the . . . device, would prescribe it for any class of patient.”

Consideration of the Restatement (Third) should not stop with design defect cases. Section 6(d) specifically addresses the learned intermediary doctrine as follows:

(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.

This language is unduly contorted because of the Institute’s preference for the term “not reasonably safe,” as opposed to “unreasonably dangerous.” However, the message is clear that a product manufacturer or supplier need go no further than giving the physician, sufficient information regarding inherent and unavoidable risks of the product to permit the healthcare provider, and thereby the patient, to make an appropriate therapeutic risk-benefit analysis. Section 6(d)(2) contemplates direct patient warnings in instances where the manufacturer knows that a physician will either not be involved or will have limited involvement in recommending or prescribing the product. This exception is discussed in comment (e) and is generally relegated to vaccines dispensed to the patient without the involvement of a healthcare provider.

Section 6(e) discusses the liability of retailers and distributors. Their exposure attaches in manufacturing defect cases, which is consistent with the existing “stream of commerce” rationale for liability. However, subsection (e)(2) also contemplates exposure for non-manufacturing retail sellers

in limited instances where their *negligence* in supplying the product is a proximate cause of the plaintiff's injury. The example given in comment (h) involves direct warning pamphlets provided by the manufacturer to the pharmacy, which it fails to give the patient at the time the drug is dispensed.

This exception would also encompass the negligence of the pharmacist in *Happel v. Wal-Mart Stores, Inc.*, 199 Ill. 2d 179 (2002), who dispensed a prescribed medication he knew was contraindicated because of the plaintiff's allergies. Liability in that situation is founded upon negligence principles, as it is the retailer's failure to exercise ordinary care that makes an otherwise adequate warning ineffectual.

Conclusion

In Illinois, the learned intermediary doctrine in prescription drug and medical device cases has reached a crossroads. Borne of the synergy between protective federal regulation and recognition of the medical profession's technical competence to make decisions combining the patient's needs and the product's palliative's properties, the rule is a logical barrier to liability. That barrier has generally been perceived as a bar to product liability actions whether based on design defects or the failure to warn. As otherwise expressed, where an adequate warning is given, a product's potential for injury is mediated and it is not unreasonably dangerous. Restatement (Second) of Torts, § 40A, comments i and j.

Hansen v. Baxter Healthcare creates a comparative challenge to the doctrine's application in cases where the product's manufacturer has knowledge of its potential risks which is "superior" to that of the medical profession, without regard to the basic adequacy of the prescribing physician's understanding. Of far greater significance is *Hansen's* challenge to the theoretical principles which underpin the rule. If, as the *Hansen* court reasons, a product may be defective and unreasonably dangerous because of its inherent design, without regard to what the prescribing health care providers know or are told about its properties and use, the doctrine will be a faint muffler against the Klaxon of liability. The din of imminent exposure will become particularly loud if the "consumer expectation test" is applied at the patient level rather than the physician level.

Drafters of the Restatement (Third) of Torts anticipated the problem of *alternative* design defect accountability in § 6(c). There, a design defect will be actionable only if the risk of harm is so great 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.*" The *Hansen* court invited consideration of § 6. The authors submit that the integrity of the learned intermediary doctrine in Illinois depends upon acceptance of the invitation and able advocacy in its pursuit.

Endnotes

¹ The exception to this lies in the risk/benefit analysis which alternatively defines "unreasonably dangerous" product. *Lamkin v. Towner*, 138 Ill. 2d 510, 529 (1990).

² Punitive damages were subsequently remitted.

³ The language of Section 6(c) is sufficiently broad to encompass both the "consumer expectation" and "risk - utility" alternatives in a defective design case.

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