Chapter 39
Medical Product Liability

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BACKGROUND

The drug and medical device industries in America have dramatically changed since the beginning of the twentieth century. Early pharmaceutical companies generally produced a generic line of medications to serve pharmacists' needs,[1] spending comparatively little on research, development, and marketing. Federal regulation had its inception with the passage of the Food and Drugs Act of 1906,[2] primarily targeting the adulteration and misbranding of drugs. The emergence of antibiotics, other advanced pharmaceuticals, cosmetics, and complex medical devices necessitated enactment of the Federal Food, Drug, and Cosmetic Act of 1938 (FDCA).[3] This act required pre-market approval (PMA) of new drugs and was the first to regulate the labeling of medical devices. In 1997, the Food and Drug Administration Modernization Act (FDAMA)[4] was enacted to control the burgeoning market in over-the-counter (OTC) drugs.

Prior to the mid-twentieth century, medical devices consisted mainly of relatively simple mechanical surgical instruments. There were a few implants, such as metal or plastic plates used for cranial reconstruction, although surgeons usually fabricated these intraoperatively. Manufacturer liability generally resulted from the inopportune breakage of a surgical instrument. In response to the increasing complexity of medical devices such as pacemakers and functioning implants, Congress passed the Medical Device Amendments of 1976 (MDA),[5] which included provisions for pre-market approval.

Generally, liability for manufactured products is governed by the concepts of strict liability that eliminate the need to prove negligence for an injury caused by a defective product.[6] Difficulties in proof of negligence and a desire to place the burden resulting from injury on the least vulnerable party led to the development of this concept. The formal adoption of strict liability as the foundation of medical product liability jursiprudence can be traced to the near universal acceptance of Section 402A of the Restatement (Second) of Torts published in 1965.[7] Over the succeeding 33 years, the case law of the various states carved out so many exceptions to this basic view that some observers prematurely concluded that the exceptions had devoured the rule. This culminated in the publication of the Restatement (Third) of Torts: Products Liability[8] (Restatement Third), eschewing strict liability for a more negligence-based approach to medical products liability. The response of the various states to Restatement Third was underwhelming. Seven years after its publication the majority of courts[9] forthrightly refused to adopt its grounding in negligence, preferring to maintain their allegiance to strict liability, although actual decisions in many cases might be the same under either approach.

Despite their claimed adherence to the principles of strict liability, the courts have treated medical products differently than other manufactured products. One reason for this deference is the recognition that there is an interaction between the patient's body and the drug or device. When a drug is ingested or a device implanted, the response of an individual may be difficult to predict, sometimes influenced more by the individual's physiology than the product's design. Adverse reactions may be due to hypersensitivity or allergy, interactions with other drugs, exaggerated or insufficient responses, unavoidable side effects, or activation of physical illness. While adverse reactions to drugs are one of the major causes of illness, hospitalization, and even death,[10] the beneficial effects enjoyed by the vast majority of users usually outweigh them. Most commentators agree that a prescription drug should not be considered defective simply because an unusually sensitive user develops an adverse reaction[11] and that the ideal of a drug safely designed for every individual may be illusory. These comments are equally applicable to the wide array of available medical devices such as pacemakers, joint implants, heart valves, breast implants, sutures and staples, and various diagnostic and surgical instruments. Furthermore, these devices must not only function as intended, but they must do so for the life of the patient, a daunting requirement for any manufactured item. In addition to recognizing the unique obstacles facing drugs and medical devices, the courts have also acknowledged that it would not be in the public's interest to apply the concepts of strict liability so rigidly as to dissuade manufacturers from bringing new products to the marketplace.

These policy interests have shaped the medical product case law resulting in multiple departures from the traditional rules of strict liability. Some of these exceptions favor plaintiffs,[12] making it easier to prove manufacturer liability, often with minimal evidence.[13] Others exemptions favor defendants, most notably comment k to Section 402A of the Restatement (Second) of Torts.[14] Comment k distinguishes

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some "unavoidably unsafe products" from most other products by providing that the manufacturer should not be held strictly liable for injury resulting from their use when their utility outweighs their risk.[15] While comment k's example and text focus on pharmaceuticals, Section 402A and the comment actually concern "any product" including medical devices. While some courts,[16] commentators,[17] and the Restatement (Third) consider the medical products industry sufficiently unique to warrant special treatment, others believe it should be governed by the same strict liability as other industries.[18] A third group contends that companies should be strictly liable but defines the role of liability differently, holding manufacturers to a lesser standard.[19]

PRODUCT DEFECTS

Although the Second Restatement's comment k describes some products as "unavoidably unsafe," that protection extends only to design defects and does not immunize against claims for manufacturing defects or inadequate warnings.

Manufacturing Defects

Manufacturing defects affect those products that deviate from the manufacturer's design or specifications and are thus different than the usual item that "comes off the assembly line."[20] Typically these defects are easily identified because the products are flawed, for example, a chipped orthopedic implant or a contaminated vaccine. Even though the cause of a manufacturing defect is usually negligence, difficulty in proof mandates a strict liability standard, without regard to the manufacturer's reasonableness in protecting its process from error. A consumer expectation test is often used because the consumer expects a product to be free of defects.

Design Defects

Whereas a manufacturing defect involves isolated deviations from the norm, a design defect involves an entire line of products. Products are manufactured to specifications but remain unreasonably dangerous for intended use.[21] Difficulty in identifying a design defect arises when the courts attempt to define "reasonable danger."[22] The definition of a design defect can be formulated using a four-prong test involving (1) the feasibility of an alternative design, (2) which at the time of manufacture was (3) commercially available, and (4) would not destroy the product's utility.[23] Another approach utilizes the consumer expectation test that weighs whether a product is unreasonably dangerous beyond the peril contemplated by the ordinary consumer.[24] This test has fallen from favor because it relies on the term "unreasonable" as a requirement of defectiveness. Reasonableness is a negligence concept[25] and if a danger is generally known to the ordinary consumer, the product is not per se defective.[26] More commonly used[27] is the risk–utility test,[28] which balances the danger associated with a product against its utility to the consumer. Rather than evaluating the manufacturer's reasonableness, the emphasis is on the safety of the product including the severity of risk, likelihood of harm, benefits of the product, and feasibility of an alternative design.[29] Many courts refuse to classify a product as unreasonably dangerous if the drug or device's utility to mankind is considered greater than the potential for injury to an individual.[30] Finally, some jurisdictions offer an alternative test using a bifurcated standard—either consumer expectation or risk–utility,[31]—thereby expanding the recovery potential for plaintiffs.

In 1988, the California Supreme Court in *Brown v. Superior Court*[32] analyzed many of these approaches and arrived at what it considered to be the consensus view for prescription drug liability. That view is that drug manufacturers are not strictly liable for injuries caused by their products so long as the drug was "properly prepared" and accompanied by appropriate warnings that were "either known or reasonably scientifically knowable."[33] Other courts, however, hold that the "FDA's decision of product marketability disposes of the defect issue,"[34] reasoning that, if the FDA approves a product, "the product must be considered unavoidably unsafe as a matter of law and outside the parameters of strict liability for defective design."[35]

Failure to Warn of Known Adverse Reactions

Pharmaceutical manufacturers are required to adequately warn of known dangers in the administration of their product.[36] "A product sold without such warning is in a defective condition."[37] Far more problematic are those adverse effects that remain undiscovered until a reaction occurs in the ultimate consumer. The majority of courts have been reluctant to impose an imputed knowledge of unknown defects upon manufacturers or to rigidly apply strict liability.[38] Others consider an undiscovered side effect a defect and impose the same strict liability as for known defects.[39] Traditionally, device or drug manufacturers have not been required to warn end users but rather only their physician "learned intermediaries."[40] With the advent of direct to consumer marketing, exceptions have developed.[41]

CAUSATION AND DAMAGES

Causation

As in actions for negligence, causation must be proved in strict tort liability. Prosser states that "[s]trict liability eliminates both privity and negligence; but it still does not prove the plaintiff's case."[42] The standard elements of a prima facie case, as enumerated in Section 402A of the Restatement (Second) of Torts, are: (1) proof that the product was defective, (2) proof that the defect existed at the time it left the control of the defendant, (3) proof that the defect created a product that was unreasonably dangerous for the intended or foreseeable use, and (4) proof that the defect caused the injury.[43] Within the pharmaceutical industry, causation is most commonly proved through epidemiological and statistical studies, expert testimony,

direct or circumstantial evidence, or a combination of these methods.[44] In situations in which the plaintiff is unable to identify the defective product's specific manufacturer, an industry-wide allocation of responsibility has been devised.[45] Liability may be imposed on every manufacturer of a generic product. It is then the burden of the various defendants to prove that they did not supply the defective product.[46]

Most courts view the terms "user" and "consumer" liberally. Historically, privity was required before permitting recovery. Today, the end user may be far removed from the initial privity of contract.[47] The foreseeability of the injury caused by a product is an issue in many courts,[48] some rejecting the foreseeability of harm approach and instead examining the foreseeability of use.[49] If it is foreseeable that an individual will be a user, that individual is a potential plaintiff.[50] Moreover, if the patient were to ingest multiple drugs, each drug might be viewed as a cause-in-fact of the subsequent harm.[51]

In a failure-to-warn context, the plaintiff must prove that lack of proper warning was the proximate cause of the injury. The failure to warn must be the direct link between the product and the injury.[52] The plaintiff must further show that the manufacturer either knew or should have known about the danger of harm from the drug.[53] When multiple drugs are involved, one manufacturer's failure to warn may lead to liability if it was a substantial factor in bringing about the user's injury.[54]

Damages

Similar to negligence litigation, strict liability provides for property and personal damage recovery.[55] In both negligence and strict liability, proof of damages is an essential element of a prima facie case. Commentators differ in their views regarding punitive damage awards in strict liability litigation. Some assert that punitive damage awards should be granted as punishment for wanton, willful, reckless, malicious, or outrageous conduct.[56] Other jurisdictions grant punitive damage awards to deter those who might commit the same extreme wrongdoing.[57] Most jurisdictions authorize punitive damages for any combination of the preceding reasons.[58]

Punitive damage awards are common in strict liability litigation involving pharmaceutical products.[59] The plaintiff has the burden of proving the defendant's egregious wrongdoing to a level of clear and convincing evidence.[60] While punitive damage awards penalize inappropriate manufacturing practices and deter product suppliers from making economic decisions, they unfortunately do not remedy the product's defects.[61] The most common drug cases in which punitive damages are granted are those where the manufacturer had knowledge of adverse reactions but failed to properly warn of the danger.[62] In addition, failure to fully disclose scientific data adverse to a new drug application, failure to report adverse effects in the course of post-marketing surveillance, and failure to monitor for adverse effects all may lead to awards of punitive damages.[63]

DEFENSES

Assumption of Risk

A consumer's *assumption of risk* is a "form of contributory negligence which consists of voluntary and unreasonable encounter of a known danger."[64] If the consumer knew of the product's defect but disregarded the danger and used the product, he or she may be barred or limited in seeking recovery from the manufacturer.[65] The defendant must prove that the plaintiff knew and understood the danger and "voluntarily and unreasonably" consented to being exposed to it.[66] Assumption of the risk is an essential concept in pharmaceutical litigation defense. When adequate warning is given to the physician and the physician disregards these dangers, then the physician and patient have assumed some of the risk for potential adverse reactions.

Comparative Fault

Comparative fault measures the plaintiff's fault in comparison to the manufacturer's fault and places a percentage value on each. Most states with comparative negligence statutes have applied a comparative fault schema to strict tort liability litigation.[67] In a pure comparative fault system a plaintiff may recover the percentage of damage caused by the defendant, regardless of the fault attributable to the plaintiff.[68]

The principles of strict liability do not envision the manufacturer as an ensurer for all product-induced injuries. Comparative fault ensures equity in allocating risks and preventing manufacturers and innocent consumers from bearing the costs attributable to those who fail to use products carefully. Most courts that permit a defense of comparative fault also permit the defenses of assumption of risk and misuse,[69] considering them culpable conduct. Juries are usually instructed to combine the percentage from each of these defenses as an offset to the manufacturer's liability.[70]

Product Misuse

The product misuse defense is applicable when the consumer has used a product for a purpose not reasonably foreseeable to the manufacturer.[71] Comment h of Section 402A provides that "if the injury results from abnormal handling, . . . the seller is not liable." To assert this defense, the plaintiff's misuse of the product must be a contributing cause of the injury[72] and unforeseeable. The definition of "unforeseeable" is critical; taking four times the standard dose of a medication may be foreseeable but taking five times may be unforeseeable. There is no standard fixed or arbitrary cutoff; the fact-finder must establish foreseeability on a case-by-case basis.

Blood and Device Shield Statutes

Section 402A makes clear that any seller of a defective product, even a mere "retailer," is strictly liable. This holds true even if the seller in not "engaged solely" in selling. Statutes have been enacted in most states to protect

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hospitals and other health care providers from liability for unknowingly "selling" defective blood products to patients.[73] These "blood shield" laws posit that in providing blood to patients for a charge, hospitals and blood banks are not "selling" but rather providing a service.[74] However, these statutes do not extend to manufacturers of defective blood products that have been prepared from whole blood collected from multiple donors,[75] although tissue banks may be protected.[76] The concept of protecting health care providers from sellers' liability has been expanded to include protection for those who supply breast implants,[77] orthopedic implants,[78] and other devices.[79]

Learned Intermediary

A prescription drug or device manufacturer's duty to warn is usually satisfied by providing information to the physician rather than the patient.[80] Provision of warnings to this "learned intermediary" is a defense to failure-to-warn claims regardless of whether the physician has actually heeded them in writing the prescription or otherwise advised the patient. Exceptions may exist where the product is usually prescribed on a commodity basis, for example, birth control pills,[81] contraceptive devices,[82] and vaccines.[83] The defense may not be applicable in cases where prescription drugs are marketed directly to consumers, such as nicotine patches,[84] implantable contraceptives,[85] or in cases in which the drug's usage has been promoted for an off-label indication.[86] Manufacturers marketing drugs over the Internet may find the learned intermediary defense unavailable in failure to warn claims.[87]

Federal Preemption of State Law Tort Claims

Both the pharmaceutical and medical device industries are subject to comprehensive federal regulation by the FDA. This text provides a general discussion of these regulations elsewhere, but we are here concerned with their utility in the defense of medical product tort claims. First, by maintaining full regulatory compliance, manufacturers may claim to have produced a product that is, as a matter of law, free of design defects and one that provides adequate warnings.[88] Second, manufacturers frequently defend state law liability actions by claiming federal preemption under the FDCA and MDA. In practice, these two defenses are often merged under the label of "preemption."

The currently controlling decision on federal preemption of medical device claims is *Medtronic Inc. v. Lohr*, handed down by a sharply divided U.S. Supreme Court in 1996.[89] Lohr filed suit in Florida state court against Medtronic based on the failure of a pacemaker lead. The case was removed to federal court, where the district court granted Medtronic's summary judgment on the grounds that Lohr's claims were preempted by the MDA. Under *Lohr*, a determination must first be made as to whether the device underwent full FDA review either with a pre-MDA "new drug application" (NDA) or modern-day "pre-market approval" (PMA) versus mere approval under MDA Section 510(k). The latter is granted to devices that are "substantially equivalent" to other devices already on the market and does not subject the device to an extensive review of safety and effectiveness. When the device has been subjected to a PMA-equivalent process, state law tort claims that ordinarily would require a design or warnings inconsistent with those approved by the FDA are preempted under MDA Section 360(k). Those devices marketed under a 510(k) process, as was the pacemaker in *Lohr*, may be subject to state warning requirements. For the most part, federal and state courts have followed this interpretation of *Lohr* for both design[90] and warning defects,[91] despite some exceptions.[92]

Although the FDA regulation of the content of pharmaceutical warnings is exercised at the same word-for-word level of scrutiny as for PMA devices, there is no equivalent 360(k) federal preemption for drugs.[93] Thus, virtually all courts consider the FDA-mandated pharmaceutical warnings to be minimal standards, permitting state law failure-to-warn actions to proceed.[94] This situation persists despite the fact that it would be difficult for manufacturers to maintain different labels for different jurisdictions or to predict what warnings would immunize them from every conceivable state jurisdiction failure-to-warn claim.[95] These decisions have been reached,[96] although the FDA itself opined, in an unrelated *amicus* brief, [97]that deviations from FDA-approved warning language might be impermissible. Defects in the design or formulation of drugs similarly lack any federal preemptive protection.[98] Finally, the Supreme Court has held that even in cases in which there was "fraud-on-the-FDA," preemption is not vitiated.

Untimeliness

As with any tort claim, timely filing of product liability claims is limited by the relevant statute of limitations. The accrual of the cause of action may be tolled by application of the discovery rule in a manner similar to its use in actions for medical negligence.[99] Typically the accrual is construed to be the date on which the plaintiff knew or should have known of the potential for a product liability claim, regardless of whether the defendant was precisely known.[100] When more than one cause of action is possible, e.g., both medical negligence and product liability, the accrual dates are usually deemed to coincide.[101] In a situation where, notwithstanding the plaintiff's due diligence, he or she is unaware of the fact that a defective medical product may have been a cause of the injury, a separate and later date of accrual for product liability may be established due to the delayed discovery.[102]

CURRENT ISSUES

Failure to Warn[103]

Products that are both properly designed and correctly manufactured may still be considered dangerous and defective if not accompanied by proper warnings.[104] The supplier of any product, including the manufacturer of pharmaceuticals, is under a duty to use reasonable care to

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adequately warn of the risks associated with the use of its product.[105] This duty extends to the risks known to the manufacturer, to those which through reasonable care it should have known,[106]and to those risks of which knowledge might be imputed.[107] The "unavoidably dangerous" protection afforded medical products under the Restatement (Second) of Torts, Section 402A, comment k, does not apply unless the manufacturer has provided an adequate warning of potential adverse reactions.[108] The protection does not extend to those manufacturers who have failed to follow FDA guidelines for testing and marketing of their product.[109]

Drugs and medical devices are an exception to the rule requiring a warning of danger to the ultimate consumer.[110] The drug manufacturer's duty to warn includes a warning to physicians of the special risks that accompany normal use.[111] In the majority of cases there is no duty to warn the patient directly[112] except in the case of drugs marketed directly to the consumer.[113] In the case of pharmaceutical warnings the physician is considered to be the "learned intermediary," and in most instances the duty to warn ends when an adequate effort is made by the manufacturer to instruct physicians of the drug's potential side effects.[114, 115] Once the manufacturer has provided the physician with the necessary information, it is then the physician's duty to warn the patient.[116]

The manufacturer's duty to warn does not end with the purchase of the drug by the patient. The manufacturer is considered an expert with regard to its product[117] and must maintain post-marketing surveillance of its products. As an expert, the manufacturer has the duty to stay abreast of new scientific information in the field and the obligation to warn physicians of newly discovered hazards caused by the product.[118] If a previously unknown hazard is discovered after the drug has reached the marketplace, the manufacturer is required to make reasonable efforts to inform physicians and, ultimately, consumers.[119] This requirement is usually satisfied by notifications in the form of "Dear Doctor" letters,[120] "black-box"[121] product labeling, or directly to physicians via detail persons.

The manufacturer is responsible for performing studies of its product when adverse reactions are reported. The results of these studies, if adverse to the product, must be reported to the FDA who may then require further disclosure to physicians.[122] This duty to report new adverse findings extends to more than the manufacturer's own research but includes information available in the scientific and medical literature. Constructive knowledge of potential side effects is presumed with the publication of articles in scientific journals that relate to the product.[123]

The adequacy of warnings is a major issue in determining its reasonableness. If the warning is adequate, the defendant drug producer will usually prevail, even if the product is unavoidably unsafe.[124] The warning is considered adequate when it is obviously displayed, when it gives a fair appraisal of the extent of the danger, and when it properly instructs the user in how to use the product.[125] A warning is deemed adequate when it "warns with the degree of intensity demanded by the nature of the risk."[126] It may, however, be inadequate if it is "unduly delayed, reluctant in tone or lacking in a sense of urgency."[127]

In 1996 the California Supreme Court held that prescription drug manufacturers might be strictly liable under state law for failure to warn, so long as the risk of injury is either actually known or scientifically ascertainable at the time of the drug's distribution.[128] In 1996, in *Wagner v. Roche Laboratories*, the Ohio Supreme Court held that expert testimony that a drug manufacturer knew or should have known of the synergistic side effects of its drug with certain antibiotics was specific enough and of sufficient probative value to create under state product liability law a question of fact as to the adequacy of warnings contained in an FDA-approved package insert.[129]

Violation of Consumer Protection Statutes

Recently, medical product liability plaintiffs have begun to avail themselves of various state consumer protection statutes. These laws permit claims for any unfair trade practices, including those for manufacturing defects, design defects, or failures to warn.[130] In addition to possibly circumventing the learned intermediary defense,[131] the statutes may provide for significant statutory damages, punitive damages, attorney fees,[132] and recovery in the absence of actual damages.[133] So far, the majority of courts have held that the learned intermediary doctrine applies to consumer protection claims,[134] but there have been exceptions.[135]

Direct to Consumer Advertising

As a consequence of ethical restrictions and limitations on drug marketing to physicians, and a growing consumer interest in their own health care, the volume of direct to consumer advertising (DTCA), particularly on television, has surged. In 1985 and 1999, the FDA issued regulations specifying the disclosure requirements for print and electronic media prescription drugs advertisements directed at consumers.[136] Not surprisingly, this shift in drug marketing has led to the argument by plaintiffs and accepted by at least one court[137] that the learned intermediary doctrine is not applicable in the case of DTCA. In *Perez v. Wyeth Labs*, a case involving an implantable contraceptive, the court held that the role of physician in prescribing drugs does not break the chain of causation for a manufacturer's failure to warn patients of harmful side effects.[138] Although, to date,[139] no other court[140] has followed *Perez*, others have been sympathetic to its logic,[141] and it may be only a matter of time before the dam is breached.

Federal Vaccine Liability Protection

Occasionally the government accepts responsibility for drug defects. In 1976 the U.S. government statutorily accepted liability for any adverse reactions to the swine flu immunizations.[142] The government took the position of the manufacturer for the purpose of liability.[143] This legislation was repealed in 1978.[144] A similar program of "no-fault compensation" was created by the National Childhood Vaccine Injury Act.[145] This legislation has a dual purpose.

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First, it allows easier access to compensation for those children who have suffered hypersensitivity reactions to vaccines.[146] Second, it provides liability protection for manufacturers of a vaccine, allowing them to continue their production.[147] In the waning days of 2005, anticipating a possible "bird flu" pandemic, Congress passed the Pandemic Influenza Act of 2006[148] providing near blanket liability protection[149] to manufacturers of vaccines that have been declared "countermeasures" to any pandemic. Unlike previous vaccine acts, the statute does not provide any compensation to those who might be injured.

Physician and Pharmacist Liability

Many physicians and pharmacists are not fully informed of the potential side effects associated with the drugs they prescribe. One study revealed that less than 13% of drug use was evaluated as rational, 21.5% was considered questionable, and amazingly, more than 65% was judged irrational.[150] Because of the prevalence of drug use in the treatment of disease, many malpractice cases have pharmaceutical components.

The application of traditional liability rules to pharmaceutical manufacturers is problematic. For example, the defined consumer of prescription drugs is the physician, not the patient. The patient has little input into the drug selected by the physician. The physician holds a position as the "learned intermediary" and, as such, takes on some of the manufacturer's liability even in the case of a product defect.[151] Physicians and pharmacists who find themselves targeted in a suit resulting from a defective product have some recourse.[152] There is a potential tort action against the manufacturers of the defective product both for the injury to the patient and for damage to reputation and earnings.[153] In many circumstances this action leads to plaintiffs playing one potential defendant against another.[154]

Mass Tort Litigation

Mass tort litigation is a term denoting the legal circumstance in which a product is alleged to have actually caused, or to have the potential to cause, future injury to a large number of individuals. Typically, multiple legal actions are filed in both state and federal courts that may eventually result in formal class certification at either the state or federal level.[155] Because of the often serious nature of these injuries and the widespread use of prescription drugs and medical devices, pharmaceutical and medical device manufacturers are frequent targets of mass tort litigation. Even a casual awareness of legal events will bring to mind litigation surrounding Bendectin, breast implants, the Dalkon Shield contraceptive device, DES, HIV-contaminated blood products, penile implants, defective pacemaker leads, defective heart valves, and the FenPhen diet drugs. Numerous other medical products have been the subjects of such litigation with less publicity. The majority of these cases have arisen in the past 20 years.[156] It is beyond the scope of this chapter to discuss the complexities of class actions as they relate to medical product liability.

Securities Fraud

Under various provisions of the Securities Exchange Act of 1934, shareholders of a medical products manufacturer may be entitled to claim damages for misstatement or omissions[157] about a drug or device that eventually lead to a loss in the value of their shares. While some of the act's provisions may only result in an investigation by the SEC, others provide for a private right of action and recovery of damages.[158] Also possible are shareholder derivative claims and similar claims under the provisions of ERISA[159] and RICO,[160] with the latter providing for treble damages and attorneys' fees.[161] This type of litigation, still in its infancy as a tool in product liability litigation, is both complex and expensive and likely practical only in the context of a class action.[162]

CONCLUSION

The public should be free to purchase goods without fear of defects. Strict tort liability has arisen as a valid means to ensure that medical products perform function without causing injury. On the other hand, it is unreasonable to expect all products to be totally safe and risk-free for consumers. A knife with a dull blade might be safer than one with a sharp blade, but part of the sharp knife's efficacy is due to the cause of its dangerous propensity, namely, its sharpened edge. Ice cream would be safer without its heavy cholesterol content that clogs our arteries, but the joy of eating it comes from its richness. Medication and medical devices are unique because they are used with the knowledge that despite their enormous benefits, in a certain number of individuals there will be serious side effects.

Endnotes

1. *See* Staudt, *Determining and Evaluating the Promotional Mix*, Modern Medicine Topics 8 (July 1957).
2. Food and Drugs Act of 1906, ch. 3915, 34 Stat.768.
3. Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C.A. §301 (2005).
4. Food and Drug Administration Modernization Act of 1997, PL 105-115, 111 Stat.2296.
5. Medical Device Amendments of 1976, Pub.L. 94-295, §1(a), 90 Stat. 539.
6. *Greenman v. Yuba Power Prod.*, 59 Cal. 2d 57, 377 P. 2d 897, 27 Cal. Rptr. 697 (1963).
7. Restatement (Second) of Torts §402A (1965).
8. Restatement (Third) of Torts: Products Liability (1998).
9. *Mele v. Howmedica, Inc.*, 348 Ill. App. 3d 1, 16 808 N.E. 2d 1026, 1039, 283 Ill. Dec. 738, 751 (2004).
10. Tally & Laventurier, *Drug-Induced Illness*, 229 J.A.M.A. 1043 (1974).
11. *See, e.g.*, Restatement (Second) of Torts §402A, comment c (1965).
12. *See* Comment, *DES and a Proposed Theory of Enterprise Liability*, 46 Fordham L. Rev. 963 (1978).
13. *See Wells v. Ortho Pharmaceutical Corp.*, 788 F. 2d 741 (11th Cir. 1986), *cert. denied*, 479 U.S. 950 (1986).
14. Restatement (Second) of Torts §402A, comment k (1965).

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15. Wertheimer, *The Biter Bit: Unknowable Dangers, The Third Restatement, and the Reinstatement of Liability Without Fault*, 70 Brook. L. Rev. 889 (2005).
16. *See, e.g., Johnson v. American Cyanamid Co.*, 239 Kan. 279, 285, 718 P. 2d 1318, 1323 (1986) (quoting Restatement (Second) of Torts §402A, comment k [1965]).
17. *See, e.g.*, Scott, *Medical Product and Drug Causation: How to Prove It and Defend Against It*, 56 Def. Couns. J. 270 (1989); Leighton, *Introduction to the Symposium on Chemical and Food Product Liability*, 41 Food Drug Cosm. L. J. 385 (1986); Schwartz, *Unavoidably Unsafe Products*, 42 Wash. & Lee L. Rev. 1139 (1985).
18. McClellan, *Drug Induced Injury*, 25 Wayne L. Rev. 1 (1978); Maldonado, *Strict Liability and Informed Consent: "Don't Say I Didn't Tell You So,"* 9 Akron L. Rev. 609 (1976); Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1 (1973); Keeton, *Product Liability: Drugs and Cosmetics*, 25 Vand. L. Rev. 131 (1972); *see, e.g., Brochu v. Ortho Pharmaceutical Corp.*, 642 F. 2d 652 (1st Cir. 1981).
19. Britain, *Product Honesty Is the Best Policy: A Comparison of Doctor's and Manufacturer's Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect*, 79 N.W.U. L. Rev. 342 (1984); Fink, *Education in Pharmacy and Law*, 26 J. Legal Educ. 528, 538 (1974).
20. *Barker v. Lull Engineering Co.*, 20 Cal. 3d 413, 573 P. 2d 443, 143 Cal. Rptr. 225 (1978)
21. Comment, *Can a Prescription Drug Be Defectively Designed?: Brochu v. Ortho Pharmaceutical Corp.*, 31 De Paul L. Rev. 247 (1981).
22. Birnbaum, *Unmasking the Test for Design Defect: From Negligence to Strict Liability to Negligence*, 33 Vand L. Rev. 593 (1980).
23. Isaacs, *Drug Regulation, Product Liability, and the Contraceptive Crunch: Choices Are Dwindling*, 8 J. Leg. Med. 533 (1987) (strict liability and duty to warn).
24. Restatement (Second) of Torts §402A, comment g (1965).
25. *Id.* at §395.
26. *Id.* at §402A, comment i.
27. *See, e.g., Phillips v. Kimwood Mach. Co.*, 269 Or. 485, 525 P. 2d 1033 (1974); *Dosier v. Wilcox-Crittendon, Co.*, 45 Cal. App. 3d 74, 119 Cal. Rptr. 135 (1975).
28. *See, e.g., Boutland of Houston, Inc. v. Bailey*, 609 S.W. 2d 743, 746 (Tex. 1980).
29. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L. J. 825, 829 (1973).
30. *See contra, Brochu, supra* note 18.
31. *Barker*, supra note 20 (permitting the use of either the consumer expectation test or the risk–utility test).
32. *Brown v. Superior Ct.*, 751 P. 2d 470 (Cal. 1988).
33. *Id.* at 482.
34. *See, e.g., Collins v. Ortho Pharmaceutical Corp.*, 195 Cal. App. 3d 1539, 231 Cal. Rptr. 396 (1986).
35. *Id.*
36. Restatement (Second) of Torts §402A, comment j (1965).
37. Restatement (Second) of Torts §402A, comment h (1965).
38. *See* Werthheimer, *supra* note 15 at 900.
39. *See, e.g., Green v. Smith & Nephew AHP, Inc.*, 629 N.W. 2d 727 (Wisc. 2001); *Sternhagen v. Dow Co.*, 935 P. 2d 1139 (Mont. 1997).
40. *See also* discussion *infra*, Learned Intermediary.
41. *See also* discussion *infra*, Direct to Consumer Advertising.
42. Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 Minn L. Rev. 791, 840 (1966).
43. Restatement (Second) of Torts §402A (1965).
44. Middlekauff, *The Current Law Regarding Toxic Torts: Implications for the Food Industry*, 41 Food Drug Cosm. L. J. 387, 404–405 (1986).
45. Comment, *Industry Wide Liability*, 13 Suffolk U. L. Rev. 980 (1979); *Mulcahy v. Eli Lilly & Co.*, 386 N.W. 2d 67 (Iowa 1986) (DES market share liability).
46. Comment, *The Market Share Theory: Sindell's Contribution to Industry Wide Liability*, 19 Hou. L. Rev. 107 (1982).
47. Restatement (Second) of Torts §402A, comment l (1965).
48. *Helene Curtis Indus. v. Pruitt*, 385 F. 2d 841, 859–864 (5th Cir. 1967); *Bigbee v. Pacific Tel. & Tel. Co.*, 34 Cal. 3d 49, 665 P. 2d 947, 192 Cal. Rptr. 857 (1983).
49. *See, e.g., Baker v. International Harvester Co.*, 660 S.W. 2d 21 (Mo. 1983).
50. *Winnett v. Winnett*, 57 Ill. 2d 7, 310 N.E. 2d 1 (1974).
51. *Basko v. Sterling Drug, Inc.*, 416 F. 2d 417 (2nd Cir. 1969).
52. *Motus v. Pfizer Inc.*, 196 F. Supp.2d 984 (C.D. Cal. 2001).
53. Restatement (Second) of Torts §402A, comment j (1965).
54. Basko, *supra* note 51.
55. *See* Restatement (Second) of Torts §402A (1965).
56. *See* Restatement (Second) of Torts §908(2) (1965).
57. *Chrysler Corp. v. Wolmer*, 499 So. 2d 823 (Fla. 1986).
58. *See, e.g., Miller v. Watkins*, 200 Mont. 455, 653 P. 2d 126 (1982); *Newton v. Standard Fire Ins. Co.*, 291 N.C. 105, 229 S.E. 2d 297 (1976).
59. *See Hoffman v. Sterling Drug*, 485 F. 2d 132, 144–147 (3rd Cir. 1973).
60. *Acosta v. Honda Motor Co.*, 717 F. 2d 828, 833 (3rd Cir. 1983).
61. *Neal v. Carey Canadian Mines*, 548 F. Supp. 357 (E.D. Pa. 1982), *aff'd, Van Buskirk v. Carey Canadian Mines*, 791 F. 2d 30 (3rd Cir. 1986).
62. *See G.D. Searle & Co. v. Superior Court*, 49 Cal. App. 3d 22, 122 Cal. Rptr. 218 (1975); *Roginsky v. Richardson-Merrell, Inc.*, 378 F. 2d 832 (2d Cir. 1967); *Toole v. Richardson-Merrell, Inc.*, 251 Cal. App. 2d 689, 60 Cal. Rptr. 398 (1967).
63. *Wooderson v. Ortho Pharmaceutical Corp.*, 681 P. 2d 1038 (Kan. 1984)
64. Restatement (Second) of Torts §402A, comment n (1965).
65. This is applicable only to *implied* assumptions of risk that are considered to be culpable conduct under a jurisdiction's contributory or comparative negligence statutes.
66. *Smith v. Clayton & Lambert Mfg. Co.*, 488 F. 2d 1345, 1349 (10th Cir. 1973).
67. *Daly v. General Motors Corp.*, 20 Cal. 3d 725, 575 P. 2d 1162, 144 Cal. Rptr. 380 (1978).
68. *Mulherin v. Ingersoll-Rand Co.*, 628 P. 2d 1301, 1303–1304 (Utah 1981).
69. *See generally* Fischer, *Products Liability: Applicability of Comparative Negligence to Misuse and Assumption of the Risk*, 43 Mo. L. Rev. 643 (1978).
70. *See, e.g., Duncan v. Cessna Aircraft Co.*, 665 S.W. 2d 414 (Tex. 1984).
71. *Perfection Paint & Color Co. v. Konduris*, 147 Ind. App. 106, 107, 258 N.E. 2d 681, 682 (1970).
72. *Basko, supra* note 51.
73. *See Roberts v. Suburban Hosp. Assn.*, 532 A. 2d 1081, 1086 (Md. 1987).
74. *See, e.g., Chauvin v. Sisters of Mercy Health*, 818 So. 2d 833 (La. 2002); *id.*
75. *See, e.g., JKB v. Armour Pharmaceutical Co.*, 660 N.E. 2d 602 (Ind. 1996); *In Re Factor VIII or IX Concentrate Blood Products Litigation*, 159 F. 3d 1016 (7th Cir. 1998).
76. *See, e.g., Cryolife, Inc. v. Superior Court of Santa Cruz*, 110 Cal. App. 4th 1145, 2 Cal. Rptr. 3d 396 (2003).

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77. *See, e.g., In re Breast Implant Product Liability Litigation*, 503 S.E. 2d 445 (S.C. 1998).
78. *See, e.g., Cafazzo v. Central Medical Services*, 668 A. 2d 521 (Pa. 1995); *Budding v. SSM Healthcare System*, 19 S.W. 3d 678 (Mo. 2000); *Royer v. Catholic Medical Center*, 741 A. 2d 74 (N.H. 1999).
79. *See, e.g., Brandt v. Boston Scientific Corp.*, 204 Ill. 2d 640, 792 N.E. 2d 296, 275 Ill. Dec. 65 (2003).
80. *See, e.g., Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1303 (Minn. 1988).
81. *See, e.g., MacDonald v. Ortho Pharmaceutical Corp.*, 394 Mass. 131, 475 N.E. 2d 65 (1985), *cert. denied* 474 U.S. 920 (1985).
82. *See, e.g., Hill v. Searle Laboratories*, 884 F. 2d 1064 (8th Cir. 1989), *but see In re Norplant Contraceptive Products Liability Litigation*, 165 F. 3d 374 (5th Cir. 1999).
83. *See, e.g., Davis v. Wyeth Laboratories, Inc.*, 399 F. 2d 121 (9th Cir. 1968).
84. *See, e.g., Edwards v. Basel Pharmaceuticals*, 933 P. 2d 298 (Okla. 1997).
85. *Perez v. Wyeth Labs., Inc.*, 734 A. 2d 1245 (N.J. 1999).
86. *See, e.g., Proctor v. Davis*, 682 N.E. 2d 1203 (Ill. 1997).
87. *See generally,* Graham & Vest, *Doctors, Drugs, and Duties to Warn*, 72 Def. Couns. J. 380 (2005).
88. Products Liability Symposium, *Statutory Compliance and Tort Liability: Examining the Strongest Case*, 30 U. Mich. J. L. Ref. 461 (Spring 1997).
89. 116 S.Ct. 2240 (1996).
90. *See, e.g., Mitchell v. Collagen Corp.*, 126 F. 3d 902 (7th Cir. 1997); *Richman v. Gore*, 988 F. Supp. 753 (S.D. N.Y. 1997); *Martin v. Telectronics*, 105 F. 3d 1090 (6th Cir. 1997); *Worthy v. Collagen Corp.*, 967 S.W. 2d 360 (Tex. 1998); *Martin v. Medtronic*, 254 F. 3d 573 (5th Cir. 2001).
91. *See, e.g., Brooks v. Howmedica*, 273 F. 3d 785 (8th Cir. 2001).
92. *See, e.g., Niehoff v. Surgidev Corp.*, 950 S.W. 2d 816 (Ky. 1997); *Goodlin v. Medtronic*, 167 F. 3d 1367 (11th Cir. 1999).
93. *Eve v. Sandoz*, 2002 W.L. 181972, 2 (S.D. Ind. 2002).
94. *Motus v. Pfizer Inc.*, 127 F. Supp. 2d 1085, 1096 (C.D. Cal. 2000).
95. *Id.* at 1095.
96. *Cartwright v. Pfizer Inc.*, 369 F. Supp. 2d 876 (E.D. Tex. 2005).
97. *Motus v. Pfizer Inc.*, 358 F. 3d 659 (9th Cir. 2004). It is unclear whether the court considered the FDA's *amicus* brief in reaching its decision.
98. *See, e.g., Abbot v. American Cyanamid Co.*, 844 F. 2d 1108 (4th Cir. 1988).
99. *Fox v. Ethicon Endo-Surgery*, 35 Cal. 4th 797, 808, 110 P. 3d 914, 920, 27 Cal. Rptr. 3d 661, 668 (2005).
100. *Id.*
101. *Id.* at 812, 923, 671.
102. *See generally Fox, supra* note 99.
103. *See also supra*, discussions of Learned Intermediary and Federal Preemption.
104. *See e.g., Basko, supra* note 51; *see also Jacobson v. Colorado Fuel & Iron Corp.*, 409 F. 2d 1263, 1271 (9th Cir. 1969).
105. Restatement (Second) of Torts §12 (1965).
106. *See, e.g., Lindsay v. Ortho Pharmaceutical Corp.*, 637 F. 2d 87 (2d Cir. 1980); *Sterling Drug, Inc., v. Cornish*, 370 F. 2d 82 (8th Cir. 1966); *Incollingo v. Ewing*, 444 Pa. 263, 282 A. 2d 206 (1971), *rev'd on other grounds*, 491 Pa. 561, 421 A. 2d 79 (1977).
107. *See supra* note 38.
108. *Davila v. Bodelson*, 103 N.M. 243, 704 P. 2d 1119 (1985).
109. *Id.*
110. *See, e.g., Buckner v. Allergan Pharmaceuticals*, 400 So. 2d 820 (Fla. 1981).
111. *See, e.g., Fellows v. USV Pharmaceutical Corp.*, 502 F. Supp. 297 (Md. 1980) (the manufacturer has a duty to provide warnings to physician, but the duty does not extend to the patient); *Ezagui v. Dow Chemical Corp.*, 598 F. 2d 727 (2nd Cir. 1979).
112. *Id.*
113. *See* discussion *infra*, Direct to Consumer Adverstising.
114. *Reyes v. Wyeth Laboratories*, 498 F. 2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974).
115. *See Leesley v. West*, 165 Ill. App. 3d 135, 518 N.E. 2d 758 (App. Ct.), *appeal denied*, 119 Ill. 2d 558, 522 N.E. 2d 1246 (1988); *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301 (Ala. 1984); *Mauldin v. Upjohn Co.*, 697 F. 2d 644 (5th Cir. 1983).
116. *See Crain v. Allison*, 443 A. 2d 558, 562 (D.C. App. 1982); *Salis v. United States*, 522 F. Supp. 989, 1000 (M.D. Pa. 1981).
117. *Barson v. E.R. Squibb & Sons*, 682 P. 2d 832 (Utah 1984).
118. *Id.* at 834 (citing *McEwan v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P. 2d 522 [1974]).
119. *Schenebeck v. Sterling Drug*, 423 F. 2d 919 (8th Cir. 1970).
120. These are mailings sent directly to all practicing phsyicians calling attention to new labeling requirements.
121. These are warnings prominently displayed in a black box on drug package inserts and PDR entries.
122. *See Schenebeck, supra* note 11; *O'Hare v. Merck & Co.*, 381 F. 2d 286 (8th Cir. 1967)
123. *Feldman v. Lederle Laboratories*, 97 N.J. 429, 479 A. 2d 374 (1984); *see also* Gilhooley, *Learned Intermediaries, Prescription Drugs, and Patient Information*, 30 St. Louis L. J. 633 (1986).
124. *Formella v. Ciba-Geigy Corp.*, 100 Mich. App. 649, 300 N.W. 2d 356 (1980).
125. Madden, *The Duty to Warn in Products Liability: Contours and Criticism*, 89 W.Va. L. Rev. 221, 310–320 (1987); *Richards v. Upjohn Co.*, 95 N.M. 675, 679, 625 P. 2d 1192, 1196 (Ct. App. 1980).
126. *Seley v. G.D. Searle & Co.*, 67 Ohio St. 2d 192, 198, 423 N.E. 2d 831, 837 (1981).
127. *Id.* at 837.
128. *Carlin v. Sutter Court Superior Ct.*, 13 Cal. 4th 1104, 920 P. 2d 1347, 56 Cal. Rptr. 2d 162 (1996).
129. *Wagner v. Roche Labs.*, 85 Ohio St. 3d 457, 709 N.E. 2d 162 (1999).
130. Graham & Vest, *supra* note 87.
131. Garbutt & Hofmann, *Recent Developments in Pharmaceutical Products Liability Law*, 58 Food Drug L.J. 269, 282 (2003).
132. Graham & Vest, *supra* note 87 at 383.
133. Garbutt & Hofmann, *supra* note 131 at 282.
134. Graham & Vest, *supra* note 87 at 386.
135. *Rivera v. Wyeth-Ayerst Laboratories*, 121 F. Supp. 2d 614 (S.D. Tex. 2000).
136. 21 C.F.R. §202.1(e)(1).
137. *Perez*, *supra* note 85.
138. *Id.*
139. January 2006.
140. *In re Meridia Products Liability Litigation*, 328 F. Supp. 2d 79, 812 (Ohio 2004).
141. *Id.* at 812.
142. National Swine Flu Immunization Program of 1976, Pub. L. No. 94-380, 90 Stat. 1113; *see also Ducharme v. Merrill-Nat'l Labs.*, 574 F. 2d 1307 (5th Cir.), *cert. denied*, 439 U.S. 1002 (1978).
143. 90 Stat. 1116.

144. Health and Human Services Amendments of 1978, Pub. L. 95-626, 92 Stat. 3551.
145. Pub. L. 99-660, 100 Stat. 3755 (codified at 42 U.S.C. §§300aa-1 to 33 [1986]).
146. 100 Stat. 3758 (codified at 42 U.S.C. §300aa-10 [1988]).
147. 100 Stat. 3758–59 (codified at 42 U.S.C. §300aa-11 [1988]).
148. 42 U.S.C. 319F-3.
149. Id. at (a)(1).
150. Silverman & Lee, *Pills, Profits and Politics* 333, 389–390 (University of California Press, Berkeley 1974).
151. Comment, *Strict Tort Liability/Negligence/Prescription Drugs: A Pharmaceutical Company Owes No Duty to a Non-Patient Third Party to Warn Doctors or Hospitals of the Side Effects of a Drug and a Hospital or Doctor Owes No Duty to a Non-Patient Third Party to Warn a Patient of the Effects of a Prescription Drug*, 77 Ill. B. J. 227 (1988); Comment, *Torts: Duty to Warn—Incorrect Prescription of Unavoidably Unsafe Drugs*, 22 Kan. L. Rev. 281 (1984).
152. *See* Merrill, *Compensation for Prescription Drug Injuries*, 59 Va. L. Rev. 1, 50–68 (1973).
153. *See, e.g., Oksenholt v. Lederle Laboratories*, 294 Or. 213, 656 P. 2d 293 (1982); Mobilia, *Allergic Reactions to Prescription Drugs: A Proposal for Compensation*, 48 Alb. L. Rev. 343, 364–365 (1984).
154. *See* Willig, *Physicians, Pharmacists, Pharmaceutical Manufacturers: Partners in Patient Care, Partners in Litigation?*, 37 Mercer L. Rev. 755 (1986).
155. Norman, *Class Actions: A Practitioner's Tool*, 31 WTR Brief 48 (2002).
156. Cabraser, *Class Action Update 2002: Mass Tort Trends, Choice of Law Rule 23(F), Appeals, and Proposed Amendments to Rule 23*, SH009 ALI-ABA 1189 (2002).
157. *See, e.g., In re Bayer AG Securities Litigation*, 2004 WL 2190357 1 (S.D.N.Y.).
158. *See generally* Welsh & Karg, *The Recent Expansion of Traditional Products Liability–Personal Injury Claims into More Complex Claims and Investigations*, SL038 ALI-ABA 347, 354–355 (2005).
159. Employment Retirement Income Security Act, 29 U.S.C. §1001.
160. Racketeer Influenced Corrupt Organization provisions of the Organized Crime Control Act of 1970, 18 U.S.C. §1962.
161. Welsh & Karg, *supra* note 158 at 356–357.
162. *See, e.g., In re Bayer*, supra note 157 *In re Bayer AG Securities Litigation*, 2005 WL 2222273 (S.D.N.Y.).