XII. Products Liability

Frank J. Galvin, Jr.*

Ortho Pharmaceutical Corp. v. Chapman was probably the most significant case decided during this year’s survey period. The decision may set new precedents in the area of strict liability, particularly with respect to prescription drugs and comment k of section 402A of the Restatement (Second) of Torts.2

A. The Duty to Warn: Prescription Drugs

In Ortho, the court found that comment k of section 402A of the Restatement (Second) of Torts3 sets forth a recognized exception to strict liability with respect to the duty to warn for unforeseeable risks and dangers associated with prescription drugs, vaccines, and other unavoidably unsafe products.4 The plaintiff had instituted a cause of action against the defendant Ortho Pharmaceutical Corporation for internal injuries suffered as a result of taking an oral contraceptive manufactured by the defendant. The plaintiff’s claim for liability was founded upon theories of negligence, express or implied warranty, and strict liability. On appeal, the plaintiff did not allege that her injury was the result of defective design or manufacture of the contraceptive, but rather claimed that the “lack of adequate warnings rendered it unreasonably dangerous.”5 The plaintiff had argued that comment k dealt with products that were an absolute public necessity.6 The court of appeals, however, found that com-

*Member of the Indiana Bar. B.S., Fordham University, 1965; J.D., Georgetown University, 1968.

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2RESTAMENT (SECOND) OF TORTS § 402A, comment k (1965).

Comment k states in pertinent part:

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. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician.

Id.

388 N.E.2d at 545 (citing Basko v. Sterling Drug, Inc., 416 F.2d 417, 425 (2d Cir. 1969)).

388 N.E.2d at 545.

4Id.
ment k posed a more fundamental question—"whether marketing of the product is justified in light of the known risks." A decision of this nature involves balancing the product's public utility with the risks and dangers inherent in the use of the product. The court noted, however, that when such balancing justifies marketing a product, a manufacturer should provide proper warnings informing the user of the risk of harm.

The court initially held that with respect to prescription drugs a duty to warn does not arise "until the manufacturer knows or should know of the risk" presented in the use of its product. The court reasoned that a manufacturer "cannot be required to warn of a risk unknown to science" and, therefore, can only be held responsible for that knowledge held by experts in the particular field during the period in which the plaintiff uses the product in question.

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7Id.
8Id. The underlying rationale for this holding was set forth in Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076, (5th Cir. 1973), cited in 388 N.E.2d at 546, in which the court stated:

Strict liability may not always be appropriate in such cases because of the important benefits derived from the use of the product. This is especially so with respect to new drugs that are essential in treating disease but involve a high degree of risk. It may also be so with respect to other commercial products possessing both unparalleled utility and unquestioned danger. As a practical matter, the decision to market such a product requires a balancing of the product's utility against its known or foreseeable danger.

493 F.2d at 1088-89. Professor Wade proposes a more complex method for determining whether the product's utility outweighs the dangers:

Factors involved in making this determination include, among others, the following: (1) [The usefulness and desirability of the product, (2) the availability of other and safer products to meet the same need, (3) the likelihood of injury and its probable seriousness, (4) the obviousness of the danger, (5) common knowledge and normal public expectation of the danger (particularly for established products), (6) the avoidability of injury by care in use of the product (including the effect of instructions or warnings), and (7) the ability to eliminate the danger without seriously impairing the usefulness of the product or making it unduly expensive.

Wade, Strict Tort Liability of Manufacturers, 19 Sw. L.J. 5, 17 (1965).

9388 N.E.2d at 546 (citing Borel v. Fibreboard Paper Prods. Corp., 493 F.2d 1076). In Borel, the court decided that the ultimate consumer should be allowed to make his own determination about whether use of the product is justified in light of the known risks.

10388 N.E.2d at 548.

11Id.

12Id.

13Id. at 549. The court found this conclusion was supported, in part, by a portion of comment k that states:

"It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug
The *Ortho* court recognized that the authorities are split with respect to conditioning the duty to warn on the manufacturer’s knowledge.14 Some courts have assumed knowledge;15 others, including the *Ortho* court, have found that it would be unreasonable to hold a manufacturer liable for unforeseeable harm simply because the manufacturer had supplied the public with a product of substantial utility.16 The criticism of this latter approach has been that it “shifts the emphasis away from the condition of the product (strict liability) and back to the reasonableness of the manufacturer’s conduct (negligence).”17

It is apparent that the *Ortho* court’s requirement of knowledge of the risk on the part of the drug manufacturer before the duty to warn will arise narrows the difference between strict liability and negligence.18 The court in *Ortho* observed that the language in *Fort Wayne Drug Co. v. Flemion*,19 which involved a negligent breach of the duty to warn, accurately described the theory of an action under section 402 with respect to prescription drugs.20 In *Fort Wayne Drug*, the court held that “[i]t is well settled that a man who delivers an article, which he knows to be dangerous or noxious, to another person, without notice of its nature and qualities, is liable for any injury which may reasonably be contemplated as likely to result.”21

Although the standard and proof necessary to recover are identical under both theories, there is a theoretical difference between negligent breach of the duty to warn and strict liability based on the absence of proper warnings. The *Ortho* court found that section 402A required an additional conclusion of law beyond a finding of negligence.22 In addition to finding a manufacturer negligent in failing to adequately warn of the risks present, the conclusion must also be drawn that the product was in a defective and unreasonably dangerous condition. Because this conclusion does not require an ad-

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14 Id. at 547 (quoting Restatement (Second) of Torts § 402A, comment k (1965)).
15 388 N.E.2d at 546.
17 388 N.E.2d at 547-48.
18 Little v. PPG Indus., Inc., 579 P.2d at 946, quoted in 388 N.E.2d at 547.
19 See 388 N.E.2d at 550.
21 388 N.E.2d at 551.
22 ‘93 Ind. App. at 47, 175 N.E. at 672 (quoting Wellington v. Downer Kerosene Oil Co., 104 Mass. 64 (1870)).
23 388 N.E.2d at 551.
ditional finding of fact, however, the aforementioned comparison of the duty to warn in a negligence or a strict liability claim is, in effect, a "distinction without a difference." 23

B. Adequacy of Warnings

The court in Ortho examined the standards governing the adequacy of a warning and found that a warning must be reasonable under the facts and circumstances of each case. 24 The court then considered several methods of determining reasonableness and found that, as a practical matter, the "reasonableness" of a warning is decided by resort to negligence concepts. 25

The court in Spruill v. Boyle-Midway, Inc. 26 stated that "if a warning of the danger is given and this warning is of a character reasonably calculated to bring home to the reasonably prudent person the nature and extent of the danger, it is sufficient to shift the risk of harm from the manufacturer to the user." 27 Similarly, the court in Sterling Drug, Inc. v. Yarrow 28 found that what is reasonable depends upon the nature and gravity of the dangers present. 29 More specifically, in Bituminous Casualty Corp. v. Black & Decker Manufacturing Co., 30 it was held that for a warning to be adequate it must be in such form that it could reasonably be expected to catch the attention of the reasonably prudent man in the circumstances of its use [and] . . . be of such a nature as to be comprehensible to the average user and to convey a fair indication of the nature and extent of the danger to the mind of a reasonably prudent person. 31

The Bituminous court further noted that a warning should have the requisite "degree of intensity" to sufficiently alarm the ordinary user and allow him to take the necessary precautions. 32

Ortho concluded that a proper warning must be adequate in its factual content, its expression of facts, and in the manner in which it is communicated. 33

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24388 N.E.2d at 553.
25Id. at 552-53.
26908 F.2d 79 (4th Cir. 1962).
27Id. at 85.
28908 F.2d 978 (8th Cir. 1969).
29Id. at 994, cited in 388 N.E.2d at 562.
31Id. at 872-73, quoted in 388 N.E.2d at 552.
32518 S.W.2d at 873.
33388 N.E.2d at 552.
C. Ultimate Users

The court in Ortho noted a well-recognized second limitation on the liability of manufacturers with respect to the duty to warn for prescription drugs\(^\text{34}\) and found that because prescription drugs cannot be obtained without a physician’s authorization, a manufacturer’s duty to warn extends only to those who would prescribe such medicine, not to the actual user.\(^\text{35}\) The Ortho court, examining Reyes v. Wyeth Laboratories,\(^\text{36}\) noted the rationale for this exception:

“Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug, as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative.”\(^\text{37}\)

Thus, the ultimate user’s safety is placed in the hands of the physician. If the manufacturer’s warnings fully apprise the physician of the risks involved, the manufacturer may assume that the doctor will exercise well-reasoned and well-informed judgment on behalf of the patient.\(^\text{38}\)

D. Unreasonably Dangerous and Defective Drugs

Under section 402A of the Restatement (Second) of Torts, a manufacturer is subject to liability to an ultimate consumer injured by a product sold “in a defective condition unreasonably dangerous.”\(^\text{39}\) The Ortho court found comment k of section 402A

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\(^{34}\)Id. at 548.


\(^{36}\)498 F.2d 1264 (5th Cir. 1974).

\(^{37}\)388 N.E.2d at 549 (quoting 498 F.2d at 1276).

\(^{38}\)The court in Reyes recognized, however, that when there is no intervening physician to make an informed judgment on behalf of the ultimate consumer, “‘it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning.’” Id. (quoting Davis v. Wyeth Laboratories, Inc., 399 F.2d 121, 131 (9th Cir. 1968)).

\(^{39}\)RESTATMENT (SECOND) OF TORTS § 402A (1965). See IND. CODE § 33-1-1.5-3(a) (Supp. 1979). Although the Restatement speaks in terms of “sellers,” the manufacturers of defective and unreasonably dangerous products are, nevertheless, included. See RESTATMENT (SECOND) OF TORTS § 402A, comment f (1965).
especially significant in determining the relationship between the meaning of "defective condition unreasonably dangerous" and prescription drugs. Comment k states that unavoidably unsafe products—especially drugs and vaccines—are not unreasonably dangerous or defective when properly prepared and accompanied by adequate directions and warnings. The court followed this reasoning and thus interpreted comment k to mean, with respect to drugs, that unavoidably unsafe or dangerous products are per se defective and unreasonably dangerous when not accompanied by proper warnings. Generally, however, a product is not unreasonably dangerous for purposes of section 402A unless it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics."

The court in Reyes found that the presence of a dangerous virus in a particular vaccine did not necessarily render the product "unreasonably dangerous" under section 402A. Although the court acknowledged that the vaccine may have constituted an "unavoidably unsafe product" within the definition of comment k, it further noted that "in terms of the user's interests, a product is 'unreasonably dangerous' only when it is 'dangerous to an extent beyond that contemplated by the ordinary consumer.'"

Burton v. L.O. Smith Foundry Products Co., displayed reasoning similar to Reyes and contrary to the Ortho approach. The Bur-

\[388\] N.E.2d at 545-46.
\[388\] Restatement (Second) of Torts § 402A, comment k (1965). For the text of comment k, see note 3 supra.
\[388\] N.E.2d at 552. But see Keeton, Product Liability and the Meaning of Defect, 5 St. Mary's L.J. 30, 32 (1973); Wade, supra note 8, at 14-15. In Reyes, the court found that "defective condition" has no independent meaning apart from "unreasonably dangerous." 498 F.2d at 1272-73.
\[388\] Restatement (Second) of Torts § 402A, comment i (1965).
\[498\] F.2d at 1273.
\[Id.\] (quoting Restatement (Second) of Torts § 402A, comment i (1965)). Of course, an injured consumer will normally be barred from recovery when he voluntarily uses the product with full knowledge of the dangers present. See comment n of § 402A, which states in pertinent part:

The form of contributory negligence which consists in voluntarily and unreasonably proceeding to encounter a known danger, and commonly passes under the name of assumption of risk, is a defense under this Section as in other cases of strict liability. If the user or consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery.

See also Meadowlark Farms, Inc. v. Warken, 376 N.E.2d 122 (Ind. Ct. App. 1978). In Meadowlark, the court found that a plaintiff impliedly assumes those risks of which he has actual knowledge and appreciation. Id. at 133. In addition, the plaintiff is presumed to have actual knowledge of those risks and dangers expressly contracted for. Id.

\[529\] F.2d 108 (7th Cir. 1976).
ton court found that a duty to warn is required only in those instances in which it can reasonably be assumed that the ordinary consumer would be "ignorant of the facts which a warning would communicate." The court, citing Posey v. Clark Equipment Co., found that cautionary instructions and warnings are not required when the ordinary user of such a product would normally realize the danger without a warning.

In Burton, the court considered the issue whether the supplier of a highly flammable compound was under a duty to warn of the combustible risks posed by the presence of kerosene in the compound. The court recognized that a product may be considered defective and unreasonably dangerous under section 402A when the manufacturer fails to warn of the dangers or risks involved in the use of the product, even though the product may be "virtually faultless in design, material, and workmanship," an approach similar to Ortho. The court held, however, that because one can reasonably expect the ordinary user of kerosene to be aware of its combustible propensities, the manufacturer was under no duty to warn of that danger. The manufacturer's sole duty was to make known those risks involved in the use of the product which were dangerous but not obvious.

It is noteworthy that the court in Ortho recognized similarities between section 402A and section 388 of the Restatement (Second) of Torts, which is basically founded upon the "common law cause of action for failure to exercise reasonable care to inform users of the dangerous qualities of a chattel." Section 388(a) indicates that a supplier is subject to liability for injuries suffered by users of that chattel if the supplier "knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied." The language of section 388(a) is similar to that used by the Ortho court in drawing a distinction with respect to prescription drugs. Section 388(b), however, states that a supplier of goods will only be liable if he "has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition," an

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47 Id. at 111.
48 409 F.2d 560 (7th Cir. 1969), cited in 529 F.2d at 111.
49 529 F.2d at 111.
50 Id. (citing Nissen Trampoline Co. v. Terre Haute First Nat'l Bank, 332 N.E.2d 820 (Ind. Ct. App. 1975), rev'd on other grounds, 358 N.E.2d 974 (Ind. 1976)).
51 529 F.2d at 111-12.
52 RESTATEMENT (SECOND) OF TORTS § 388 (1965).
54 RESTATEMENT (SECOND) OF TORTS § 388(a) (1965), quoted in 388 N.E.2d at 549 n.7.
55 RESTATEMENT (SECOND) OF TORTS § 388(b) (1965), quoted in 388 N.E.2d at 549 n.7.
approach more closely analogous to the Reyes and Burton decisions than to Ortho.

The court in Stapinski v. Walsh Construction Co.\textsuperscript{56} held that with respect to section 388, the seller had no duty to warn of all dangers in a product.\textsuperscript{57} The seller should only be required to make the buyer aware of those dangers the reasonable person would not discover. The court stated: "Where a purchaser is aware or should be aware that an article is dangerously defective, and the purchaser uses the article . . . , the liability for injuries to third persons therefore rests upon the purchaser . . . ."\textsuperscript{58}

The Ortho court's reference to section 388, combined with the holdings in Reyes and Burton, suggest that a manufacturer need not provide warnings when the ordinary user knows or should have known of the product's dangerous propensities. The court's language in Ortho, however, does not lend itself to the interpretation that this test of "unreasonably dangerous," arising under comment i of section 402A, will be the determining factor under strict liability when comment k and prescription drugs are considered. Instead, the Ortho court held that a dangerous drug must be accompanied by proper warnings to be free from defect, regardless of whether the danger would be one contemplated by the ordinary consumer who purchases it.

The "ordinary consumer" interpretation would certainly lessen the manufacturer's duty to warn. This conclusion appears more convincing in view of the court's holding in Ortho that a duty to warn involving prescription drugs should extend only to members of the medical profession,\textsuperscript{59} who as the consumers to whom the duty to warn is owed, can reasonably be expected to know more dangers without the benefit of warning. Thus, fewer products would be unreasonably dangerous when not accompanied by proper warnings.\textsuperscript{60} It is foreseeable, though, that conflicts will arise concern-

\textsuperscript{56}388 N.E.2d 473 (Ind. Ct. App. 1978).
\textsuperscript{57}Id. at 477.
\textsuperscript{58}Id.
\textsuperscript{59}388 N.E.2d at 548.
\textsuperscript{60}A different result was reached in Mueller & Co. v. Corley, 570 S.W.2d 140 (Tex. Ct. App. 1978). See also Helicoid Gage Div. of Am. Chain & Cable Co. v. Howell, 511 S.W.2d 573, 578 (Tex. Ct. App. 1974). In Mueller, the defendants petitioned the court to instruct the jury that the term "unreasonably dangerous" would mean the product was dangerous to an extent not contemplated by the ordinary physician. 570 S.W.2d at 145. The product in question was a silicone breast prosthesis which had ruptured after its implant accompanying a subcutaneous mastectomy. The defendants argued that a prosthesis is a specialized medical product, requiring a physician's skill and judgment in the determination of its use. The defendants therefore asserted that the physician, rather than the user, would be required to determine whether the product exposed the user to an unreasonable risk of harm. The court found that because the defective con-
ing the duty of a manufacturer to warn of dangers inherent in prescription drugs which are clearly obvious to the ordinary physician.

E. Proximate Cause

Products liability cases do not differ from ordinary negligence cases in the requirement that cause and fact must be established.\(^6\) It is necessary to prove not merely that the product caused harm, but also that the defect was the causative agent. This is normally established by applying the *sine qua non* or but-for test to the injury-causing event. However, either the most probable cause of the accident, or a proximate cause occurring concurrently and in combination with other causes, is held to be sufficient.\(^6\)

In *Dias v. Daisy-Heddon*,\(^6\) the plaintiffs appealed from a judgment rendered in favor of the defendant Daisy-Heddon on the basis of a complaint which had charged the defendant with placing a defective and unreasonably dangerous air rifle in the stream of commerce. The plaintiffs contended that the instructions accompanying the rifle had failed to "adequately warn of the dangers associated therewith"\(^6\) and that the design of that particular model was unreasonably dangerous. The court of appeals found, as a matter of law, that it could not conclude that the defendant's design or instructions for the particular rifle were the proximate cause of the plaintiff's injury.\(^6\)

Under the theory of strict liability, the plaintiff must demonstrate that the defective condition of the defendant's product was the proximate cause of the plaintiff's harm.\(^6\) The court recognized the presumption under Indiana law, however, that when a warning is given, "the seller may reasonably assume that it will be read and heeded; and a product bearing such a warning, which is safe for use if it is followed, is not in [a] defective condition, nor is it unreasonably dangerous."\(^6\) The court found that a jury could have decided that if the warnings had been followed, the injury would not

\(^6\) 588 N.E.2d at 555.
\(^6\) Id. at 224.
\(^6\) Id. at 225.
\(^6\) Id.
\(^6\) Id. (citing RESTATEMENT (SECOND) OF TORTS § 402A, comment j (1965)).
have occurred. Thus, the alleged defective design of the gun would not be the proximate cause of the injury, and the plaintiff would be precluded from recovering under section 402A.

The court in *Ortho* proceeded one step further by noting that the negligence of the user-physician in failing to heed a warning will not relieve a manufacturer of liability when the defendant’s failure to provide *adequate* warnings may have contributed to the harm. In *Ortho*, the manufacturing company argued that there were several circumstances which would necessarily preclude a finding that the alleged inadequate warnings were the proximate cause of the plaintiff’s injury. The defendant primarily contended that the physician would not have relied on Ortho’s warnings even if they had properly accompanied the product. The defendant asserted, therefore, that the warnings, or lack thereof, could not have been the proximate cause of the plaintiff’s ingestion and subsequent injury because the doctor’s prescription was not influenced by the absence of any warnings. The defendant also contended that the physician’s own negligence was the proximate cause of the harm. The court, however, found that there was sufficient evidence available for a reasonable person to determine that the defendant’s warnings were unduly delayed or lacked a sense of urgency sufficient to attract the attention of the prescribing physician.

A number of jurisdictions have considered the issue of proximate cause and the intervening negligence of the attending physician in cases involving inherently dangerous drugs. The majority of cases have held that the intervening negligence of a physician is not a proximate cause defense when the inadequacy of the manufacturer’s warnings may have contributed to the injury.

In *Stevens v. Parke, Davis & Co.* the court found that the defendant’s over-promotion of its product was an inducement to the physician to disregard the warnings and that the disregard was therefore not an intervening cause of the decedent’s injury. Also, in *Sterling Drug, Inc. v. Yarrow*, the court found that the failure of a physician to gather information from other sources about the dangerous propensities of the defendant’s drug did not relieve the manufacturer of liability. Similarly, the manufacturer in *Sterling
Drug, Inc. v. Cornish\textsuperscript{77} alleged that the physician’s failure to “keep up” with current medical literature and the manufacturer’s own literature was an intervening proximate cause. The court summarily rejected this contention and said that the sole issue was whether the manufacturer had made reasonable efforts to warn of the dangers present.\textsuperscript{78}

The Ortho court found that the failure of the user to read and follow directions may have been a causative agent of the harm; but it could not find, as a matter of law, that the inadequacy of the warning was not a contributing factor to the plaintiff’s negligence.\textsuperscript{79} Reasonable foreseeability, therefore, is the ultimate test of proximate cause. Contribution to the harm from an intervening cause fails to alter the test.\textsuperscript{80}

\textsuperscript{77} 370 F.2d 82 (8th Cir. 1966).
\textsuperscript{78} "Id. at 85.
\textsuperscript{79} 388 N.E.2d at 557-58.