

**RECENT DEVELOPMENTS IN DRUG AND MEDICAL DEVICE LITIGATION:
STATUS OF THE LEARNED INTERMEDIARY DOCTRINE AND THE
RESTATEMENT (THIRD) OF TORTS**

Written by

Josh Greenbaum, Esq. & Matthew F. Henry, Esq.
COZEN O'CONNOR
jgreenbaum@cozen.com
[mfhenry@cozen.com](mailto:mfhenny@cozen.com)

Presented by

Josh Greenbaum, Esq.
COZEN O'CONNOR
1900 Market Street
Philadelphia, PA 19103
(800) 523-2900
(215) 665-2000
jgreenbaum@cozen.com

Atlanta
Charlotte
Cherry Hill
Chicago
Dallas
Las Vegas*
Los Angeles
New York
Newark
San Diego
San Francisco
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**Affiliated with the Law Offices of J. Goldberg & D. Grossman.*

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I. INTRODUCTION

Recent developments in drug and medical device litigation have had an impact on the outcome of such product liability cases. The most important issue concerning drug and medical device litigation today is the status of the “learned intermediary doctrine.” This doctrine, which excuses manufacturers of drugs and medical devices from their general duty to warn the ultimate user of their product of the risks associated with the product, has been challenged in recent years and such manufacturers may soon find themselves liable to individual plaintiffs that had previously been unable to establish a cause of action against them.

The introduction of the Restatement (Third) of Torts has similarly impacted drug and medical device litigation. By specifically addressing manufacturers’ and sellers’ post-sale duties (including the post-sale duty to warn and the post-sale duty to recall defective products), the Restatement (Third) has formally recognized that such parties may be exposed to potential liability far broader than previously thought. Further, the Restatement (Third) also has created debate concerning the way that it treats design defects in prescription drugs and medical devices.

II. THE LEARNED INTERMEDIARY DOCTRINE

A. INTRODUCTION

One of the most debated and controversial aspects of drug and medical device litigation involves the use and scope of the learned intermediary doctrine. This doctrine establishes an exception (in the drug and medical device area) to the general rule that a drug or medical device manufacturer owes a duty to warn users of the potential risks of its product. Under the learned intermediary doctrine, a drug or medical device manufacturer has no duty to warn the ultimate user of the risks of its product.¹ Instead, the manufacturer must warn only the prescribing physician, who acts as a “learned intermediary” standing between the patient and the

manufacturer.² Even if the manufacturer fails to warn of a risk, therefore, it is not liable if the prescribing physician was independently aware of the risk or if the warning would not have changed the physician's decision to prescribe the drug or device.³ Further, if the dangers posed by a particular product have been "generally appreciated" by the medical community, the manufacturer has no duty to warn of those dangers.⁴

Courts commonly recognize four justifications for the learned intermediary doctrine:

1. Warnings directly from the manufacturer to the patient can undermine the doctor-patient relationship.
2. The doctrine of informed consent requires doctors to warn patients about treatment, so doctors have an obligation to advise patients about the risks of a drug or device.
3. A prescribing doctor can personally communicate warnings to patients, while a manufacturer can only provide a written product insert.
4. Doctors can respond to the individual needs and abilities of the patient and convey warnings that the patient understands.⁵

Recently, there have been several arguments advancing certain exceptions to the general rule in certain circumstances. As expected, few of these issues have been conclusively determined. However, several courts around the country have commented on these proposed new exceptions and have offered arguments both for and against their recognition.

B. EXISTING EXCEPTIONS

Prior to the Restatement (Third) of Torts: Products Liability, and to a certain extent continuing today, there has been only one generally accepted exception to the learned intermediary doctrine, for mass immunizations.⁶ Where a vaccine is designed to be distributed in an "assembly line" fashion and no physician evaluates the drug for each patient's needs and medical history, the learned intermediary doctrine does not apply.⁷ This exception applies only if the physician-patient relationship is nonexistent. Thus, if a personal physician prescribes a

vaccine to a patient, the exception does not apply, even if the doctor makes no individualized judgment.⁸

While the majority of courts have been reluctant to recognize additional exceptions to the general rule, at least three jurisdictions have established second exceptions. Massachusetts recognized an exception for oral contraceptives on the grounds that the decision to take such a medication is a personal choice and the doctor often plays a limited role.⁹ An Oklahoma court, on the other hand, established an exception to the doctrine where the manufacturer of a nicotine patch provided FDA-mandated warnings directly to the patient.¹⁰ Lastly, a Wisconsin court held that the learned intermediary doctrine did not bar a claim where a manufacturer failed to provide federally mandated warnings with an oral contraceptive.¹¹

Despite these notable distinctions, the vast majority of courts have been reluctant to recognize any of these exceptions. For example, the majority of jurisdictions have held that brochures or package inserts provided directly to the patient, whether federally mandated or not, do not create exceptions to the doctrine.¹² Further, in another interesting Massachusetts decision, a court refused to create an exception to the doctrine for weight-loss drugs, despite the argument that these drugs are “personal choice” drugs similar to oral contraceptives.¹³

C. POTENTIAL FUTURE EXCEPTIONS

Although the jurisdictions that have recognized these additional exceptions are few, the fact that they entertained such arguments has set the stage for potential exceptions in two distinct areas: circumstances involving direct-to-consumer advertising (DTC) and situations where the FDA exerted its authority to regulate advertisements for prescription drugs under the Federal Food, Drug, and Cosmetic Act (FDCA).¹⁴

1. Direct-to-Consumer Advertising

Direct-to-consumer (hereinafter “DTC”) advertising largely concerns the situation where a consumer, due to commercials or other forms of advertising, seeks out a treatment (generally lifestyle enhancing and not medically necessary) that he or she might not have otherwise received.¹⁵ The argument concerns whether the manufacturers of the advertised products should still be afforded the protection of the learned intermediary doctrine despite the fact that the advertising itself has diminished the role of the intermediary physician.

Those in favor of DTC advertising state that the DTC ads provide consumers with information about new treatments for illnesses, call consumers’ attention to symptoms that they may suffer from, and encourage patients to seek medical assistance.¹⁶ On the other hand, by placing the decision to seek out any of these advertised products directly on the consumer, the argument follows that the manufacturer has itself eliminated the learned intermediary from the equation and should thus be liable.

2. FDA Regulation of Advertisement

FDA regulation of the advertisement of prescription drugs requires that: a “brief summary” of the package insert be included in the advertisement; that all side effects, contraindications, and effectiveness of the product are disclosed; and that easy access to the package insert be provided.¹⁷ Manufacturers have found that it is not practical to provide all of this information on television or radio ads and have instead been forced to rely on so-called “reminder” ads and “help-seeking” ads that are exempt from the “brief summary” requirement.¹⁸ “Reminder” ads call the consumers attention to the name of the drug, but they do not describe the conditions that they treat, while “help-seeking” ads simply advise consumers that treatment may be available for a certain condition.¹⁹

In 1999, the FDA issued a guidance on consumer-directed broadcast advertisements which provides clear, concise direction for drug advertisements via television, radio, or telephone communication systems.²⁰ According to these regulations, broadcast advertisements must include only a “major statement” of the major risks of a drug and offer “adequate provision” for dissemination of the approved package labeling.²¹ A manufacturer can meet its “adequate provision” requirement by: providing a toll free telephone number where consumers can obtain package insert information, specifying the location of print advertisements, maintaining a Web page showing package labeling, and suggesting consumers contact prescribing physicians for further information.²²

As manufacturers attempt to advertise their products to the consuming public, either by using DTC advertising or by following the guidelines promulgated by the FDA, they may be unwittingly eroding the basis for the learned intermediary doctrine. Whereas patients once visited their physicians to seek advice from a doctor concerning a specific symptom, now patients request the specific medication that they are seeking based on information they have obtained through the manufacturers’ advertisements. Instead of relying on the physicians recommendation after examination, these patients have become the primary decision maker concerning the treatment that they receive.

If the physician is now secondary to the patient when it comes to a decision regarding treatment due to the manufacturers’ advertisements, then these manufacturers’ are potentially exposing themselves to liability that they were previously shielded from by the learned intermediary doctrine. Case law concerning the effect of DTC advertising to the learned intermediary doctrine has been mixed.

D. CASE LAW CONCERNING DTC ADVERTISING AND EXCEPTIONS TO THE LEARNED INTERMEDIARY DOCTRINE

Several courts have considered whether DTC advertising affects the learned intermediary doctrine. Only one, however, has specifically concluded that DTC advertising does, in fact, abrogate the learned intermediary doctrine such that the manufacturer of the drug or medical device directly advertised to consumers owes a duty to warn the ultimate user directly.

In 1999, the New Jersey Supreme Court determined specifically that drugs marketed directly to consumers fall outside the learned intermediary doctrine.²³ Several plaintiffs asserted that DTC advertising of Norplant (a surgically implanted contraceptive) precluded the defendant from asserting the defense of the learned intermediary doctrine.²⁴ Both the trial court and an intermediate appellate court ruled that such advertising did not abrogate the learned intermediary doctrine. The New Jersey Supreme Court reversed, however, recognizing an exception to the learned intermediary doctrine where the drug or medical product in question is directly advertised to consumers.²⁵

The court noted that there are four traditional bases for the doctrine: (1) reluctance to undermine the doctor-patient relationship; (2) the absence in the era of “doctor knows best” of need for the patient’s informed consent; (3) the inability of the drug manufacturer to communicate with patients; and (4) the complexity of the subject.²⁶ The court then determined that these policy reasons are absent in the DTC advertisement situation.²⁷ The court specifically stated that the DTC “alters the calculus” of the doctrine and “believes . . . the premises on which the learned intermediary doctrine rests.”²⁸ The court went on to say, “[w]hen 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.”²⁹

Other courts had previously commented on the issue, but had not specifically adopted the exception as the New Jersey Supreme Court recently did. In 1991, a federal district court in Massachusetts recognized in a footnote that “[i]n an appropriate case, the advertising of a prescription drug to the consuming public may constitute . . . [an] exception to the learned intermediary rule.”³⁰ The court noted that by “advertising directly to the consuming public, the manufacturer bypasses traditional patient-physician relationship, thus lessening the role of the ‘learned intermediary.’”³¹ While the court did not apply this exception in this case, the fact that it was mentioned as a possibility indicates that other courts may be willing to recognize additional exceptions to the learned intermediary doctrine.

Also in 1991, the Alaska Supreme Court similarly indicated that DTC advertising may be a basis for an exception to the learned intermediary doctrine.³² In a footnote the court discussed certain circumstances that may obligate the manufacturer to warn the ultimate consumer directly:

With certain types of prescription drugs, the role of the doctor in the decision to use a specific product is significantly reduced. Examples of such atypical prescription products include . . . drugs marketed under a strategy designed to appeal directly to the consuming public. These are areas where courts have held that manufacturers have a duty to warn patients directly.³³

While the above quoted language was not the basis for the court’s holding in this case, the fact that the court mentioned this possibility indicates that drugs marketed under a strategy designed to appeal directly to the consuming public may be a basis for the imposition of a duty on the part of the manufacturer to warn the ultimate consumer directly.

In 1999, the Fifth Circuit confronted this issue directly and determined that the presence of DTC advertising does not provide the basis for another exception to the learned intermediary

doctrine.³⁴ Five plaintiffs each had suffered negative side effects from the contraceptive Norplant. The district court found that the learned intermediary doctrine applied to the situation and entered summary judgment for the defendant. On appeal, the plaintiffs argued that the learned intermediary doctrine should not apply due to the physician's reduced role in the selection of the proper contraceptive and the defendant's "aggressive" marketing of Norplant.

The 5th Circuit agreed with the district court and declined to recognize an exception to the doctrine under these circumstances.³⁵ Concerning the limited role of the physician the court stated,

Although it may be true that physicians may seek to provide greater freedoms to their patients in selecting an appropriate form of contraception, Norplant is nevertheless a prescription drug. The record makes it clear that physicians play a significant role in prescribing Norplant and in educating their patients about the benefits and disadvantages to using it.³⁶

Concerning the defendant's marketing, the court stated,

This argument is critically weakened by the absence of any evidence on the record that any of the five plaintiffs actually saw, let alone relied, on any marketing materials issued to them by [the defendant]. Given this deficiency, even if such an exception to the doctrine should apply, summary judgment would still be appropriate in this case. Two of our cases applying Texas law in this area have concluded that, as long as a physician-patient relationship exists, the learned intermediary doctrine applies.³⁷

Thus, based on the above, the court refused to recognize the exception to the learned intermediary doctrine.

E. THE IMPACT OF THE RESTATEMENT (THIRD) OF TORTS ON THE LEARNED INTERMEDIARY DOCTRINE

The American Law Institute (ALI) approved the Restatement (Third) of Torts in 1997. Since that time, this approval has been described as "the most important development in the past

three decades for those who must live in the ‘nuts and bolts’ world of product liability law.”³⁸ It remains uncertain if the Restatement (Third) of Torts will have an impact similar to its predecessor, the Restatement (Second) of Torts. In most states products liability law, including drug and medical device litigation, is well-settled. Thus, the majority of courts no longer require the assistance and guidance that the Restatement (Second) once provided. However, it is clear that the Restatement (Third) may influence drug and medical device products liability law in several contexts, including the learned intermediary doctrine.

Section 6 of the Restatement (Third) embodies the new general rules regarding the liability of a commercial seller or distributor for harm caused by defective prescription drugs and medical devices.³⁹ Section 6 provides:

(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:

- (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.⁴⁰

As a whole, the Restatement (Third) was designed to reflect recent developments in products liability law since the Restatement (Second). Section 6(d) specifically deals with the learned intermediary doctrine. Two of the Comments following § 6 discuss this doctrine and its modern interpretation.

1. Comment b, “Rationale”

Comment b to § 6 discusses the modern rationale behind the learned intermediary doctrine.

The rationale supporting this “learned intermediary” rule is that only health-care professionals are in a position to understand the significance of the risks involved and to assess the relative

advantages and disadvantages of a given form of prescription based therapy. The duty then devolves on the health-care provider to supply the patient such information that the patient can make an informed choice as to therapy. Subsection (d)(1) retains the “learned intermediary” rule. However, in certain limited therapeutic relationships the physician or other health-care provider has a much-diminished role as an evaluator or decisionmaker. In these instances it may be appropriate to impose on the manufacturer the duty to warn the patient directly.⁴¹

The final sentence of the quoted language of this comment specifically recognizes that there may be circumstances in which the manufacturer does have a duty to warn the ultimate user directly. However, as the language does not specify the exact “limited therapeutic relationships” where this duty is triggered, it remains up to the courts to define exactly what those situations are. At the very least, however, this comment provides support for arguments promoting additional exceptions to the learned intermediary rule. So long as a plaintiff can establish that the prescribing physician had little to do with the ultimate decision concerning treatment, that plaintiff may be able to convince a court that the duty to warn of the risks of the prescribed drug or device rested with the manufacturer rather than the prescribing physician. Simply put, this comment opens the door for multiple situations to be considered exceptions to the learned intermediary doctrine.

2. Comment e, “Direct Warnings to Patients”

Comment e recognizes that the learned intermediary doctrine continues to require a manufacturer of a drug or medical device to warn health-care providers rather than the ultimate recipient of the prescribed treatment. “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.”⁴²

However, the comment specifically mentions three areas in which “courts should consider imposing tort liability on drug manufacturers that fail to provide direct warnings to consumers.”⁴³ Initially, the court noted the long recognized exception stated in Subsection (d)(2), concerning situations where drugs are dispensed or administered to patients without the personal intervention or evaluation of a health-care provider (the mass immunization exception). The second instance noted in the comment is where a governmental regulatory agency has mandated that patients be informed of risks attendant to the use of a drug.⁴⁴ The last involves the situation where a manufacturer has advertised a prescription drug and its indicated use in the mass media.⁴⁵

While the comment suggests that these situations be carefully considered, the comment does not definitively state that manufacturers should warn the consumers directly in these situations. In fact, the comment clarifies its position by stating that “[t]he Institute leaves to developing case law whether exceptions to the learned intermediary rule in these or other situations should be recognized.”⁴⁶ Courts themselves, therefore, are going to have to make the policy determination of whether new exceptions to the learned intermediary doctrine should be established.

It is not surprising that the Restatement (Third) recognizes potential exceptions for these situations. In fact, as discussed above, courts of various jurisdictions have already discussed these potential exceptions. However, by specifically noting that courts “should” consider imposing tort liability on drug manufacturers in these circumstances, the drafters of the Restatement (Third) have legitimized those courts’ concerns. It seems that this recognition can only serve to bolster any effort to create new exceptions to the learned intermediary doctrine.

F. OTHER RECENT LEARNED INTERMEDIARY DOCTRINE CASE LAW

1. Warnings on Physician Samples

One court has recently upheld the learned intermediary doctrine in a claim that drug manufacturers must place warnings on physicians' samples.⁴⁷ The manufacturer had sent a box of samples to a physician. The box contained a warning concerning the enclosed blister cards, yet the warning was not repeated on the blister cards themselves. Plaintiff was given several cards by her physician. Years later, plaintiff's husband took some of the samples and died. Plaintiff's husband had been told that he was allergic to nonsteroidal anti-inflammatory drugs and apparently had attempted to determine whether the samples would be harmful to him by checking two medical reference books. When he could not find any reference to the drug sample he ingested some and died due to a severe anaphylactic reaction.

On a certified question from the Second Circuit, the Supreme Court of Connecticut recognized the learned intermediary doctrine and held that it applied to plaintiff's claim despite the argument that, as with the sophisticated user defense, the adequacy and proper receipt of the warning were questions of fact. The court determined that the sophisticated user defense is not analogous to the learned intermediary doctrine because drugs can only be obtained from a doctor "who is in the best position to convey adequate warnings based upon the highly personal doctor-patient relationship."⁴⁸ The court further declined to establish a new exception to the learned intermediary doctrine and reaffirmed that the that exceptions apply only where there is a lack of communication between patients and doctors or where patients "essentially control" the selection of the treatment.

2. Independent Intermediary

The Fourth Circuit recently determined that in order for a special relationship (i.e. a consultant for the manufacturing company) between the prescribing doctor and the drug manufacturer to abrogate the learned intermediary doctrine, the physician must be “so close to the [manufacturer] that he could not exercise independent professional judgment.”⁴⁹ Otherwise, the mere existence of a consulting relationship between a manufacturer and a doctor does not create a duty on the part of the manufacturer to warn the ultimate consumer.⁵⁰

3. Over-the-Counter Drugs

One New York Court recently determined that the learned intermediary doctrine does not apply to over-the-counter drugs.⁵¹ Plaintiff was prescribed Motrin but was also advised by his physician that he could take over-the-counter strength Motrin when the prescription ran out. The defendant, Upjohn, argued that because the prescribing physician instructed the plaintiff on what medication to take, the doctor acted as a learned intermediary. The court declined to agree, stating that Upjohn “opted to forgo the shelter of the learned intermediary doctrine when it sought, and obtained, the right to market its product in over-the-counter strength directly to the consumer without the protective filter of the prescription process.”⁵²

4. Extension of the Doctrine to Non-Physicians

Several recent cases have discussed whether the learned intermediary doctrine applies to non-physicians. One Texas court has held that an advanced practice nurse who can prescribe medication and treat patients without physician supervision is considered a learned intermediary.⁵³ Several other courts have concluded that the learned intermediary protects a pharmacist who dispenses prescriptions as ordered by the prescribing physician.⁵⁴

However, some courts have restricted the protection afforded to the pharmacist. One court held that if the pharmacist gives a warning, he is responsible for the warnings,⁵⁵ and another has held that where the pharmacist knows that the prescribed drug is a possible “deadly poison” for the patient and the pharmacist is the “last chance to avoid serious injury or death,” the pharmacist must warn the patient.⁵⁶

G. CONCLUSION

Despite recent attempts to diminish the viability of the learned intermediary doctrine it remains alive and well. However, how long it remains substantially intact remains unclear. It is possible that many courts, when given the opportunity, will read the language in the Restatement (Third) and the comments thereto as providing the necessary support to significantly diminish the protection afforded to manufacturers of drugs and medical devices. It is equally possible that the comments will remain just that, and the courts will simply continue to evaluate the circumstances of each case and apply the doctrine as broadly as it was prior to the publishing of the Restatement (Third). Regardless, each jurisdiction will decide for itself whether the Restatement (Third) and the principles contained therein warrant changing the face of drug and medical device litigation by significantly diminishing the learned intermediary doctrine.

III. OTHER IMPACTS OF THE RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY

The Restatement (Third) of Torts: Products Liability will also affect drug and medical device litigation in matters other than the learned intermediary doctrine. Unlike the Restatement (Second) of Torts: Products Liability, the Restatement (Third) specifically addresses liability standards for prescription drugs and medical devices. The products that are specifically within the scope of the Section 6 of the Restatement (Third) are those “legally sold or otherwise distributed only pursuant to a health care provider’s prescription.”⁵⁷

A. PRESCRIPTION DRUG AND MEDICAL DEVICE DESIGN DEFECT CASES

The Restatement (Third) of Torts: Products Liability § 6 (c) represents the ALI's views concerning prescription drug design defect cases. Section 6 (c) "does not restate existing case law."⁵⁸ Rather, the ALI "opted for a fresh look at the question of design liability for prescription products and utilized the case law to illuminate the underlying issues in this difficult area."⁵⁹ Specifically, the "black-letter" standard of Section 6 (c) provides:

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.⁶⁰

According to comment b to Section 6 (c), the courts' traditional refusal to impose design defect liability in prescription drug and medical device cases is due to the fact that such products offer a "unique set of risks and benefits."⁶¹ Thus, whereas a product may be harmful to one individual, it may be life-saving to another. Section 6 (c) recognizes this principle by providing that a drug is not defectively designed if it provides a net benefit to any class of patients. A prescribing physician is required to weigh the risks and benefits of the drug (even those determined to be "high-risk") and determine whether it is appropriate for a particular patient.

The new Restatement has not been received without criticism. A chief complaint made by some courts and commentators is that the new Restatement is unfair because it virtually immunizes prescription drug manufacturers from liability for defective design. The new

Restatement's reporters, James A. Henderson and Aaron D. Twerski have responded to such criticism, stating:

Our critics have misread the prescription drug design provision of the new Restatement. It does not immunize prescription drug manufacturers for defective design. Plaintiffs may establish defectiveness by showing that safer alternative drugs were available on the market that reasonable health care providers would have prescribed in place of a defendant's drug for all classes of patients.⁶²

In other words, drug manufacturers cannot escape design defect liability simply by proving that a prescription drug provides a net benefit to a class of users. Instead, a plaintiff can prevail on a design defect claim if he or she can prove that when the allegedly defective drug was prescribed a safer alternative was available (i.e., FDA approved during the relevant time period) and that physicians would have prescribed that drug instead of the defendant's drug for all patients.

A few courts have discussed the new Restatement's effect on design defect cases. In Sita v. Danek Medical, Inc., 43 F. Supp. 2d 245 (E.D.N.Y. 1999), plaintiffs alleged that a screw implanted in the plaintiff's spine was defectively designed after it fractured during spinal fixation surgery. Danek moved for summary judgment on all counts, including plaintiff's design defect claim. The court recognized that the plaintiff bears the burden of presenting evidence that the "product, as designed, presented a substantial likelihood of harm and feasibly could have been designed more safely."⁶³

In response to plaintiff's allegations, Danek presented the opinions of 270 orthopedic spine and neurological surgeons, all of whom maintained that the use of internal fixation devices, such as that used in plaintiff's surgery, is the accepted standard of care in the medical

community. While plaintiffs argued that the surgeons were biased due to their financial relationship with the spine fixation device industry, the court was not persuaded and held that plaintiffs failed to show that the screws at issue were defectively designed. Instead, the court concluded that the device was “reasonably safe for use in exactly the same manner in which that system was used.”⁶⁴ Interestingly, in a footnote to the court’s opinion, the court noted that the plaintiff’s had requested that the court examine their claim under the design defect standard as written in the Restatement (Third). The court rejected plaintiff’s claim under this standard as well, writing, “[i]t seems apparent that in adopting the use of spinal screw systems as the industry standard of care, ‘reasonable health-care providers’ have determined that the ‘foreseeable risks of harm’ posed by the use of spinal screw systems do not outweigh their ‘foreseeable therapeutic benefits.’”⁶⁵

At least one court has severely criticized the standard found in § 6(c) and declined to adopt it.⁶⁶ Freeman v. Hoffman-La Roche, 618 N.W.2d 827 (Neb. 2000) is the most thorough analysis of Section 6(c). Plaintiff claimed that she developed multiple health problems after treatment of chronic acne with Accutane, which she alleged was defective, misbranded, and mislabeled. The district court dismissed plaintiff’s action with prejudice.

On appeal, the Nebraska Supreme Court was asked to decide whether the plaintiff had stated a cognizable design defect claim. After noting that Nebraska courts generally apply the consumer expectations test for strict liability, the court discussed whether Section 6 (c) of the Restatement (Third) should be adopted. In concluding that it should not, the court listed four criticisms of § 6(c). First, the court wrote that by applying the “reasonable physician” standard, the Restatement (Third) does not restate the law, as “there is no support in the case law for the application of a reasonable physician standard in which strict liability for a design defect will

apply only when a product is not useful for any class of persons.”⁶⁷ Rather, “the majority of courts apply some form of risk-utility balancing that focuses on a variety of factors, including the existence of a reasonable design.”⁶⁸

Second, the court stated that the reasonable physician test has been criticized as being artificial and difficult to apply. This test requires the fact finder to assume that the prescribing physician knows as much about the drug product as the manufacturer, and ignores other concerns of commentators that physicians tend to prescribe drugs that they are familiar with even when studies indicate that there are better alternatives available.⁶⁹

Third, the court notes that the rule lacks flexibility and treats drugs of unequal utility equally. Since the rule only requires that the drug be useful to a class of patients, a drug used for cosmetic purposes but which causes serious side effects would be treated the same as a drug that treats a deadly disease but also has serious side effects.⁷⁰ As a result, this rule has been described as a standard that in effect will never allow liability.

Finally, the court noted that the test allows a consumer’s claim to be defeated simply by a statement from the defense’s expert witness that the drug at issue had some benefit for any single class of people.⁷¹ Based on these observations the court declined to adopt § 6(c) of the Restatement (Third) of Torts. Few other courts have visited the issue of whether or not to adopt § 6(c), but the virtual impossibility of proving a design defect case under the reasonable physician standard indicates that the majority of courts will follow the lead of the Nebraska Supreme Court.

B. MANUFACTURING DEFECTS

The Restatement (Third) provides that a product contains a manufacturing defect when, at the time of sale or distribution, it “departs from its intended design even though all possible

care was exercised in the preparation and marketing of the product.”⁷² With regard to prescription drugs and medical devices, courts have generally imposed “true” strict liability, i.e., liability without regard to fault, in evaluating a manufacturing defect claim. Thus, manufacturers of prescription drugs and medical devices are not treated any differently than commercial sellers of other products with respect to manufacturing defects.⁷³ Subsection 6 (c) therefore, embraces the traditional rule and does not effectuate a change in the law.

C. THE POST-SALE DUTY TO WARN

The Restatement (Second) of Torts § 402A covered products that were defective when sold but did not impose any sort of post-sale duties on manufacturers, sellers or distributors. The Restatement (Third), however, follows the holdings of many courts and clearly broadens the potential liability of a commercial product seller or distributor for the harm caused by its possible failure to warn of product defects.⁷⁴ Section 10 of the Restatement (Third) embodies the new general rule regarding the post-sale duty to warn.⁷⁵ Section 10, entitled “Liability of Commercial Product Seller or Distributor for Harm Caused by Post-Sale Failure to Warn” provides:

- (a) one engaged in the business of selling or otherwise distributing products is subject to liability for harm to persons or property caused by the seller’s failure to provide a warning after the time of sale or distribution of a product if a reasonable person in the seller’s position would provide such a warning.
- (b) a reasonable person in the seller’s position would provide a warning after the time of sale if:
 - (1) the seller knows or reasonably should know that the product poses a substantial risk of harm to persons or property; and
 - (2) those to whom a warning might be provided can be identified and can be reasonably assumed to be unaware of the risk of the harm; and
 - (3) a warning can be effectively communicated to and acted upon by those to whom a warning might be

provided; and

- (4) the risk of harm is sufficiently great to justify the burden of providing a warning.

Several aspects of the new post-sale duties section warrant discussion. Initially it should be noted that the duty is not limited to manufacturers. The plain language of § 10 makes it clear that the post-sale duties are equally applicable to distributors. Second, § 10 does not require an antecedent defect in order to impose liability for failure to warn. In other words, a manufacturer or distributor of a product may be liable for failing to warn of a defect that did not exist at the time of the sale or distribution.⁷⁶ The use of the “reasonable person” standard in § 10 shows that any potential post-sale liability will be evaluated according to traditional concepts of negligence.

The evaluation of whether a post-sale duty to warn exists consists of several determinations. Initially, in order for a post-sale duty to warn to arise, the post-sale risk must “become known.”⁷⁷ Such a risk becomes known “when new information is brought to the attention of the seller, after the time of sale, concerning risks (from latent defects) accompanying the product’s use or consumption.”⁷⁸ Second, in order for such a duty to arise the product must pose a substantial risk of harm. If the product related accident at issue is one that would occur infrequently or is unlikely to cause substantial harm there can be no post-sale duty to warn.⁷⁹ Third, according to § 10(b)(2), the manufacturer or distributor must be able to identify the product users who require the warning before any duty can arise. While sometimes difficult, in certain circumstances the manufacturer or distributor will have a duty to warn despite the inability to directly identify all of the product’s users. Section 10 lists the following factors to determine whether a product’s users are identifiable: the type of product; the number of units sold; the number of potential users; and the availability of records identifying the customers.

Finally, the manufacturer or distributor must be able to effectively communicate a warning to the identified users.⁸⁰

Debate continues as to whether the imposition of post-sale duties are beneficial. Proponents of the Restatement (Third) stress the special ability of manufacturers and sellers to obtain post-sale information regarding latent product defects.⁸¹

Opponents, however, argue that the practical difficulties of identifying consumers and the costs of distributing a post-sale warning outweigh the considerations of imposing a post-sale duty.⁸² While the costs of traditional point of sale warnings are low and can be included in the price of the product, the provision of post-sale warnings is much more expensive and must be borne entirely by the seller. Further, the identification of current users of the product is labor intensive, especially in situations where the product has changed hands. Another critical aspect is that post-sale duties apparently last for the life of the product (absent a statute of repose). Therefore, the longer a product's life span, the more responsibility the manufacturer or distributor will face. This in turn could prevent manufacturers from aggressively seeking out technological or safety improvements for fear of the expensive post-sale duties that such advancements would create.

One court has imposed a post-sale obligation on the manufacturer/seller, finding a continuing duty to test a product's safety to be part of the overall duty to warn. The court required a continuing duty to test the safety of an intrauterine contraceptive device is subsumed in the duty to warn.⁸³

In cases involving prescription drugs the courts have imposed a continuous duty to keep abreast of scientific developments touching upon the manufacturer's product and to notify the medical profession of additional side effects discovered from its use. The drug manufacturer's

duty to warn is, therefore, commensurate not only with its actual knowledge gained from research and adverse reaction reports, but also with its constructive knowledge as measured by scientific literature and other available means of communication.⁸⁴

D. THE DUTY TO RECALL

Section 11 of the Restatement (Third) concerns a manufacturer's duty to recall. While the Restatement (Third) declines to extend a common law duty to recall, a seller may (1) assume a duty to recall or (2) one may be imposed by governmental or administrative bodies. Section 11 provides:

One engaged in the business of selling or otherwise distributing products is subject to liabilities for harm to persons or properties caused by the seller's failure to recall a product after the time of sale or distribution if:

(a)(1) a governmental directive issued pursuant to a statute for administrative regulation specifically requires the seller or distributor to recall the product; or the seller or distributor, in the absence of a recall required under subsection (a)(1), undertakes to recall the product; and

(b) the seller or distributor fails to act as a reasonable person in recalling the product.

In rejecting a common law duty to recall, the Restatement (Third) recognizes the burden that such a duty would place on manufacturers and acknowledges that governmental agencies are best suited for examining the issues that surround a decision to recall a product.

Duties to recall products necessarily impose significant burdens on manufacturers. Many product lines are periodically redesigned so that they become safer over time. If every improvement in product safety were to trigger a common law duty to recall, manufacturers would face incalculable costs every time they sought to make their product lines better and safer.

This expense may force manufacturers to abandon research and development to improve the product or its safety.

Moreover, even when a product is defective, any involuntary duty to recall should be imposed on a seller only by a governmental directive issued pursuant to statute or regulation. According to comment a of § 11, issues relating to product recalls are best evaluated by governmental agencies capable of gathering adequate data regarding the ramifications of such undertakings. Absent a specific recall directive by a governmental regulatory authority, no duty to act can be imposed. However, if a recall is required by such a body, noncompliance by a seller will subject it to liability.⁸⁵

Another factor that should be noted is that the timing of a governmental recall directive can impact the potential liability a seller may face. In order to find the seller liable, the governmental directive must require the defendant seller to recall the product during the time period in which the plaintiff alleges the duty was breached.

Absent a governmental recall directive, the only other recall situation where § 11 would impose liability is where the seller “undertakes to recall a [defective] product” and “fails to act as a reasonable person in recalling the product.”⁸⁶ The rationale for this rule derives from the general rule that one who assumes a duty, and thus, induces others to forebear from acting, must act reasonably in carrying out the assumed duty.

Critics of § 11 argue that the lack of a duty to recall fosters poor public policy. Since a manufacturer or distributor has no duty to recall unless it assumes such an undertaking, manufacturers are less likely to assume such a duty. Thus, indirectly § 11 discourages voluntary recalls.

Generally, claims alleging a manufacturer or seller's post-sale duty to recall or retrofit are asserted under negligence or strict liability theories. Rather than focusing on the condition of the product, the plaintiffs' assertions generally focus on the manufacturer's conduct. Plaintiffs have alleged that the manufacturer negligently failed to act following the sale to remedy a defective product and/or is strictly liable for failing to do so, or that the manufacturer breached a continuing duty to fix its product. Successful plaintiffs have proffered evidence or testimony that the manufacturer had knowledge of the product's defect and had somehow retained significant control over it (i.e., by assuming responsibility for ongoing maintenance) and/or that the product absent certain safety devices was inherently dangerous. In fact, a linchpin of a successful claim could be the use of a jury instruction that recognizes that such a duty to recall does exist.

Defendants, however, are most successful when the manufacturer argues that no legal basis exists for the imposition of such a duty absent a recall ordered by a government agency or evidence that the product was defective when sold. Defense counsel could also argue that the plaintiff's claim is barred by his or her own assumption of the risk or contributory negligence, applicable statute of limitations, or the fact that the manufacturer did not retain control over the product.⁸⁷ As standard practice, however, defendants in such actions will start out by moving the court for a pre-trial ruling that a post-sale duty to recall or retrofit does not exist under the law of that jurisdiction.

E. CONCLUSION

The Restatement (Third)'s standard concerning design defects for prescription drugs and medical devices has not been well received, and may be considered the most controversial aspect of the Restatement (Third). Legal scholars have said that Section 6(c) is not a true "restatement"

of the law as the court opinions on the subject were, in many cases, “unintelligible” making a true “restatement” impossible to draft. The departure from a risk-utility analysis in favor of a reasonable physician test has set a high standard for a plaintiff to prevail in such an action. While the Nebraska Supreme Court rejected Section 6 (c) outright, it is not clear whether other jurisdictions will follow suit.

Unlike its treatment of drug and medical device design defect theories, the Restatement (Third) does not effectuate a change in the law with respect to liability based on a manufacturing defect theory. Indeed, manufacturing defects are treated the same as all other products.

At first glance, it would appear that the Restatement (Third) has significantly broadened the liability of manufacturers and sellers by holding them liable for post-sale duties to warn and, in limited circumstances, recall. However, these duties imposed by the Restatement (Third) really reflect nothing more than what some courts have already recognized, applied and judged reasonable.

Rules concerning manufacturers’ and sellers’ post-sale duties to warn and recall will continue to develop on a jurisdiction-by-jurisdiction and a case-by-case basis. Although the Restatement (Third) has influenced certain cases involving the post-sale duty to warn, it is perhaps most valuable to courts presented with claims related to product recalls, as that has traditionally been the most poorly defined and least understood of all the post-sale duties.

¹ Sterling Drug, Inc. v. Cornish, 370 F.2d 82, 85 (8th Cir. 1966).

² See, e.g., Miller v. Bristol-Myers Squibb Co., 121 F. Supp. 2d 831, 838 (D. Md. 2000).

³ See, e.g., Grenier v. Medical Eng’g Corp., 243 F.3d 200, 205 n.4 (5th Cir. 2001); Porterfield v. Ethicon, Inc., 183 F.3d 464, 467 (5th Cir. 1999); Linsley v. C.R. Bard, Inc., 2000 U.S. Dist. LEXIS 4675 (E.D. La. 2000).

⁴ Hansen v. Baxter Healthcare Corp., 723 N.E.2d 302, 312 (Ill. App. Ct. 1999).

⁵ Dabney J. Carr IV and Bryony H. Bowers, “Recent Developments in Learned Intermediary Doctrine,” The Brief, Tort & Insurance Practice Section, Winter 2002, v. 31 No. 2, p. 23.

⁶ Id. at 21.

⁷ See, Id.; Reyes v. Wyeth Lab., Inc., 498 F.2d 1264, 1277 (5th Cir. 1974).

⁸ See, Carr & Bowers, *supra*, note 5, p. 21.

⁹ MacDonald v. Ortho Pharm. Corp., 475 N.E.2d 65, 70 (1985)

¹⁰ Edwards v. Basel Pharm., 933 P.2d 298 (Okla. 1997).

¹¹ Lukaszewicz v. Ortho Pharm. Corp., 510 F.Supp. 961 (E.D. Wis. 1981).

¹² See, Carr & Bowers, *supra*, p. 21; Martin v. Ortho Pharm Corp., 661 N.E.2d 352, 356 (Ill. 1996); West v. G.D. Searle, 879 S.W.2d 412 (Ark. 1994); In re Norplant Contraceptive Prods. Liab. Lit., 165 F.3d 374, 379 (5th Cir. 1999); Pumphrey v. C.R. Bard, Inc., 906 F. Supp. 334 (N.D. W. Va. 1995); Reeves v. Ortho Pharm. Corp., 765 F. Supp. 1287 (E.D. Mich. 1991); but see Perez v. Wveth Labs, Inc., 161 N.J. 1, 734 A.2d 1245, 1256 (1999).

¹³ See, Carr & Bowers, *supra*, p. 21; Linnen v. Wveth-Averst Lab., 1999 Mass. Super. LEXIS 552, *8 - *10 (1999).

¹⁴ See, 21 U.S.C. §§ 301-397; 21 C.F.R. § 202.1(a)(3), (b)(1)(e).

¹⁵ See, Carr & Bowers, *supra*, p. 21; Perez v. Wyeth Lab., 734 A.2d 1245, 1257 (N.J. 1999).

¹⁶ Marshall, Comment, “Keeping the Duty to Warn Patients of the Risks and Side Effects of Mass-Marketed Prescription Drugs Where it Belongs: With Their Physicians,” 26 Dayton L. Rev. 95, 100-01 (2000).

¹⁷ 21 C.F.R. § 202.1(a)(3), (b)(1)(e).

¹⁸ See, Carr & Bowers, *supra*, p. 21.

¹⁹ Id.

²⁰ Guidance for Industry; Consumer-Directed Broadcast Advertisements, 64 Fed. Reg. 43, 197 (1999).

²¹ See, Carr & Bowers, *supra*, p. 21.

²² Id.

²³ Perez v. Wyeth Lab., 734 A.2d 1245 (N.J. 1999).

²⁴ Id.

²⁵ Id.

²⁶ Id. at 1255.

²⁷ Id.

²⁸ Id. at 1254, 1256.

²⁹ Id. at 1256 (quoting 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))).

³⁰ Garside v. Osco Drug, Inc., 764 F. Supp. 208, 211 n.4 (D. Mass. 1991), *rev’d* on other grounds, 976 F.2d 77 (1st Cir. 1992).

³¹ Id.

³² Shanks v. Upjohn Co., 835 P.2d 1189, 1195 n.7 (Alaska 1991).

³³ Id. at 1195 n.7.

³⁴ In re: Norplant Contraceptive Prods. Liab. Litig., 165 F.3d 374, (5th Cir. 1999).

³⁵ Id. at 379.

³⁶ Id.

³⁷ Id.

³⁸ Victor E. Schwartz, The Restatement (Third) of Torts: Products Liability: A Guide to its Highlights, 34 TORT and INS. L.J. 85 (1998).

³⁹ Restatement (Third) of Torts: Products Liability § 10 (1997).

⁴⁰ Id.

⁴¹ Id. cmt. b.

⁴² Id. cmt. e.

⁴³ Id.

⁴⁴ Id.

⁴⁵ Id.

⁴⁶ Id.

⁴⁷ Vitanza v. Upjohn Co., 257 Conn. 365, 2001 WL 866885 (Conn. 2001).

⁴⁸ Id.

⁴⁹ Talley v. Danek Med., Inc., 179 F.3d 154 (4th Cir. 1999).

⁵⁰ Id.

⁵¹ Yugler v. Pharmacia & Upjohn Co., N.Y. Sup. Ct., N.Y. Cty., No 104362/98 (Apr. 26, 2001).

⁵² Id.

⁵³ Wyeth-Ayerst Lab. Co. v. Medrano, 28 S.W.3d 87 (Tex. Ct. App. 2000).

⁵⁴ In re Rezulin Prods. Liab. Litig., 133 F.Supp. 2d 272, 291 (S.D.N.Y. 2001); Morgan v. Wal-Mart, Inc., 30 S.W.3d 455, 461-62 (Tex. Ct. App. 2000); Lansdell v. Am. Home Prods. Corp., 1999 U.S. Dist. LEXIS 22540, *2 (N.D. Ala. 1999).

⁵⁵ Kasin v. Osco Drug, Inc., 728 N.E.2d 77, 80-81 (Ill. App. Ct. 2000).

⁵⁶ Happel v. Wal-Mart, Inc., N.E.2d 656 (Ill. App. Ct. 2000).

⁵⁷ Restatement (Third) of Torts: Products Liability §6(a) (1997).

⁵⁸ See James A. Henderson and Aaron D. Twerski, “Drug Designs Are Different,” 111 Yale L.J. 151, 180 (October 2001).

⁵⁹ Id.

⁶⁰ Restatement (Third) of Torts: Products Liability §6(c) (1997).

⁶¹ Restatement (Third) of Torts: Products Liability §6(c) (1997) cmt. b.

⁶² Henderson and Twerski, *supra*, note 58, at 152.

⁶³ Sita v. Danek Medical, Inc., 43 F. Supp. 2d 245, 255 (E.D.N.Y. 1999).

⁶⁴ Id. at 255-56.

⁶⁵ Id. at 256, n. 9.

⁶⁶ Freeman v. Hoffman-La Roche, Inc., 260 Neb. 552, 618 N.W.2d 827 (2000).

⁶⁷ Id. at 566.

⁶⁸ Id.

⁶⁹ Id.

⁷⁰ Id. at 567.

⁷¹ Id.

⁷² Restatement (Third) of Torts: Products Liability §§ 2(a), 6(b)1 (1998).

⁷³ Restatement (Third) of Torts: Products Liability § 6 (1997) cmt. c.

⁷⁴ John F. Kennedy and F. Laurens Brock, “Postsale Duty to Warn, Retrofit, and Recall,” *The Brief*, Winter 2002, V. 31 No. 2, p. 14.

⁷⁵ Restatement (Third) of Torts: Products Liability §10 (1997).

⁷⁶ Id. cmt. a.

⁷⁷ Kennedy and Brock, *supra* note 57, p. 14.

⁷⁸ Restatement (Third) of Torts: Products Liability §10 (1997) cmt. c.

⁷⁹ Id. cmt. d.

⁸⁰ Id. § 10(b)(3).

⁸¹ Kennedy and Brock, *supra* note 57, p. 14.

⁸² Id.

⁸³ Kociemba v. G.D. Searle & Co., 707 F. Supp. 1517 (D.C. Minn. 1989).

⁸⁴ Wooderson v. Ortho Pharm. Corp., 681 P.2d 1038, 1050-51 (Kan. 1984). See also, Schenebeck v. Sterling Drug, Inc., 423 F.2d 919, 922 (8th Cir. 1970) (applying Arkansas law); O’Hare v. Merck & Co., 381 F.2d 286 (8th Cir. 1967) (applying Minnesota law); Baker v. St. Agnes Hosp., 421 N.Y.S.2d 81, 85 (N.Y. App. Div. 1979).

⁸⁵ Restatement (Third) of Torts: Products Liability § 11 cmt. a.

⁸⁶ Id. § 11(b).

⁸⁷ For example, Texas courts have specifically refused to recognize a post-sale duty to recall or retrofit absent evidence that the manufacturer/seller assumed duty or retained control over the product. See Douglas R. Richmond, *Expanding Products Liability: Manufacturers’ Post-Sale Duties to Warn, Retrofit and Recall*, 36 Idaho L. Rev. 7 (1999)(citing Dion v. Ford Motor, 804 S.W.2d 302 (Tex. Civ. App. 1991)).