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Recommended Citation

Edward M. Swartz, *Products Liability: Manufacturer's Responsibility for Defective or Negligently Designed Medical and Surgical Instruments*, 18 DePaul L. Rev. 348 (1969)

Available at: <https://via.library.depaul.edu/law-review/vol18/iss2/2>

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PRODUCTS LIABILITY: MANUFACTURER'S
RESPONSIBILITY FOR DEFECTIVE OR
NEGLIGENTLY DESIGNED MEDICAL
AND SURGICAL INSTRUMENTS

EDWARD M. SWARTZ*

INTRODUCTION

THE CODMAN-Shurtleff Drill, equipped with a Smith automatic perforator, is a mechanical drilling and biting device powered by compressed air. In principle it is similar to many electrically powered carpenter's tools, but it is used by neurosurgeons to drill holes through the cranium, that portion of the skull which encloses the brain. This drill is equipped with a crude self-regulating device. Theoretically the drill and bit continue to operate and move forward only so long as they encounter the resistance of the hard, bony cranium. As soon as the bit breaks through the cranium, encountering the soft membranes covering the brain, the lack of resistance theoretically causes the gears to disengage. Although the drill continues to rotate, the bit stops moving forward, so that it will not continue to cut through the brain itself. The neurosurgeon accustomed to using this device depends on this simple regulator to stop the perforator bit for him. Having used this surgical tool successfully many times before, he accepts the infallibility of the machine almost as an article of faith.

Such reliance on the perfection of manufactured surgical products is often tragically ill-founded. There is at least one case known to this author where it is claimed the drill bit failed to disengage after pene-

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trating the cranium. The drill continued to move forward into the brain, lacerating brain tissues and causing irreparable brain damage. The manufacturer of the Codman-Shurtleff Drill allegedly designed and put on the market a product so defective and faulty that ordinary use would cause it to malfunction even in the most expert surgical hands.

The destruction of a human mind by a "runaway" electric drill certainly must be considered a dramatic example of the injury causing potential inherent in nearly all medical and surgical instruments today, but similar examples are all too common. More frequently than has been recognized, a patient's injury or death may be traced neither to the negligence of physicians or hospital personnel, nor to unforeseen acts of God, nor to the patient's underlying disease; but it can be proximately traced to the unexpected by-product of faulty design, defective manufacturing and assembly, or inadequate operating instructions. In such cases the responsibility for injury or death rests with the manufacturer. This article will examine the role that products liability litigation can and should play in order to give meaning and substance to that responsibility.

Medical and surgical instruments are the tools of a profession dedicated to the art of healing. Because such instruments are used with this laudable intent, it is all too easy to overlook the fact that they are still nothing more than specialized, mechanical, or electrical tools. They are subject to the same defects of design, durability, construction, and assembly as are the tools of the factory and machine shop. The law has come to recognize that mechanical and electrical tools in general are a common source of serious injury or death. In this time of rapidly evolving products liability, law attorneys must become aware that there is nothing sacrosanct about the specialized tool we call a medical or surgical instrument. It is not necessarily safer than any other tool. It is made by manufacturers equally as fallible, human, and prone to error and negligence as their brethren in any other branch of industry. But with medical and surgical instruments the consequences of such error and negligence may be exceptionally devastating.

Modern medical and surgical instruments must serve widely differing functions. Their diversity of design is commensurate with the entire broad sweep of modern specialized medical practice. Surgical equipment may be as basic as a scalpel, a simple cutting blade whose essential design has remained unchanged for centuries. The other end

of the spectrum of surgical complexity encompasses newly designed electrosurgical and cryosurgical equipment, heart valves, monitoring devices, anesthesia machines, and countless other highly specialized machines. It goes without saying that the criteria for safe design, manufacture, and function of such diverse standard medical products as catheters, hypodermic needles, X-ray and fluoroscopic units, orthopedic prostheses, sutures, and endoscopes, must be developed individually. Products liability law has come to recognize this diversity, but at the same time has established certain basic elements of safe, non-negligent design and manufacture which all products must satisfy.

The need for such a minimum standard is apparent. Medical and surgical instruments share one crucial similarity. All are designed for intimate contact with the human body. Such contact is often far closer than that which the consumer has with the typical household or industrial product. It is more serious than the consumer's contact with foods and beverages, for they are meant to be ingested normally, while medical and surgical instruments by their very nature are designed to interfere, deliberately, and often violently, with the anatomy and physiology of the human body. Of the branches of products liability litigation only drugs and medications, a kindred and more thoroughly developed branch, share the two crucial characteristics—bodily intimacy and deliberately disruptive effect.

It can be said, therefore, that within the products liability field, medical and surgical instruments must occupy a special place. Precisely because such instruments have the potential to heal, they have exceptional potential to injure as well.

Yet the expanding scope of products liability litigation has not embraced all types of products equally. There has been relatively little reported litigation involving manufacturers of medical and surgical instruments even in the past decade which has witnessed the rapid development of products liability law through the liberalization of breach of warranty concepts and the development of strict liability in tort. The reasons for this dearth of medical instruments litigation are multifold. Physicians are, on the whole, a highly discriminating class of purchasers and provide manufactures with intelligent and articulate feedback about defective products, often preventing serious injury before it could occur. And, as with all products liability litigation, there exists the problem of educating the injured person about his

rights. In the majority of cases of personal injury no lawsuit is ever brought because the patient, or consumer, is never taught that a legal remedy is available to him. He considers his injuries a tragic act of God, accepts them resignedly, and fails to contact an attorney.

But a major reason for the lack of litigation in the medical instruments area can be traced to lack of imagination among plaintiffs' personal injury attorneys. It is all too easy for the attorney, as does the lay plaintiff, to overlook the fact that medical instruments rather than the physician user, may be the cause of serious injury or death. Furthermore, many attorneys have been trained and conditioned to think only of more traditional theories of recovery.¹ When his client is a patient injured by a defective medical or surgical instrument, the attorney thinks first of a malpractice action against the physician who used the instrument. He may then include a negligence action against the hospital or physician who supplied the instrument, based primarily on failure to inspect and repair defects. The manufacturer often escapes suit entirely. Even when recovery is attempted the manufacturer may ultimately escape because of jurisdictional problems, failure to prove negligent design, or failure to prove the defect traceable to the manufacturer rather than to subsequent use. Nevertheless, a negligence, breach of warranty, or strict liability action against the instrument manufacturer should be more than an inviting but rarely used alternative. In cases where permanent injury is traceable to a medical or surgical instrument it is often the soundest course of action to make the action against the manufacturer the action of choice.

¹ The same preoccupation with traditional theories of recovery is apparent in the bulk of scholarly comment on liability for injuries caused by medical and surgical equipment. The primary targets of the commentators remain the physician and the hospital. See Annot., 79 A.L.R.2d 401 (1961), describing the liability of a manufacturer or seller for injury caused by medical and health supplies, appliances, and equipment. The annotation illustrates the paucity of case material involving true surgical instruments, since many of the cases deal with quasi-therapeutic devices purchasable by the layman at the drug store on his own initiative. A somewhat more helpful article is Campbell, *Defective Surgical Instruments and Medical Products*, 12 DEFENSE L. J. 249 (1963). The article is directed at medical and surgical instruments, vaccines, blood transfusions, and other tools and techniques used by the medical profession. It deals with actions against physicians and hospitals as well as against manufacturers and suppliers. Once again the number of cases collected is small. An excellent and thorough article, Leff, *Medical Devices and Paramedical Personnel: A Preliminary Context for Emerging Problems*, [1967] WASH. U.L.Q. 322, discusses the legal problems involved in fixing liability for defective instruments upon the physician or hospital, but deliberately chooses to make only passing mention of manufacturer's liability. Similarly, a student comment, 17 HASTINGS L.J. 359 (1965), proposes imposition of strict liability upon the user physician but ignores the manufacturer.

LIABILITY OF PHYSICIANS AND HOSPITALS

Before we consider in detail the pitfalls and advantages of products liability actions against manufacturers of injury-producing medical and surgical instruments, it is helpful to review briefly the problems associated with alternative theories of recovery.

The most obvious is, of course, a malpractice action against the physician who operated the culprit instrument. There are many cases in which the offending instrument is used in a negligent manner, and in such cases an ordinary malpractice action is unquestionably the primary theory of recovery. Frequently there is no evidence that the instrument was defective or negligently designed in any way. The classic example is the case involving a scalpel which slips, or a dental drill which slips.² It is important to realize, nevertheless, that in several types of malpractice cases negligent design or failure to warn or instruct may be a hidden culprit. Consider the following three situations of hidden design dangers:

1. Irradiation injuries from X-ray or fluoroscopy equipment: The number of cases involving injuries of radiation burns caused by overexposure to X-rays is legion.³ In many of these cases, especially earlier decisions, it developed that the machines were not equipped with dosage-regulators, timers, radiation filters, proper shielding and other safety devices.⁴ In addition, manufacturers of X-ray machines and fluoroscopes, failed to warn physicians and instruct them how to take precautions against radiation injury to patients and themselves. At the very least such cases are examples of concurrent negligence. The physician's negligence in giving an overdosage would not be considered an intervening cause if the manufacturer represented that its machine had safe shielding devices and failed to warn and instruct about radiation hazards, thus making it reasonably foreseeable that the physician would act on the basis of the manufacturer's misrepresentations.

2. Esophagoscopes and gastroscopes are tubes which enable physicians to see the interior walls of the esophagus and stomach. Three types of scopes are commonly used today. The Hirschowitz and Eder-Hufford scopes are rigid metal tubes equipped with a flexible rubber

² Higdon v. Carlebach, 348 Mich. 363, 83 N.W.2d 296 (1957).

³ Dunlap, *Medicolegal Aspects of Injuries From Exposure to Roentgen Rays and Radioactive Substances*, 1 OCCUPATIONAL MEDICINE 237 (1946).

⁴ Gross v. Robinson, 203 Mo. App. 118, 218 S.W. 924 (1920).

obturator at the tip. Recently the flexible LoPresti fiberoptic scope, using shielded light wires, has come into use. The problem is to navigate the esophagus, especially the cricopharyngeal cartilage area near the Adam's apple, without perforating the esophageal wall. This is a delicate and dangerous maneuver. Perforation of the wall is the basis for a malpractice action. A uniformly safe scope has not yet been designed, so that the scope, even in a physician's hands, must be considered a dangerous instrumentality. The possibility of a negligent design action, or an action based on strict liability in tort, should not be overlooked.

3. Catheter sequestration: A catheter is a plastic tube of very small diameter which is inserted into the patient's vein through a metal needle. Parts of catheters once inside the body break off and float through the bloodstream.⁵ It is possible to lacerate and weaken the catheter tubing as it is inserted through the needle into the vein, so that it will break off more easily. This risk may be seriously increased by negligent design of the catheter-needle apparatus. In similar situations attorneys have all too often let the obvious malpractice claim blind their eyes to the potential action against the manufacturer.

The second type of malpractice lawsuit is brought against the physician when the instrument he is nonnegligently using proves to be defective. The malpractice standard of care is generally defined as the exercise of that degree of care, judgment, and skill which is exercised by other physicians in the same or similar localities under similar circumstances.⁶

With respect to the use of instruments which prove to be defective, the malpractice standard of care has been interpreted to impose liability only if the physician knew or in the exercise of reasonable care should have known of the instrument's defect.⁷ This criterion is normally

⁵ Taylor v. Milton, 353 Mich. 421, 92 N.W.2d 57 (1958), (filiform tip of urethral catheter); Dickerson v. St. Peter's Hospital, 342 P.2d 293 (Wash. 1967).

⁶ Although a physician is relieved of malpractice liability if he complies with customary medical practice, it is important to note that no such excuse is available in actions against manufacturers of medical instruments. Compliance with industry standards or customs is no bar to recovery based on negligence, if it be found that the customary practice of the entire industry is negligent. See Chapman v. Brown, 198 F. Supp. 78, *aff'd*, 304 F.2d 149. (9th Cir. 1962). This may prove a noteworthy advantage of products liability theories over recovery based on malpractice.

⁷ Nelson v. Swedish Hospital, 241 Minn. 551, 64 N.W.2d 28 (1954); Cohran v. Harper, 115 Ga. App. 277, 154 S.E.2d 461 (1967); Johnston v. Black Co., 33 Cal. App. 2d 363, 91 P.2d 921 (1939).

reduced to a question of fact, whether the defect was patent or latent, and if latent, whether it would be discoverable through reasonable inspection and tests.⁸ Negligence liability has been imposed on physician users and upon owner-suppliers for failure to inspect for patent defects.⁹ Occasionally negligence liability has been imposed on the owner-supplier of the defective instrument, whether this defendant be hospital or physician, for failure to make reasonable testing and inspection for latent defects.¹⁰ But if the latent defect is not discoverable through testing, the owner-supplier generally is not held liable for failure to test or inspect.¹¹ Many decisions have held that the owner is under no duty to test for latent defects at all, apparently assuming that such duty rests entirely with the manufacturer.¹²

Attempts to impose a stricter standard of liability upon the physician user or upon the physician or hospital owner-supplier have met with negligible success. Such attempts to circumvent the malpractice standard have taken three paths: (1) *res ipsa loquitur*, (2) breach of warranty, and (3) strict liability in tort.

Res ipsa loquitur is generally applied in situations where (1) the accident is of a sort which ordinarily does not occur unless someone was negligent, (2) the defendant must be responsible for any possible negligence that might have taken place, and (3) the plaintiff must be free from any possible contributory negligence.¹³ As with most malpractice cases, the third criterion is easily met. The first two are highly problematical when applied to cases involving defective instruments. It is clear that medical and surgical instruments, just like nonmedical tools, may break down eventually after repeated use. This may be the result of ordinary nonnegligent wear and tear. Until we reach the question of manufacturer's liability for failure to design durability into its instrument, it becomes apparent that medical and surgical instru-

⁸ *Clary v. Christiansen*, 54 Ohio L. Abs., 254, 83 N.E.2d 644 (App. 1948); *Tennant v. Barton*, 164 Wash. 279, 2 P.2d 735 (1931); *Payne v. Garvey*, 264 N.C. 593, 142 S.E.2d 159 (1965).

⁹ *South Highlands Infirmary v. Camp*, 279 Ala. 1, 180 So.2d 904, 14 A.L.R.3d 1245 (1965); *Payne v. Garvey*, 264 N.C. 593, 142 S.E.2d 159 (1965); *Nelson v. Swedish Hospital*, 241 Minn. 551, 64 N.W.2d 28 (1954).

¹⁰ *Tennant v. Barton*, *supra* note 8.

¹¹ *Crowe v. McBride*, 25 Cal. 2d 318, 153 P.2d 727 (1944); *Ratliffe v. Wesley Hospital*, 135 Kan. 306, 10 P.2d 859 (1932).

¹² *See Hine v. Fox*, 89 So. 2d 13 (Fla. 1956).

¹³ PROSSER, TORTS § 39 (3d ed. 1964); 2 HARPER & JAMES, TORTS §§ 19.6-19.9 (1956).

ments may frequently break down in the absence of negligence by either physician user, physician or hospital owner, or manufacturer.

The majority of *res ipsa loquitur* approaches have floundered on the second criterion. The defect may be traceable to the manufacturing process, rather than to negligent handling by the physician user or the physician or hospital owner. In such a case, the malpractice defendant cannot be responsible for the negligence which caused the defect. A majority of decisions have adopted this approach.¹⁴ A minority of decisions have applied *res ipsa loquitur*, often using it as a rationale for an inarticulate imposition of strict liability on the physician or hospital.¹⁵

The second attempt to extend physician and hospital liability for injuries caused by defective instruments has been through the breach of warranty theory, codified in the *Uniform Commercial Code* § 2-313 (express warranty), § 2-314 (implied warranty of merchantability), and § 2-315 (implied warranty of fitness). As we shall see, this approach has substantial merit in actions against manufacturers. But as against physicians and hospitals it is a weak reed. Breach of warranty theory demands a sale, and although the ultimate beneficiary need not be the purchaser,¹⁶ the defendant at least must be a seller of the instrument. But physicians simply do not sell medical instruments to patients when they use the instruments upon them.

No reported case has involved the sale of a defective medical device by a physician to a patient. Plaintiffs in certain situations have claimed that a defendant hospital has sold them defective medical products. The best known example is that of blood contaminated by viral hepatitis where courts have been generally unwilling to find that a contract for the sale of blood was made.¹⁷ Beyond the blood transfusion cases,

¹⁴ *Kaplan v. State*, 198 Misc. 62, 95 N.Y.S.2d 890 (Ct. Claims 1950); *Shoumatoff v. Wiltbank*, 226 N.Y.S.2d 576 (1962); *Inouye v. Black*, 238 Cal. App. 2d 31, 47 Cal. Rptr. 313, 14 A.L.R.3d 961 (1965); *Huffman v. Lindquist*, 37 Cal. 2d 465, 234 P.2d 34, 29 A.L.R.2d 485 (1951); *Johnston v. Black Co.*, 33 Cal. App. 2d 363, 91 P.2d 921 (1933); *Wilt v. McCallum*, 214 Mo. App. 321, 253 S.W. 156 (1923).

¹⁵ *Hurt v. Susnow*, 192 P.2d 771 (Cal. 1948); *Dierman v. Providence Hospital*, 31 Cal. 2d 290, 179 P.2d 803 (1947); *Martin v. Aetna Casualty & Surety Co.*, 239 Ark. 95, 387 S.W.2d 334 (1965); *Bence v. Denbo*, 98 Ind. App. 52, 183 N.E. 326 (1934).

¹⁶ U.C.C. § 2-318 (1968).

¹⁷ *Sloneker v. St. Joseph's Hospital*, 233 F. Supp. 105 (D. Colo. 1964); *Perlmutter v. Beth David Hospital*, 308 N.Y. 100, 123 N.E.2d 792 (1954); *Dibblee v. Groves Latter-Day Saints Hospital*, 12 Utah 2d 241, 364 P.2d 1085 (1961); *Gile v. Kennewick Public Hospital*, 48 Wash. 2d 774, 296 P.2d 662 (1956); *Koenig v. Milwaukee Blood Center*, 23 Wis. 2d 334, 127 N.W.2d 50 (1964).

consider *Cheshire v. Southampton Hospital Association*,¹⁸ a case where plaintiff alleged that he had been sold a defective intramedullary pin which broke in his leg. He sued the hospital specifically claiming breach of warranty. The complaint was held to be good, but the court noted that at trial plaintiff must prove the existence of an independent sales contract. The "sale" of the intramedullary pin was, as in the blood transfusion cases, merely a part of a general services contract. It seems apparent from cases such as these that liability for injury caused by defective instruments can not logically be distorted to fit the breach of warranty mold.

The third attempt to circumvent malpractice requirements has involved proposed extensions of the burgeoning strict liability in tort doctrine. As with recovery based on breach of warranty, it will be seen that such actions are highly fruitful if directed at the instrument manufacturer, but that actions to subject the physician or hospital to strict liability have found no success. The reason for this failure is similar to the inapplicability of breach of warranty doctrines. In recent history, breach of warranty actions have been considered the logical offspring of the law of sales. Although strict liability formulations have eliminated the privity requirement in the law of sales, so that the plaintiff no longer need be a buyer, such formulations have not dispensed with the requirement that defendant be a seller.¹⁹

One noteworthy decision, *Magrine v. Krasnica*,²⁰ involved just such an attempt to extend strict liability to a dentist, when the hypodermic needle he was using for a mandibular block anesthesia broke off in plaintiff's jaw. Both the trial court and the appellate court held that strict liability would not apply where the dentist had not manufactured or sold the needle, where he was a nonnegligent user, and where the defect was latent and undiscoverable.

Strict liability, therefore, is a theory which comfortably fits only actions against manufacturers and others along the chain of sale. Its logical formulation appears to resist extension to physician users of defective instruments in the performance of their medical services, although logic need not completely rule out the possibility of judicial extension in this direction. But with the development of strict liability

¹⁸ 53 Misc. 2d 355, 278 N.Y.S.2d 531 (Sup. Ct. 1967).

¹⁹ RESTATEMENT OF TORTS 2d § 402A.

²⁰ 94 N.J. Super. 228, 227 A.2d 539 (Hudson County Ct. 1968), *aff'd*, 100 N.J. Super. 223, 241 A.2d 637 (App. Div. 1968).

as a potent plaintiff's weapon against manufacturers, the pressure to develop strict liability against physicians in defective instruments cases should decrease. A "deep-pocket" defendant, who is actually responsible for the defective instrument, is far more likely a recovery target than a strained malpractice action against a nonnegligent physician.

As has been noted, the hospital which owns and supplies the defective instrument is frequently joined as defendant with the physician user. The negligence formulation discussed above, based on failure to inspect for defects, applies equally to hospitals as to physicians. Indeed the hospital, because it is the permanent owner of the instrument and has continuous contact with it, has been held to a somewhat stricter inspection standard. It will be held liable for negligent failure to discover a patent defect such as frayed insulation causing a short circuit in electrical wiring.²¹ It will be required to make periodic inspection and examination, perhaps even to test for latent defects if they are reasonably discoverable.²²

Somewhat independent of the duty to test, the hospital may be held liable for negligently supplying defective equipment per se.²³ Hospitals and physicians, although not held to a duty to inspect for latent undiscoverable defects, may be under the duty to guard against reasonably foreseeable dangers resulting therefrom, for example, by grounding anesthesia machines²⁴ or shielding therapeutic light bulbs.²⁵

It can not be denied that malpractice actions against physicians, or actions against physicians and hospitals for negligent maintenance and failure to inspect, may often prove a valuable adjunct to litigation against the medical instrument manufacturer. In cases where the physician's misuse of the instrument is clearly negligent and easily proven (*e.g.*, scalpel slips, esophageal perforations, catheter sequestration) the malpractice action alone will often suffice to permit adequate recovery

²¹ *Delling v. Lake View Hospital Ass'n.*, 310 Ill. App. 155, 33 N.E.2d 915 (1941); *Taylor v. Beekman Hospital*, 270 App. Div. 1020, 62 N.Y.S.2d 637 (1946); *Smith v. American Cystoscope Makers*, 44 Wash. 2d 202, 266 P.2d 792 (1954).

²² *Stafford v. St. Clair's Hospital*, 19 Misc. 2d 710, 187 N.Y.S.2d 351 (Sup. Ct. 1959).

²³ *Id.* *Woodhouse v. Knickerbocker Hospital*, 266 App. Div. 839, 43 N.Y.S.2d 518 (1943); *Peck v. Charles B. Towns Hospital*, 275 App. Div. 302, 89 N.Y.S.2d 190 (1949); *Shepherd v. McGinnis*, 257 Iowa 35, 131 N.W.2d 475 (1964); *Holtfoth v. Rochester General Hospital*, 304 N.Y. 27, 105 N.E.2d 610 (1952).

²⁴ *Andrepoint v. Ochsner*, 84 So. 2d 63 (La. App. 1955).

²⁵ *Crowe v. McBride*, *supra* note 11.

for the plaintiff. The same should hold true in cases where proof of negligent maintenance or failure to inspect for patent defects is readily available (*e.g.*, defective insulation, inadequate sterilization). Even in those actions where the manufacturer is the primary recovery target, the hospital and physician should be joined wherever possible. In such cases when the manufacturer raises its standard defense that the defect was caused by misuse or ordinary use after purchase, the manufacturer will then in effect be helping the plaintiff's case against the co-defendant hospital or physician. Similarly, a hospital's or physician's defense of nondiscoverable latent defect may bolster the plaintiff's case against the manufacturer. Thus the development of actions against the instrument manufacturer should not lead the plaintiff's attorney to ignore entirely the more traditional approaches to recovery.

CURRENT TRENDS IN PRODUCTS LIABILITY LAW

A short summary of the state of products liability law today will help to place litigation against medical instruments manufacturers in proper context. The rationale of products liability litigation follows two well recognized theories of recovery: breach of warranty and negligence. To this has recently been added strict liability in tort, premised on the sale of a product in a defective condition which is unreasonably dangerous to the user. The history of products liability law is that of a gradual broadening of recovery against sellers and manufacturers, first through the expansion of recovery based on negligence, then through the development of actions based on breach of warranty, and at present through the evolution of negligence and warranty theories into that of strict liability in tort.

When the injured patient plaintiff seeks recovery based on the negligence of the medical instrument manufacturer, he must, if his theory of action is to succeed, prove that the defendant manufacturer departed from standards of due care, with respect to negligent design, manufacture, assembly, packaging, false and deceptive advertising, failure to test and inspect for defects, or failure to warn and give adequate instructions. It has been established beyond question, since *MacPherson v. Buick Motor Co.*,²⁸ that any instrument negligently made by a departure from any of the above standards of due care, becomes inherently and imminently dangerous, and that the manufacturer therefore

²⁸ 217 N.Y. 382, 111 N.E. 1050 (1916).

owes the duty of due care to the general public and not just to the immediate purchaser.²⁷

An action based on the theory of breach of warranty is theoretically quite different. It is closely linked with a contract of sale between defendant and plaintiff, which is the reason why privity of contract has been the principle stumbling block to the maintenance of breach of warranty actions. The traditional warranty theory requires plaintiff's reliance, to his detriment (including personal injuries but not limited thereto), on an express or implied assertion by the defendant about the nature of his product. Simply put, the basis of the breach of warranty action is that plaintiff has been injured as the proximate result of defendant's product's nonconformance with defendant's assertions or warranties.

The *Uniform Commercial Code* codifies definitions of seller's warranties: Section 2-313 deals with express warranties; Section 2-314 deals with implied warranties of merchantability; and Section 2-315 deals with implied warranties of fitness for a particular purpose. A defective medical instrument may fail to satisfy any or all of these warranty types. Section 2-318 relaxes the privity requirement for family and household members and home guests, but, as is readily apparent, is of no help to the patient injured in the hospital or doctor's office. The comment to Section 2-318 indicates that the language is ostensibly neutral and is not intended to prevent the expansion of the categories of protected persons. Some courts have used this statutory neutrality to enlarge the protective ambit of Section 2-318 to include patients,²⁸ and the trend towards strict liability makes this extension likely in the majority of jurisdictions. In those jurisdictions where the privity requirement had not yet been relaxed beyond the explicit terms of Section 2-318, actions against sellers and manufacturers were limited to third party claims,²⁹ cases where the plaintiffs were the physician purchasers (as in cases involving X-ray and fluoroscopic equipment),³⁰ and cases where the purchaser's employees were injured.³¹

The important advantage of the breach of warranty action is that

²⁷ Cf. *Carter v. Yardley & Co., Ltd.*, 319 Mass. 92, 64 N.E.2d 693 (1946).

²⁸ *Bowles v. Zimmer Mfg. Co.*, 277 F.2d 868 (7th Cir. 1960) (applying Michigan law); *Ribando v. American Cyanamid Co.*, 37 Misc. 2d 603, 235 N.Y.S.2d 110 (Sup. Ct. 1962).

²⁹ *Nelson v. Swedish Hospital*, *supra* note 7.

³⁰ *Repass v. Keleket X-Ray Corp.*, 212 F. Supp. 406 (D. N.J. 1962); *Heberle v. P.R.O. Liquidating Co.*, 186 So. 2d 280 (Fla. 1966).

³¹ *Thomas v. Leary*, 15 App. Div. 2d 438, 225 N.Y.S.2d 137 (1962).

the plaintiff need not prove negligence in order to recover. He need only prove that the product was defective when sold to him, that because of the defect the product did not conform to the very broad requirements of fitness and merchantability, and that he was injured as the proximate result of the defect. There are many instances in the manufacturing and design process where error, not amounting to negligence, causes a product to be defective and injurious.

The main defect in the traditional theory of breach of warranty actions was the privity requirement. And even though medical and surgical instruments are intended for intimate contact with the human body, courts in the past have been unwilling to draw an analogy between such instruments and the traditional food and beverage exception to this privity requirement.³²

The evolution of the privity-bound breach of warranty action into strict liability in tort has been swift since *Henningsen v. Bloomfield Motors, Inc.*³³ which first expanded the scope of implied warranty actions beyond immediate purchasers:

Accordingly, we hold that under modern marketing conditions, when a manufacturer puts a new automobile in the stream of trade and promotes its purchase by the public, an implied warranty that it is reasonably suitable for use as such accompanies it into the hands of the ultimate purchaser.³⁴

The progression from traditional tort and warranty concepts to the fusion of the best of both in strict liability has been so rapid that it is difficult to determine the position taken in many jurisdictions today. But the direction of products liability law is clearly towards expanding manufacturer's liability, and the area of defective medical and surgical instruments is but one example of this new direction.

Strict liability in tort is best defined by the *Restatement (Second) of Torts*, Section 402A:

Special Liability of Seller of Product for Physical Harm to User or Consumer.

1. One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

³² *But see* *Bernstein v. Lily-Tulip Cup Corp.*, 177 So. 2d 362 (Fla. 1965), where plaintiff, a hospital patient, was scalded when a paper cup came apart. She was allowed to bring suit against the cup manufacturer, based on breach of implied warranty, because the cup was a "defective product manufactured for human consumption or other intimate bodily use."

³³ 32 N.J. 358, 161 A.2d 69 (1960).

³⁴ *Henningsen v. Bloomfield Motor, Inc.*, 32 N.J. 358, 384, 161 A.2d 69, 84 (1960).

- a. the seller is engaged in the business of selling such a product, and
 - b. it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
2. The rule stated in Subsection (1) applies although
- a. the seller has exercised all possible care in the preparation and sale of his product, and
 - b. the user or consumer has not bought the product from or entered into any contractual relation with the seller.

The principles of strict liability are clear. Section 2(b) dispenses with the privity requirement, so long as the injured patient is included as an "ultimate user or consumer."³⁵ Section 2(a) is, in the medical instruments field, even more momentous. It dispenses with the need to prove negligence in manufacture or design. All that is required is that the ultimate consumer be caused physical harm by a product which is in a defective and thus unreasonably dangerous condition.³⁶ As we shall see below, because of the trial and error nature of much of medical instruments design, a large number of medical devices are manufactured in an acknowledged imperfect, defective and unreasonably dangerous condition. The defects are often those of design, recognizable only with hindsight, but they are clearly dangerous defects nonetheless. The manufacturer in many cases exercises all possible due care in the instrument's design and manufacture, but the instrument proves defective and unfit to perform the functions for which it was designed. But the formulation of strict liability in tort leaves no room for doubt—in such cases the responsibility for personal injury must be shifted upon the manufacturer.

ACTIONS AGAINST MEDICAL INSTRUMENT MANUFACTURERS

A consideration of some of the reported decisions involving patient's suits against manufacturers of defective medical and surgical instru-

³⁵ *Supra* note 28.

³⁶ Of the reported decisions collected in the appendix to this article, the following may be said to have embraced strict liability or greatly relaxed the privity requirement so as to embrace strict liability in actual practice: *Ribando v. American Cyanamid Co.*, *supra* note 28; *Bowles v. Zimmer Mfg. Co.*, *supra* note 28; *Bernstein v. Lily-Tulip Cup Corp.*, *supra* note 32; *Putman v. Erie City Mfg. Co.*, 338 F.2d 911 (5th Cir. 1964). For an excellent survey of the status of strict liability in all United States jurisdictions, see Prosser, *The Fall of the Citadel*, 32 AM. TR. LAW. L.J. 1 (1968). At least twenty-four states have adopted strict liability in tort by statute or judicial decision and six others are essentially on the threshold of so doing.

ments should serve to illuminate many of the advantages and pitfalls inherent in this approach.³⁷

The threshold problem is one of obtaining jurisdiction over the manufacturer. Although the trend in most jurisdictions is towards statutory adoption of long-arm statutes and judicial recognition of the "minimum contacts" theory of jurisdiction,³⁸ plaintiffs who reside in less forward looking states may obtain jurisdiction only over those defendants who satisfy the court's requirements for "doing business" within the state. In the medical instruments area this problem may be especially acute. Many manufacturers sell their products to independent distributors who often only do mail-order business within the state. If the manufacturer has no agent soliciting business in the state, and only passively accepts orders from within the state, courts have regularly determined that such action was not sufficient to constitute "doing business," yet this is common practice in the business of supplying medical and surgical instruments.³⁹

The result is that the plaintiff is unable to acquire jurisdiction over the primary defendant in his home state where the accident arose. He is put to the inconvenience and expense of maintaining a suit in a foreign jurisdiction, which alone may deter suits against manufacturers. He further loses the advantage of joining all defendants in one suit, in which each may accuse the other of causing the instrument defect.

In the majority of the reported decisions where plaintiff has been permitted to recover against the medical instrument manufacturer, he has prevailed on a negligence theory. The preponderance of negligence actions, as opposed to those based on breach of warranty or strict liability, reflects foremost the privity problem and secondarily the problem whether the patient-plaintiff is an "ultimate user or consumer."⁴⁰ Of course it also reflects in large part the relative novelty of the strict liability approach.

³⁷ See the appendix to this article for a compendium of representative decisions involving medical instruments.

³⁸ See Schwartz, *Developments in Conflict of Laws and Long-Arm Statistics*, 32 AM. TR. LAW. L.J. 100 (1968); Comment, *In Personam Jurisdiction Over Non Resident Manufacturers in Products Liability Actions*, 63 MICH. L. REV. 1028 (1965).

³⁹ Gill v. Surgitool, Inc., 256 Cal. App. 2d 583, 64 Cal. Rptr. 207 (1967); Cooke-Waite Laboratories v. Napier, 166 So. 2d 675 (Fla. 1964); Heberle v. P.R.O. Liquidating Co., *supra* note 30; Smith v. American Cystoscope Makers, *supra* note 21.

⁴⁰ The "ultimate user" doctrine, together with the warranty theory requirement that

The manufacturer's actionable negligence may take several different forms. The two most common are closely linked—negligent manufacture and production,⁴¹ and negligent failure to test and inspect for defects, both patent and latent.⁴² Although it is clear that the manufacturer is under a duty to inspect for defects of all sorts, the few cases assembled are in conflict as to whether a distributor or seller is under a similar duty to inspect.⁴³ One suspects that this apparent conflict depends more on differing fact circumstances—the latent or patent defect question—than on any theoretical difficulty. One may contrast this with warranty or strict liability theory where the sale and manufacture of the defective product subjects the defendants to equal liability.⁴⁴

Of special interest is *Orthopedic Equipment Co. v. Eutsler*,⁴⁵ which would most accurately be termed a case of negligent misbranding. Defendants manufactured a Kuntscher-Cloverleaf intramedullary nail designed to be inserted into the canal of plaintiff's fractured femur. The nail was stamped "OEC 9 x 40," indicating that it would fit a

there be a sale, may perhaps explain why the medical instrument field has engendered far less litigation than its better known cousin, litigation involving defective drugs and medicines. See Annot., 79 A.L.R.2d 301 (1961), which discusses the liability of manufacturer or seller for injury caused by a drug or medicine. In most drug cases, the plaintiff either purchased the drug or was a member of the purchaser's household. Even when this was not true, as in a patient under hospital treatment, drugs have been embraced under the food and beverage exception to privity because they are intended for intimate bodily consumption. *Gottsdanker v. Cutter Laboratories*, 182 Cal. App. 2d 602, 6 Cal. Rptr. 320 (1960). It is clear that the sale and consumption of harmful medications fits much more neatly into the traditional products liability framework. It is also quite possible that cases such as *Gottsdanker* and the MER-29 litigation have made the average personal injury practitioner more aware of the products liability aspects of drug cases than of medical instrument cases, which he traditionally associates with malpractice actions.

⁴¹ *Moehlenbrock v. Parke, Davis & Co.*, 141 Minn. 154, 169 N.W. 541 (1918) (impure ether); *Pariser v. Wappler Electric Co.*, 145 Misc. 315, 260 N.Y.S. 35 (1932) (hair remover); *Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960) (intramedullary nail); *Clark v. Zimmer Mfg. Co.*, 290 F.2d 849 (1st Cir. 1961) (intramedullary nail); *Liberatore v. National Cylinder Gas Co.*, 193 F.2d 429 (2d Cir. 1951).

⁴² *Orthopedic Equipment Co. v. Eutsler*, *supra* note 41 (intramedullary nail); *Hine v. Fox*, *supra* note 12 (electro-cautery instrument); *Mitchiner v. Wright Manufacturing Co.*, (W.D. Ind. 1959) (unreported, but summarized in 6 *LAWYER'S MEDICAL CYCLOPEDIA* § 42.33) (hip prosthesis); *Nelson v. Swedish Hospital*, *supra* note 7; *Sinatra v. National X-Ray Products Corp.*, 26 N.J. 546, 141 A.2d 28 (1958).

⁴³ *Cf.*, two defective insulation cases are *Smith v. American Cystoscope Makers*, *supra* note 21 (no duty to inspect); *Sinatra v. National X-Ray Products Corp.*, *supra* note 42 (duty to inspect).

⁴⁴ *Supra* note 31; *Heberle v. P.R.O. Liquidating Co.*, *supra* note 30.

⁴⁵ 276 F.2d 455, 79 A.L.R. 390 (4th Cir. 1960).

hole having a 9 mm. diameter. The diameter of the nail actually varied from 9.27 mm. to 10.12 mm. This is abysmally defective manufacturing, as well as a blatant example of negligent failure to inspect. "Quality control" appears to have been entirely lacking. The interesting point is that plaintiff's counsel was not content with these general manifestations of negligence. He also charged a specific statutory violation—misbranding contrary to the express prohibitions of the Federal Food, Drug and Cosmetic Act.⁴⁶ *Orthopedic Equipment Co. v. Eutsler* dramatically points out the value in products liability litigation of such statutory violations—they are telling evidence of negligence. The effectiveness of statutory violations as evidence in civil cases should be materially increased by the adoption of the Medical Devices Safety Act of 1967, which proposes to apply the safety, reliability and effectiveness provisions of the Food, Drug and Cosmetic Act to the manufacture of medical devices.⁴⁷

By contrast, there are very few cases involving failure to warn or instruct adequately,⁴⁸ for this is a shadow area where negligence may be exceedingly difficult to prove. Nevertheless, the manufacturer's possible failure to warn or instruct should not be overlooked. There is a mistaken tendency prevalent among attorneys and the courts to assume that physicians, because of their long training, will be knowledgeable and experienced in the use of medical and surgical instruments.⁴⁹ This attitude is patently erroneous. Because physicians are invested with a medical degree they do not become competent in the use of the many complex and novel devices they must face in their careers. Responsible physicians will admit this and clamor for better instructional programs and material.

Anesthesiologists comprise a group of physicians who employ machines to regulate the flow of drugs into the patient, to monitor the vital functions of circulation and respiration, to monitor neuromuscular blockade, to determine adequate gas exchange, etc. Is it unreasonable to ask that physicians know how a machine works or to insist that it be maintained in functioning condition with proper calibration? Should he set out to learn how to calibrate a flowmeter, how a ventilator can function or malfunction, how to prevent burns from improperly grounded electronic apparatus, why one needs, at least, an electrical three-line plug, how

⁴⁶ 21 U.S.C. §§ 301-392 (1968).

⁴⁷ H.R. 10726, 90th Cong., 1st Sess. (1967).

⁴⁸ *McLaughlin v. Mine Safety Appliances Co.*, 11 N.Y.2d 62, 226 N.Y.S.2d 407, 181 N.E.2d 430 (1962).

⁴⁹ *Ball v. Mallinkrodt Chemical Works*, 53 Tenn. App. 218, 381 S.W.2d 563 (1964).

blood gas apparatus reads pH, Pco₂ or PO₂? Are such bits of knowledge so mystifying as to be beyond the grasp of the modern physician? Are therapeutic devices not analogous to drugs and, if one is expected to know their pharmacology, why should the "pharmacology" of machines remain ethereal? The lay public (one who lies helpless and receptive of our care) has a right to demand a degree of responsible excellence above that exhibited by the practitioner or candidate for specialty rating.⁵⁰

If courts can be made to realize the relative ignorance of the physician who uses the medical device, there is a chance that manufacturers will be held to the duty to provide warnings and instructions which are thorough and accurate. Courts have in the past buried this problem under the rubric of intervening cause. They assume, and quite rightly, that the physician is negligent when he operates a medical instrument he does not know how to use.⁵¹ The *Restatement (Second) of Torts* Section 447 provides, however, that if the physician's intervening negligence is reasonably foreseeable by the manufacturer, the manufacturer will remain liable. It should be argued that physicians do not innately know how to operate complex medical machines, that manufacturers know and foresee this, and that they are therefore under a duty to educate and warn the physicians lest they use medical products negligently.

Negligent design has been similarly overlooked as a pathway to recovery.⁵² Here is an area where the expert testimony of physicians is crucial. It is also an area where physicians will be far more willing to testify than in malpractice cases. Many fine physicians are intensely concerned with the safety of the medical products they use. Many medical articles are published which point out defects and dangers in existing medical instruments, and which suggest design modifications to improve safety. The medical profession is far more conscious of safety than the manufacturers who supply them.

As a result, physicians have often become openly angered at manufacturers' apparent disregard of safety. Such safety-conscious individuals should be the valuable allies of the legal profession. The issue of medical instruments' safety involves an excellent opportunity to

⁵⁰ Orkin, *Responsibility of Manufacturers and Consumers*, 206 J. AMER. MED. ASS. 2888, 2889 (1968).

⁵¹ O'Connell v. Westinghouse X-Ray Co., 261 App. Div. 8, 24 N.Y.S.2d 268, *rev'd* 288 N.Y. 486, 41 N.E.2d 177 (1942).

⁵² Mitchiner v. Wright Manufacturing Co., *supra* note 42; Chadwick v. Air Reduction Co., Inc., 239 F. Supp. 247 (N.D. Ohio 1965).

develop a working cooperation between physicians' and plaintiffs' attorneys, a goal which has often hitherto remained little more than wishful thinking.

A particularly flagrant example of negligent design and failure to warn will show how such negligence may be the hidden culprit in a case which at first glance appears to be pure accident or perhaps physician or hospital negligence. It should indicate beyond doubt that medical expertise is essential in evaluating a defective instrument case, and that physicians can be aroused to offer their help.

The Air-Shields Ventimeter Ventilator is a mechanical device which anesthesiologists use to assist the respiration of a patient undergoing surgery. In 1965 an article⁵³ pointed out that, by interchanging two identical corrugated tubes on the ventilator, the patient's lungs could be inadvertently blown apart by high pressure gas when the bag-fill lever was activated. Such an accident did happen. Presumably the manufacturer was informed. A year and a half later a similar accident happened at another hospital. Since the two identical tubes were designed to be disassembled, cleaned and replaced with use, such interchanging seemed inevitable.

Dr. Louis Orkin, an anesthesiologist at Albert Einstein College of Medicine, discussed this with the manufacturer. He was led to write:

Discussion with the manufacturer's representatives revealed that no one was apparently very excited about the instrument's lethal potential, and no concerted efforts were made to furnish even the most inconvenient misfit of individualized connectors, no inclusion was made in the commercial literature or 19-page *Replacement and Service Manual* of the danger of misconnection, nor did the literature indicate the availability of a kit. . . . An automobile manufacturer would have been responsible for immediate notification or repair, a pharmaceutical concern for immediate notification and/or withdrawal of a drug. Is less to be expected of a manufacturer of medical instruments?

One could write pages of such irresponsible behavior by manufacturers in their resistance to the standardization of fittings, to insure design and safety of endotracheal tubes, or acceptance of plans designed to prevent misplaced valves. . . . Always the question by the manufacturers, "Who will pay for this; will the consumer buy it?" Always the answer from the grave, "What is the worth of a human life?"⁵⁴

To return to less dramatic matters, it should be noted that contributory negligence, which in many jurisdictions defeats recovery entirely, is a much less significant factor in cases involving defective medical

⁵³ Morrow, Dixon, Townley & Herbert, *A Safety Modification of the Air-Shields Ventimeter Ventilator*, 26 *ANESTHESIOLOGY* 361 (1965).

⁵⁴ *Supra* note 50.

and surgical devices than in the general range of products liability cases. The reason for this is clear. Most victims of defective medical instruments are passive patients who are being treated or operated upon. It is the physician who has the opportunity to be contributorily negligent, not the patient-plaintiff. The few cases in which contributory negligence has been permitted to go to the jury involve physicians,⁵⁵ hospital employees,⁵⁶ or orthopedics cases where a semi-mobile patient has the opportunity to put unusual strain on the orthopedic prosthesis, thus causing it to break and reinjure the fracture site.⁵⁷

A minority of the reported decisions where the injured plaintiff has sued the medical instrument manufacturer are predicated on strict liability in tort or on its logical predecessor, breach of warranty. Privity requirements raise no problem in those cases where the injured plaintiff is also the physician purchaser.⁵⁸ Certain decisions have permitted recovery on a theory labeled breach of warranty, but at the same time have extended the warranty's protection to patients by construing them to be "direct intended users."⁵⁹ In such cases the relaxation of privity has been so complete as to constitute strict liability for all practical purposes. Later decisions in other jurisdictions have, as we have seen, recognized strict liability outright, without any attempt to rationalize why patients should be included within the warranty's protection.⁶⁰

Assuming that the plaintiff sues the manufacturer in a jurisdiction where strict liability or judicial expansion of Section 2-318 of the *Uniform Commercial Code* has eliminated the privity requirement, what further difficulties oppose the successful prosecution of the strict liability or warranty action? The foremost of these difficulties is a problem of factual proof which reaches to the heart of any products liability action. Who is responsible for creating the defect which caused the

⁵⁵ *Supra* note 51 (Physician operated under fluoroscope without knowledge of radiation hazards and sustained radiation burns on his hands—jury question on contributory negligence.).

⁵⁶ *Liberatore v. National Cylinder Gas Co.*, *supra* note 41 (Oxygen therapist injured by explosion of oxygen cylinder valve he was opening.).

⁵⁷ *Bowles v. Zimmer Mfg. Co.*, *supra* note 28; *Swanson v. Hood*, 99 Wash. 506, 170 P. 135 (1918).

⁵⁸ *Supra* note 30.

⁵⁹ *Ribando v. American Cyanamid Co.*, *supra* note 28; *Thomas v. Leary*, *supra* note 31; *Ball v. Mallinkrodt Chemical Works*, *supra* note 49.

⁶⁰ *Bowles v. Zimmer Mfg. Co.*, *supra* note 28; *Bernstein v. Lily-Tulip Cup Corp.*, *supra* note 32; *Putman v. Erie City Manufacturing Co.*, *supra* note 36.

plaintiff's injury? *Restatement (Second) of Torts* Section 402A indicates that liability is imposed on "one who sells any product in a defective condition." The primary defense on the merits to a strict liability action must therefore be that the product was not defective when sold by the manufacturer. In warranty terminology, the equivalent defense would be that the product when sold conformed to all warranties, express and implied. The equivalent of the defense in a negligence action is the claim that the manufacturer was free from negligence, and that negligent misuse by the hospital or physician, or nonactionable ordinary use, proximately caused the defect to develop after it left the manufacturer's hands.

These kindred defenses have been variously formulated in the reported opinions involving suits against manufacturers. Of course the most common formulation is that plaintiff failed to prove that the instrument was defective when sold by the defendant manufacturer or retail vendor.⁶¹ Evidence that the instrument functioned properly in previous operations or for several previous years in the hospital's possession is competent proof that the instrument was not defective when originally sold.⁶² It is apparently evidence that the instrument was caused to develop its defect through ordinary and gradual wear and tear. In such cases negligence liability, if any, would be imposed only on the hospital or physician owner for failure to inspect and repair such defects.⁶³

Apparently no reported decision has considered the cogent argument that, if a medical instrument wears down or develops a defect under normal use well before the estimated life span of the instrument has expired (as was clearly the case in both *Smith v. American Cystoscope Makers*⁶⁴ and *Nelson v. Swedish Hospital*⁶⁵), this inadequate durability is itself evidence of negligent design or defective manufacture, perhaps the use of inferior materials or components. It is important for the plaintiff's attorney to stress to the court that medical instruments are designed to interfere with human life processes. The stan-

⁶¹ *Smith v. American Cystoscope Makers*, 44 Wash. 2d 202, 266 P.2d 792 (1954); *Nelson v. Swedish Hospital*, 241 Minn. 551, 64 N.W.2d 38 (1954).

⁶² *Smith v. American Cystoscope Makers*, *supra* note 21 (fifteen previous operations); *Nelson v. Swedish Hospital*, *supra* note 61 (three years).

⁶³ *Nelson v. Swedish Hospital*, *supra* note 61.

⁶⁴ *Supra* note 21.

⁶⁵ *Supra* note 61.

dard of durability to be imposed in such circumstances should be higher than that imposed in more typical household products cases. The mere fact that the physical defect originated as a result of normal use after the medical instrument left the manufacturer's hands should not be allowed to defeat recovery where the plaintiff can prove that the subsequent development of this defect was in fact traceable to negligent design, structurally inferior component materials, or improper assembly. In other words, a true strict liability in tort standard would require the medical instruments manufacturer to design and assemble products so durable that repeated normal use will not cause defects to develop.

It is clear that if the physician or hospital misuses the manufacturer's medical product, the manufacturer will not be liable for injuries caused by defects resulting from that misuse.⁶⁶ This is in essence the reverse of the physician's defense that we have examined earlier—that the defect was not caused by his negligent handling but is traceable to the manufacturing process.⁶⁷ The importance of joining all defendants in one action is apparent. As each defendant attempts to escape liability by proving the other responsible for the defect, he becomes to that limited extent the plaintiff's ally in the eyes of the jury.

Products liability law has undergone sweeping changes in the past decades. Attorneys have witnessed a rapid evolution towards strict manufacturer's liability for all defective products, together with a concomitant expansion of products liability litigation to encompass the entire range of injuries that may be caused by a modern, complex industrial society. The development of manufacturer's liability for defective medical and surgical instruments has paralleled and partaken of this general growth in products liability law.

This article has, thus far, undertaken an examination of the current status of products liability law as it specifically relates to injuries caused by defective or negligently designed medical and surgical instruments. It has drawn comparisons with traditional but far less successful attempts to impose malpractice liability on physicians and hospitals for injuries caused by defective instruments. This article has

⁶⁶ *Ribando v. American Cyanamid Co.*, *supra* note 28 (breach of warranty recovery against manufacturer denied because of intervening negligence of physician in excessive re-use of hypodermic needle); *Magee v. Wyeth Labs, Inc.*, 214 Cal. App. 2d 340, 29 Cal. Rptr. 322 (1963) (failure to follow manufacturer's directions in administering drug).

⁶⁷ *Supra* note 14.

also considered some of the advantages and drawbacks inherent in products liability litigation that is directed particularly at the manufacturers of medical instruments.

The remainder of this article will be devoted to an examination of certain problems of medical instrument design and function—problems which, because of their prevalence or exceptional interest, seem representative of the many varied product safety hazards that the medical profession must constantly combat.

SELECTED PROBLEMS OF MEDICAL INSTRUMENT
DESIGN—THE PHYSICIAN'S VIEWPOINT

The range of potential hazards of design and defective manufacture of medical surgical instruments is truly as broad as the entire practice of modern medicine. Today's medicine is characterized by extreme specialization, complexity and variety. The reported litigation involving medical instruments is scarcely representative of that variety and complexity. It is preoccupied with certain medical and surgical devices which may be considered obvious sources of injury—hypodermic needles, orthopedic prostheses and X-ray machines, for example.

It is helpful, therefore, to examine a series of current medical and surgical product hazards which have aroused the interest of the medical profession. This examination will make no attempt to be exhaustive, but it should be somewhat more representative and far more intriguing than the simple product defects which have found their way into the case literature. One point should be kept in mind at all times. The vast majority of the reported cases concern products which have become defective or were defective when manufactured. By and large the medical profession is not concerned with such simple hazards. It is interested in problems which attorneys would classify as negligent design, or in discovering hidden dangers which are not the result of defective manufacture, but which arise from the very nature of an imperfect product. It is only in the exceptional case that the physician becomes interested in assigning blame to the instrument manufacturer. He is more frequently concerned with modifications to eliminate unexpected hazards and improve safety design.

The design of medical and surgical instruments is, as is the practice of medicine itself, still more of an art than a science. The instrument manufacturer must have exceptional foresight to anticipate the dangers

latent in the use of his product. Physicians and manufacturers alike realize that the development of medical instruments is often a slow trial and error progression from one imperfect instrument to another only slightly less imperfect. Because of these imperfections it can be said that nearly every medical and surgical instrument is inherently dangerous to life. Most instruments are innately defective even when perfectly manufactured. This is the result of the imperfect progress of the art of medical instruments design.

With distressing frequency, however, manufacturers of certain products have persisted in producing instruments which the medical profession has found to be unsafe. In such cases the role of products liability law, and especially strict liability in tort, is a comfortable one. There are situations where a product is acknowledged to be defectively designed and therefore dangerous, but where physicians will concede that the current state of the art knows no better alternative. In such cases the role of products liability law is less clear. The personal injury attorney must explain to his medical brethren that the cost of progress in medical instrument design rests all too heavily on the innocent and tragically injured patient. The burden of recompense for such injuries should, in justice, fall upon those who are responsible for, and profit from, the development of medical instruments. In conscience this must be done even in those situations where the culprit instrument, although dangerous, is the best that medical design technology can produce.

Let us now consider a series of selected examples of hazardous medical and surgical instrument design, ranging from such commonplace medical products as thermometers and surgical gloves to more esoteric and glamorous devices, such as cardiac pacemakers and aortic valves.

THERMOMETERS

The ordinary rectal thermometer is a device so commonplace and elementary that it is found in private homes as well as in hospitals and doctors' offices. The standard thermometer consists of a calibrated glass tube attached to a metal bulb containing mercury. It is of course apparent that the glass tube may shatter inside the rectal orifice. What may not be so clearly apparent is that the thermometer is an inherently dangerous instrument even when unbroken.

Cases have been reported in which thermometers have caused perforations of the rectum or the recto-sigmoid colon, which is the portion of the large intestine immediately before the rectal opening. In one

such reported case a thermometer perforated the upper rectum of an infant.⁶⁸ It is easy to understand how this may happen, and thermometer manufacturers must surely be aware of it. The rectal wall and the recto-sigmoid colon are relatively rigid structures. When the infant lies supine, any active motion, such as kicking its legs, may drive the blunt end of the thermometer into the rectal wall, causing laceration or possible perforation.

There is a simple design solution which would sharply reduce this hazard. It might be fairly difficult to make the mercury bulb of the thermometer more rounded and blunt, and even blunt objects have been known to cause perforation. But a substantial increase in safety would be gained by the development and use of shorter rectal thermometers designed specifically for infants.⁶⁹

An electronic thermistor is an electronic monitoring device used for continuous temperature monitoring of unconscious patients. The thermistor tip poses the same hazards to the rectal wall as does the ordinary bulb thermometer. A case of thermistor tip perforation of the upper rectal wall of a comatose, unconscious 10-day old infant has been reported.⁷⁰

A more extensive design reform has been proposed, which if put into manufacture would eliminate the risk of rectal perforation entirely. A modified ordinary bulb thermometer, or a modified thermistor, may be designed to be taped to the infant's umbilicus, a device both safe and comfortable and useful for continuous monitoring.

SURGICAL SPONGES

A surgical sponge is typically made of cotton gauze. It is used to absorb blood from the operation site. Cotton is used because of its high absorptive properties. Clinical cases and laboratory findings indicate that fragments of gauze or lint from the sponges may come loose and be left in the operation site. Their presence will cause the formation of foreign body granulomata, abnormal fibrous and granular tissue, which may give rise to the formation of scar tissue-like adhesions. Such adhesions may cause serious complications: bowel obstruction, inflam-

⁶⁸ Wolfson, *Rectal Perforation in Infant by Thermometer*, 111 AMER. J. DIS. CHILD. 197 (1966).

⁶⁹ *Id.* at 199.

⁷⁰ Amar, *Rectal Perforation by Electronic Thermistor in an Unconscious Patient*, 97 CAN. MED. ASS. J. 186 (1967).

mation of the fallopian tubes, and a recurrence of symptoms which mimic the patient's original complaints, so that a second operation must be performed. Particularly in cases where cotton granuloma has caused bowel obstruction and in those where granuloma formation mimics the recurrence of a local malignant tumor, major surgery is necessarily required.⁷¹

As we shall see, surgical glove powder is a source of granuloma formation at operation sites. Although cotton fibers from sponges have not been adequately recognized as a major cause of foreign body granulomata and adhesions, they may well be more significant than glove powder. Cotton gauze fragments come from sponges composed of bleached cotton, with worn, resterilized sponges more likely to shed fibers than new ones, and moist sponges less likely to shed fibers than dry ones. The design solution involves conflicting goals. Cotton is composed of multiple fibers. The use of single fiber synthetic materials, such as rayon, would be a safe substitute so far as granuloma formation is concerned, but most synthetic fibers apparently do not have the absorptive powers of cotton. Research must be directed to the development of a highly absorptive lint-free synthetic.

SURGICAL GLOVES AND GLOVE POWDER

Defective surgical gloves, ones which develop holes, most frequently at the fingertips either before or during an operation, are a prime source of bacterial wound contamination. The incidence of defective gloves has been found to range as high as thirty-five per cent, depending primarily on the accuracy and sensitivity of the glove detecting machine.⁷² It is well established that, no matter how well the surgeon scrubs his hands before the operation, he can not hope to eliminate all the bacteria upon his fingers. Experiments have demonstrated that many more bacteria will pass from the hands through a single hole in a glove than will fall into the operative wound site from the air throughout a one to two hour operation.⁷³ Because of the potential danger of post-operative wound infection, two suggestions must be

⁷¹ Sturdy, Baird, & Gerein, *Surgical Sponges: A Cause of Granuloma and Adhesion Formation*, 165 ANN. SURG. 128 (1967).

⁷² Russell, Rogue & Miller, *A New Method for Detection of the Leaky Glove*, 93. ARCH. SURG. 245 (1966).

⁷³ Cole & Bernard, *Inadequacies of Present Methods of Surgical Skin Preparation*, 89 ARCH. SURG. 215 (1964).

made. Instruments must be developed to enable the frequent and conscientious checking of surgical gloves for leaks throughout the operation, although apparently such devices have been privately improvised by physicians, sometimes in conjunction with instrument manufacturers. But manufacturers have not commercially marketed an instrument for effective testing of gloves. In addition, many cases of operative wound site contamination, which might initially appear to be malpractice lawsuits, might better be directed against the manufacturers and suppliers of surgical gloves, whose product is so poorly designed that normal use during an operation will cause leaks to develop. Studies have shown that many surgical gloves have such holes, invisible to the naked eye but highly dangerous, even before the physician ever uses them. This is a clear-cut case of a manufacturer's responsibility to test for latent defects.

Various powders have been used to lubricate the insides of surgical gloves. The gloves are powdered before sterilization, but even though this may reduce the bacterial content of the powder, glove powder itself may be the source of injury to the patient if it falls into the operative wound site. As has been discussed in connection with cotton fibers from sponges, the glove powder causes formation of granulomata and adhesions. The most common post-operative complications which result therefrom are: intestinal obstruction and peritonitis, draining sinus tracts, fistulae, and granulomatous masses at the operative site simulating tumor.⁷⁴ The history of the various substances used as surgical glove powder is instructive. In the early part of the twentieth century, lycopodium powder was used, but this was gradually abandoned in the 1930's when it was found to cause granuloma formation. Talcum powder was adopted instead, talc consisting of magnesium silicate which, because it is a rather inert chemical, was thought less likely to cause foreign body reactions. Between 1933 and 1943 talc was widely used, until significant complications due to talc granulomata were reported, including two deaths.⁷⁵ Cornstarch powder, commercially marketed under the name "Bio-Sorb" was developed in the late 1940's. It replaced talcum powder

⁷⁴ Wee, Yap & O'Neal, *Surgical Glove Powder, Still a Surgical Hazard*, 63 *MISS. MED.* 436 (1966).

⁷⁵ Eiseman, Seelig & Womack, *Talcum Granuloma: A Frequent and Serious Postoperative Complication*, 126 *ANN. SURG.* 820 (1947).

because it was considered to be harmless and absorbable into body tissues like any ingested starch.⁷⁶

But this is not the case. Starch powder used in surgical gloves causes unnecessary secondary operations due to intra-peritoneal granulomata formation.⁷⁷ As a result, the standard of due care in operative procedures requires thorough washing of gloves before the operation has begun. This, of course, is in addition to and after sterilization. A more effective method of glove powder removal may involve swabbing the gloves with washcloths or gauze sponges.⁷⁸ But these methods may only partially decrease the risk of glove powder contamination. The manufacturers of surgical gloves and glove powder should be charged with the responsibility of developing a more satisfactory, nongranular lubricant, or improved glove design. Two approaches are possible here. The greatest amount of residual glove powder is usually found near the glove cuff. The design of an improved cuff seal would significantly decrease the risk of glove powder falling from the cuff into the wound. The more radical approach, one that would eliminate the problem entirely, involves the development of a glove material whose inner lining does not require powder lubrication before sterilization.

INFLATABLE PLASTIC SPLINTS

This presents an excellent example of the product which is highly dangerous if used in accord with the manufacturer's recommendations. The inflatable plastic splint consists essentially of a double-walled transparent plastic jacket, with a slide fastener permitting attachment to the patient's extremity, and a screw valve for inflation. The plastic jacket is placed on the limb and when inflated immobilizes the limb on a cushion of air pressure. This device, which may be inflated by mouth, has proven useful in combat or accident-disaster situations.

The splints have been manufactured from clear polyvinyl plastic or neoprene coated nylon, and are available in the United States (Readisplint) and Great Britain (Jobst Institute, Inc.). It is important to note that the design of all such commercially available air splints incorpo-

⁷⁶ Lee & Lehman, *Experiments with Non-Irritating Glove Powder*, 84 SURG. GYNEC. OBSTET. 689 (1947).

⁷⁷ McNaught, *Starch Granuloma—A Present-Day Surgical Hazard*, 51 BRIT. J. SURG. 845 (1964); Blair & Blumenthal, *Starch Peritonitis*, 64 NEW YORK J. MED. 1202 (1964).

⁷⁸ Harder & Christ, *The Peril of Glove Powder*, 66 AMER. J. NURS. 761 (1966):

rates no mechanism for measuring the pressure to which the splint has been inflated. Manufacturers recommend a "maximum safe pressure" of 40 mm. Hg. Because it is difficult to inflate these splints by mouth beyond 30 mm. Hg, physicians in their offices or first-aid technicians often use an air pump or pressurized gas container.⁷⁹

Here is where the problem arises. Although the manufacturers recommend that 40 mm. Hg is a safe pressure, it is clearly unsafe. Inflation of the Jobst splint to 40 mm. Hg produces a marked reduction in blood flow through the major blood vessels of the extremities, and complete cessation of blood flow in certain subjects. A pronounced reduction in blood flow is seen at 30 mm. Hg.⁸⁰ The potential results are obvious— ischemic damage (caused by reduced blood supply) or possibly gangrene may cause major tissue necrosis leading to loss of the limb. This is especially possible in those patients who have suffered soft tissue damage as well as bone fracture in the injured limb—and this is a most common combination.

Nor need this damage be confined to pressures so high as to cause occlusion of major blood vessels. When the air pressure exceeds 20-25 mm. Hg, circulation in the small blood vessels of the fingers and toes may be impaired. The risk of occlusion of these smaller blood vessels is increased in an extremity where the blood supply has been impaired by trauma or arteriosclerotic disease.⁸¹ Immobilization of the extremity at a pressure considered effective by the manufacturer may lead to ischemic necrosis of the digits. It has been determined that the safe inflation pressure is between 20-25 mm. Hg, beyond which circulation in the digital capillaries will be impaired.⁸² The medical literature therefore recommends several precautionary measures: (1) Inflation of the splint by mouth; (2) Use of a mercury sphygmomanometer to check air pressure; (3) Removal of the splint after 12 hours because increased pressure from edema may combine with the air pressure to cause necrosis.⁸³ Needless to say, the manufacturer's recommendations

⁷⁹ Ashton, *Effect of Inflatable Plastic Splints on Blood Flow*, 2 BRIT. MED. J. 1427 (1966).

⁸⁰ *Id.* at 1430.

⁸¹ Ginsberg, Miller & McElpatrick, *The Use of Inflatable Plastic Splints*, 200 J. AMER. MED. ASS. 180 (1967).

⁸² Gardner, *An Inflatable Emergency Splint*, 29 CLEVELAND CLIN. QUART. 54 (1962); *supra* note 81, at 181.

⁸³ *Supra* note 81, at 181.

fail to instruct or warn about dangers of ischemia and the proper precautions to be taken. In a flagrant example of sacrificing safe design for cheaper costs, no manufactured splint includes even the simplest device for measuring pressure. And even were such a measuring device to be included, the manufacturer's own instructions indicate that 30-40 mm. Hg is a safe pressure, although physicians have clearly warned in the medical literature that this far exceeds safe limits. But articles buried in the medical literature can not be expected to take the place of a simple and direct cautionary instruction included in the manufacturer's directions. Instead splint manufacturers seem to be practicing deliberate deception, which is all the more dangerous if the splint is to be used by army medics and first-aid personnel rather than by trained physicians.

PHARMACEUTICAL CLOSURES—THE RISK OF CORING

Pharmaceutical closure is merely a fancy name for the stoppers, plugs, and plastic seals and lids which enclose the mouth of a bottle or vial of a drug to prevent contamination by exposure to the atmosphere. Most frequently the closure is a thin plastic or rubber membrane stretched between the aluminum rim. It is standard practice, in order to prevent exposure to the atmosphere, for the physician to withdraw the drug from the interior of the bottle by inserting the needle through this membrane cap.

A core is simply a particle of this membrane which is cut away by the hollow needle upon its insertion through the membrane. It remains hidden in the lumen of the needle and may pass with drug contents into the patient. The core is a foreign substance carried into the patient's bloodstream or, as we shall see, into the subarachnoid or epidural space. It brings with it external bacterial contamination which increases the risk of infection.

Because the pharmaceutical and container manufacturers have no solution for this problem, they have to a certain degree attempted to sweep the problem under the rug, although it presents design hazards which apply universally throughout the medical profession, for every physician has had occasion to withdraw drugs from a sterile vial. The following extract describes the coring mechanism, and at the same time gives some examples of a not uncommon attitude among manufacturers—callous disregard of the medical profession's efforts to improve the safety of medical devices.

Most stoppers in drug bottles in Canada are manufactured by the West Company of Phoenixville, Pennsylvania, U.S.A. This company has been completely uncooperative in this study and has refused answers to repeated questions over a two year period. . . .

The principal factors related to the needle are the bore of the needle and the sharpness of the heel. The heel of the needle is that part which is directly opposite the needle point. It has a sharp knife edge, the sides of which slope inward towards the centre of the heel. Thus the sloping sides of the circumference of the needle tip will, upon insertion of the needle, tend to enfold the stopper material, gathering it into the lumen, compressing the material into the bore, and making it more rigid and easily cut by the knife edge of the needle heel. As the needle advances into the stopper the cut produced by the point of the needle elongates into an arc and forms a hinged flap, a trap door or stopper material.

The forces created by the compression of the stopper material pushes this flap into the only space available: the lumen of the needle. Depending upon the sharpness of the heel of the needle and the rigidity of the closure, the heel may gouge out that portion of the closure which protrudes into the lumen, thus producing a core. . . . Generally, the larger the lumen of the needle, the greater the percentage of inorganic filler in the stopper; and the longer and hotter the sterilization process, the greater will be the production of cores and fragments.

To refer to the plug in a pharmaceutical container as "rubber" is erroneous. Some of them contain everything but rubber. Many contain only fifty per cent of latex by weight. The other fifty per cent is mostly a silica clay and compounds which are used in processing the plug, such as sulphur, titanium dioxide, barium sulphate, zinc oxide, iron oxide, thiazole, and thiuram type accelerators.

The manufacturer refuses to make the percentage composition of the pharmaceutical closures known to the medical profession. The doctors who accept responsibility for use of these products are denied knowledge of their constituents. In my opinion this is serious, in view of the fact the physicians may be injecting into the patient a drug contaminated with soluble products used in processing the plug, with cores or fragments of the stopper material, or with an epoxy-type laquer used to coat the aluminum cap.⁸⁴

Although the present state of technology concerning needle point design and the design of pharmaceutical closures is such that we cannot consider the needle and closure to be negligently designed, the manufacturer's conduct raises very real possibilities of negligent failure to warn. The syringe which is used to withdraw the drug from the vial should not then be used to inject the drug into the patient. If this is done, it is highly probable that the closure core which has lodged in the needle lumen will be injected into the patient as well. This danger will be greatly lessened if the contents of the syringe are injected through a second needle.⁸⁵ Dr. Charlebois further recommends that multidose

⁸⁴ Charlebois, *Coring: The Unseen Menace*, 13 CANAD. ANAESTH. SOC. J. 581, 585-87 (1966).

⁸⁵ Since the skin is a semi-rigid membrane just like the pharmaceutical closure, coring may occur here as well, and may cause infection because the skin surface even after

vials, in which the hazard that cores may be pushed by the needle into the drug solution is clearly present, should not be used.⁸⁶

The dangers of pharmaceutical closure and skin coring are especially pronounced in spinal and epidural anesthesia processes. In addition to the foreign bodies carried in the closure core, skin, together with the chemicals used to sterilize the epidermis at the puncture site, may be carried into the subarachnoid or epidural space, raising the potential hazards of bacterial or chemical contamination, probable etiologic agents in the development of spinal headache and arachnoiditis.⁸⁷

CRYOSURGICAL INSTRUMENTS

Cryosurgery uses the techniques of cryogeny, the science that deals with methods of producing and using extreme cold. This new surgical technique is of very recent origins, because its growth is directly traced to the development of insulating containers for the storage of liquified gases, nitrogen and other cryogens, for use in the space program. Cryosurgery has many significant advantages over more traditional methods of surgical extraction. The freezing action of the cryoprobe is controlled and highly localized, so that the surgeon can work with a narrowly limited area of treatment without disrupting bodily structures elsewhere. In addition, tissue to which freezing techniques are applied congeals painlessly, because the intense cold dulls the sensory nerve fibers. Freezing also produces hemostasis, the slowing down and stoppage of blood flow, so that the risk of hemorrhage is greatly reduced. In some cases, the freezing reaction is reversible if the temperature used is not excessively cold.⁸⁸

Three types of freezing effects are used in the varied modern applications of cryosurgery. The use of freon gas or a thermo-electric cooling device⁸⁹ enables the surgeon to work at temperatures about -30°C . At temperatures between -15°C . and -60°C . the warm, moist tissue to be extracted will adhere to the cold metal surface of the cryoprobe tip.

preparation is a fertile source of bacteria. It is thus suggested that the injection of the drug be made through a second needle, smaller than the needle used to pierce the skin originally.

⁸⁶ *Supra* note 84, at 595.

⁸⁷ Brandus, *The Spinal Needle as a Carrier of Foreign Material*, 15 CANAD. ANAESTH. Soc. J. 197 (1968).

⁸⁸ Bellows, *Introduction to Cryosurgery*, 47 INT. SURG. 310 (1967).

⁸⁹ Leden & Rand, *Cryosurgical Techniques in Head and Neck Surgery*, 33 AMER. SURG. 36 (1967).

This adhesive effect is used by ophthalmologists in the cryoextraction of cataracts, since the cataract fuses with the tip of the instrument and may be removed thereby.⁹⁰ At temperatures about -60°C . the extreme cold produces an inflammatory reaction (similar to frostbite), which has been used, for example, in the treatment of retinal detachment.

Perhaps the most dramatic use of cryosurgery is the use of liquid nitrogen (-196°C .) to destroy tumors. The extreme cold produces necrosis of the malignant tumor tissue, without affecting normal tissue about it. Cryosurgery has been effectively applied to such diverse surgical procedures as tonsillectomies, prostate reduction, cataract extraction, resection of brain tumors and of tumors of the rectum, and of many superficial skin malignancies.⁹¹

It should not be denied that cryosurgical instruments present an extremely worthwhile improvement in surgical technology, but the use of such instruments is not without its dangers. Cryosurgical devices at this stage of development must be considered inherently dangerous. Consider the complications attendant on cataract extraction: (1) the instrument may fail to freeze the lens capsule entirely; or (2) the instrument may accidentally freeze the cornea (although this is reversible without permanent damage if done at the normal -30°C . extraction temperature). If, however, the temperature produced by the cryoprobe is far colder than that desired, unexpected tissue necrosis will result. The cryosurgical instrument must be designed in such a way that the surgeon will be sure he is getting the temperature he wants.

Consider the following dramatic example of negligent design combined with the negligence of hospital personnel. A thermo-electric cryosurgical stylette is a thin pencil-shaped device used in cataract extraction. The instrument tip is to be placed on the cataract which has formed on the lens, and then turned on. Theoretically the instrument becomes extremely cold, -30°C ., and fusion between the cataract and instrument tip is then accomplished.⁹²

The instrument was so designed that, in the assembly of the stylette,

⁹⁰ Rubinstein, *Complications of Cryoextraction of Cataracts*, 51 BRIT. J. OPHTHAL. 178 (1967).

⁹¹ Bellows, *supra* note 88, at 312-14.

⁹² Thermo-electric cooling devices utilize the Peltier effect. This theory is based on the observation that a current crossing the junction of two unlike metals produces an absorption or liberation of heat, depending on the current's direction. See von Leden, *supra* note 89, at 36.

it was possible to connect the electrodes leading from the instrument to its power source backwards. An observation of the above mentioned Peltier effect should predict the result: the tip of the stylette heated to a red-hot temperature instead of freezing. In one case, the physician realized this too late, and the eye was destroyed. In fact, the electrode connections were designed with a slight misfit, but it was possible to reverse them—which a negligent but determined nurse had proceeded to do. In addition to the negligent design issues raised by the manufacturer's failure to create a more obvious misfit, clear issues of negligent failure to warn of the dangers of interchange, and negligently inadequate instructions, are also raised.

INTRACEREBRAL ELECTRODES

In the treatment of psychiatric illness which is traceable to organic brain dysfunction, in-dwelling metal electrodes may be implanted in the patient's frontal lobes and left there for continuous electroencephalograph monitoring at will over periods ranging from two to eight months.

Electrodes composed of several different metals are manufactured and sold commercially. Silver-silver chloride and copper electrodes are accurate recorders of intracerebral electrical activity because of their high sensitivity to electrical currents. Stainless steel is much less satisfactory, because it does not pick up low frequency electrical currents strongly. Nevertheless, the toxic effects of silver electrodes on brain activity are so severe that manufacturers who market silver electrodes for this use must be held liable for negligent failure to warn of the electrode's inherent dangers.

The use of silver electrodes is characterized by toxic reactions such as brain tissue necrosis, edema, demyelination, and macrophage production. Human clinical manifestations include abnormal electroencephalograph tracings, dementia, loss of memory, confusion and disorientation, and urinary incontinence.⁹³ Stainless steel electrodes, though less effective, have thus far proved inert and harmless. The extreme neurotoxicity of silver electrodes should make their use in human subjects evidence of malpractice, and should give the brain-damaged patient an action against the electrode manufacturer for failure to warn.

⁹³ Cooper & Crow, *Toxic Effects of Intra-cerebral Electrodes*, 4 MED. BIOL. ENG. 575 (1966).

METALLIC ORTHOPEDIC PROSTHESES

The wide variety of personal injuries which may be caused by metal prostheses could easily be the subject of a small book. A few problems raising issues of negligent design, negligent use of defective materials, and durability, are briefly raised here.

Foreign materials are implanted in the body for a wide variety of purposes: first, sutures for wound repair; second, screws, nails, bolts, plates and other fasteners for repair of bone fractures; third, implants used to replace damaged body parts, including parts of bones and organs, such as heart valves; fourth, metals may be used as molds to guide the shape of healing tissue.

These metal devices are placed in an extremely hostile environment. The normal body pH is approximately 7.4 (in wound areas it may fall as low as 5.5). The implant is often subjected to repeated stresses. A Naden-Reith hip prosthesis, for example, may be subjected to 500 pounds per square inch pressure millions of times whenever the patient stands or walks. The metal cage of a heart valve may be struck by the valve ball perhaps thirty million times a year. There is little wonder that metal implant devices are subject to both fatigue and corrosion, so that the implant fractures often require surgical replacement or removal. In formulating standards of defective and negligent design and manufacture of these metallic implants, it is important to realize that due care requires the construction of a product which can stand up to the body's hostile environment without developing defects which require corrective surgery.

Unfortunately, many of the metallic prostheses in use today do not meet this standard of durability. Neither the case law nor the medical profession has answered the question whether such prostheses, which admittedly have not been built to last indefinitely, are inherently defective for this very reason. While in most cases the breakage of a prosthesis within the body would not subject the manufacturer to negligence liability, we have seen that quite a contrary result may be reached under a strict liability theory if the lack of durability is treated as evidence of defectiveness.

Of course the medical profession joins with the products liability bar in desiring prostheses which are designed so durably that they will withstand the body's stresses indefinitely and thus not require a second surgical intervention just for removal. The state of metallic prostheses

design is reaching slowly towards that goal. Implants are being designed, by physicians even more than by manufacturers, which possess these properties of mechanical durability and resistance to corrosion. The standard of due care in design that the medical and legal professions are together aiming for is clear. It is the standard we require of all long-term or permanent implantation. The implant must not fail through corrosion or fracture, nor can its metals produce a toxic reaction with the bodily tissues among which it rests.

The history of metallic implants has been characterized by gradual awareness of the toxic properties of once popular metals. Silver and vanadium steel have been tried and discarded because of toxic properties and fatigue failure. At present, stainless steel and vitallium (a cobalt-chromium-molybdenum alloy) are most commonly used, and titanium is gaining increasing use, especially in the form of an alloy containing six per cent aluminum and four per cent vanadium. The ideal metallic alloy is yet to be perfected.⁹⁴

The case literature we have considered earlier contains several examples of prosthetic devices which fractured inside the body. The crucial issue is the length of time the metallic implant should be designed to last. For example, Neufeld pins are used to repair fractures of the hip and upper femur. The device is pounded into the head and neck of the femur and then screwed into the length of the femur, thus fixing the fracture of the femur in proper position. If the plate or pin breaks before the fracture heals, the defective quality of the device is clear—assuming that the patient has not put unusual strain on the device (contributory fault). If however, we are dealing with a short-term metallic implant, designed to last only until the fracture has healed, the breakage of the plate after the fracture heals must be considered differently. The manufacturer's primary defense is that the plate was not defective or negligently manufactured because it was only designed expressly to last until the fracture healed, and no longer.

The same problem arises with intramedullary pins, also a frequent subject of the case literature. Very frequently these pins do not break until six or seven months after the initial operation, after the fracture has healed and after the patient has repeatedly put weight on the prosthesis. The fact that these nails may fracture, necessitating another

⁹⁴ Laing, *Problems in the Use of Metals as Surgical Implants*, 45 J. DENT. RES. 1660 (1966).

operation and often refracturing the broken bone at the same time, may well not be enough to impose liability, although it arguably should be enough under a strict liability standard where such glaring lack of durability is evidence of dangerously defective design.

Two ways have been mentioned in which metallic prostheses may be dangerously defective. Certain older prostheses used metals which are now known to cause dangerous toxic reactions. The prostheses in use today may not be designed durably enough to withstand the stresses of normal bodily function. It is also important to mention the dangers caused by migration of prostheses, although it is not yet clear how this hazard may be reduced by design modifications.

The Moore and Thompson endoprotheses of the hip are used in the treatment of fractures of the femoral neck. A recent study has indicated that in certain patients the prostheses tend to migrate or sink down the femoral shaft.⁹⁵ Of sixty-seven cases of this sinking prosthesis, a full fifty-seven were linked with premature weight-bearing, and fourteen were traced to a catch-all category involving "mechanical mishap," including fracture of the prosthesis itself.

Several reported cases present more serious migration problems, in which orthopedic devices migrated into vital organs of the body. These include:

- (1) The migration of a Kirschner Wire from the right sternoclavicular joint into the right pulmonary artery, causing death.⁹⁶
- (2) The migration of a Kirschner Wire from the shoulder to the lung.⁹⁷
- (3) The migration of a Steinmann pin from the clavicle to the trachea.⁹⁸
- (4) The migration of a Steinmann pin from the humerus to the lung.⁹⁹

The deadly potential of migrating orthopedic equipment is clear, although at present it is doubtful that this will result in either malpractice liability or manufacturer's liability (unless it can be shown that the migration is the result of the breaking of a defective prosthesis).

⁹⁵ Harris, *Sinking Prostheses*, 123 SURG. GYNEC. OBSTET. 1297 (1966).

⁹⁶ Leonard & Gifford, *Migration of a Kirschner Wire from the Clavicle into the Pulmonary Artery*, 16 AMER. J. CARDIOL. 598 (1965).

⁹⁷ Mazet, Jr., *Migration of a Kirschner Wire from the Shoulder Region into the Lung*, 25 J. BONE JOINT SURG. 477 (1943).

⁹⁸ Kremens & Glauser, *Unusual Sequelae Following Pining of Medial Clavicular Fracture*, 76 AMER. J. ROENTGEN. 66 (1956).

⁹⁹ Tristan & Daughtridge, *Migration of a Metallic Pin From the Humerus Into the Lung*, 270 NEW ENGLAND J. MED. 987 (1964).

VASCULAR CATHETERS

A catheter is simply a plastic tube which can be inserted into the body. The catheters with which these comments will be concerned are inserted through a needle into a blood vessel. They may then be taped in place so that blood, glucose, or other fluids may be given the patient intravenously. In certain diagnostic procedures as in arteriography the catheter is manipulated through the blood vessels until its tip reaches the area to be studied under X-ray. Radiopaque contrast material is then injected through the catheter tubing directly to the vessels under consideration. Atherosclerotic narrowing of blood vessels may be diagnosed in this manner. Several such procedures are in common use today—cardiac catheterization for visualization of the coronary arteries, brachial artery angiography for visualization of the blood vessels supplying the brain, and retrograde femoral aortography for visualization of the renal arteries, for example.

Let us first consider a problem in the use of catheters for intravenous fluid therapy. This problem has been termed "catheter sequestration," and it is an interesting combination of several potential areas of negligence: negligent catheter design, negligent needle design, failure to give adequate instructions, and physician malpractice.

As outlined above, the intravenous polyethylene catheter must be inserted into the blood vessel. It is during this insertion process that difficulties arise. The standard catheter is of a smaller diameter than the needle into which it is inserted. After the needle is placed in the blood vessel, the catheter is advanced through the needle lumen and into the lumen of the blood vessel. Here is where negligent needle design is clearly implicated. When the needle tip is manufactured, it is ground level with the shaft of the needle, leaving the lower bevel or heel with a sharp cutting edge. This lower bevel of the needle nicks the plastic catheter tubing when it is inserted beyond the needle face, especially since the vessel wall holds the catheter directly over that cutting edge, at almost right angles to the length of the needle.¹⁰⁰ When the catheter is thus nicked and lacerated, a portion of it may shear off and float away in the blood stream, for unknown parts of the body.

Dr. Crawley of London has developed a modified needle which eliminates the risk of catheter laceration, and which thus should greatly

¹⁰⁰ Crawley, *Catheter Sequestration, A Complication of Epidural Analgesia*, 23 ANAESTHESIA 270 (1968).

decrease the incidence of catheter sequestration. His needle is specifically designed for use in epidural anesthesia, and contains the following design modifications: (1) the catheter emerges not at the needle tip but through an opening 2-3 mm. further up to the shaft, and (2) this opening has smooth edges so that the catheter can not be nicked thereon.¹⁰¹ This needle is now commercially marketed, but the traditional approach still prevails in needle design for intravenous cutdowns. The most that can be concluded is that a sharpened lower bevel is evidence of negligent design and manufacture, and that manufacturers of complete cutdown units (catheter and needle preassembled) should be under the duty to blunt this lower bevel edge.

Serious injury may result from catheter sequestration. For example, the following cases have been reported, and most authors agree that most cases of catheter sequestration go unreported:

(1) During an attempted insertion of a catheter into a superficial vein in the left forearm, 4 cm. of the catheter broke off and was not recovered. The patient died, and a subsequent autopsy found the catheter coiled in the right atrium.¹⁰²

(2) Because of the loss of a catheter into a cubital vein, the patient died. The autopsy disclosed the catheter lying in the right atrium and extending up the vena cava.¹⁰³

(3) A catheter migrated from the left femoral vein causing death through perforation of the right ventricle.¹⁰⁴

(4) A catheter migrated from a antecubital vein into the right lung, where it was surgically removed.¹⁰⁵

The complications of lost catheters are many: thrombosis, embolism, bacterial endocarditis, myocardial damage, coronary vessel damage, pericarditis, lung abscess, and others.¹⁰⁶ We have seen that physicians recommend that the lower bevel of the catheter needle be blunted.¹⁰⁷

¹⁰¹ *Id.* at 272.

¹⁰² Northcutt, *Intravenous Loss of Polyethylene Catheters*, 34 GP 125 (1966).

¹⁰³ Turner & Sommers, *Accidental Passage of Polyethylene Catheter from a Cubital Vein to Right Atrium*, 251 NEW ENG. J. MED. 744 (1954).

¹⁰⁴ Brown & Kent, *Perforation of Right Ventricle by Polyethylene Catheter*, 49 SOUTHERN MED. J. 466 (1956).

¹⁰⁵ Mariano, Roper & Stapler, *Accidental Migration of an Intravenous Infusion Catheter from the Arm to the Lung*, 86 RADIOLOGY 736 (1966).

¹⁰⁶ *Supra* note 102, at 126.

¹⁰⁷ *Supra* note 102, at 127.

Their recommendation for catheters is equally as simple. The lost catheter is a foreign body which should be removed as quickly as possible. In order to remove the catheter its location must be known. The original "intracath" catheter was manufactured by C.R. Bard, Inc. in 1957. Since then they have developed a radiopaque catheter which is far more visible on X-ray than its predecessor. This has made localization of catheters much simpler. However, all catheters are not yet radiopaque, and today's industry standard would not yet require catheters to be radiopaque. This should not, however, prevent a court from finding that the failure to make catheters radiopaque constituted negligence, assuming that the proximate cause issue could be resolved in plaintiff's favor.

The second catheter problem to be considered is much simpler, since it really raises a misbranding question similar to *Orthopedic Equipment Co. v. Eutsler*.¹⁰⁸ Several cases have been reported where catheters used during cardiac catheterization have become lodged within blood vessels. In one case the tip of a No. 7 Cournand catheter tore off some of the interior wall, or perhaps a valve leaflet, of the subclavian vein, which wrapped itself about the catheter causing it to wedge immobile in place within the vein.¹⁰⁹ In another case the catheter became impacted in a coronary vein, probably related to an anomalous venous development.¹¹⁰ In the former case the catheter was finally pulled loose under anesthesia; in the latter a thoracotomy to expose the vein was required. It may be suggested that, since the polyethylene catheters are marked as to diameter, a misbranding and/or failure to inspect the catheter's external diameter may cause the physician to employ a catheter which is much wider than he suspects, and which is, in fact, too wide to navigate the diameter of the coronary arteries or veins successfully. Such manufacturer's misbranding and failure to inspect would, if discovered, raise clear issues of negligence parallel to those in *Eutsler*.

Guides have been designed to aid in the catheterization of tortuous or arteriosclerotic vessels, primarily the iliac and subclavian arteries. The design and development of a lumen-following J-guide, manufac-

¹⁰⁸ 276 F.2d 455, 79 A.L.R.2d 390 (4th Cir. 1960).

¹⁰⁹ Stewart & Drake, *Lodged Catheter During Cardiac Catheterization*, 68 AMER. HEART J. 538 (1964).

¹¹⁰ Anderson & Varco, *Impaction of Cardiac Catheter in Coronary Vein*, 32 CIRCULATION 808 (1965).

tured by Cook, Inc., illustrates some of the stages and tragic consequences as physicians and manufacturers apply trial and error towards safety development.

The original J-guide was a conventional movable core guide spring heated and shaped into a J-configuration 6 mm. across. This device, being more flexible, was used instead of the J-shaped catheter. But in use the J-guide was subjected to stresses caused by repeated manipulation and the sharp bending imposed on an already heat-weakened and deformed tip. Indeed the authors who developed the guide report that such a tip broke off in a patient who had severe arteriosclerotic disease.¹¹¹

The safety guide includes an internal safety wire of small diameter which is soldered to the tip of the guide and also to the proximal end of the guide which connects with the catheter. This small strong wire protects against the loss of a broken guide tip and prevents uncoiling of the spring loops.¹¹² The advantages of the safety J-guide over the standard straight core guide are such that use of the core guide may come to be considered negligent. It has a flexible and broadly rounded leading edge; the internal safety wire prevents loss of the guide tip; and the possibility of injury to the interior vessel wall by the catheter tip is eliminated.¹¹³

HEART VALVES

This section will examine some of the dangerous and often lethal defects associated with the development of plastic artificial heart valves which have been inserted in the body to replace diseased mitral and aortic valves. Defects of design, material, and manufacture attributed to three such valves will be considered: (1) Bahnsen cusps, (2) Starr-Edwards ball valves, and (3) Kay-Suzuki disc valves.

Some general observations should be made at the start. Although the medical literature is filled with articles pointing out the design virtues and defects of different and often competing valves, and although there is no question that in certain patients the valves have been defective (at least in the sense that they were incapable of meeting the demands

¹¹¹ Judkins, Kidd, Judkins & Frische, *Lumen-Following Safety J-Guide for Catheterization of Tortuous Vessels*, 88 *RADIOLOGY* 1127 (1967).

¹¹² Dotter, Judkins & Frische, *Safety Guidespring for Percutaneous Cardiovascular Catheterization*, 98 *AMER. J. ROENTGEN* 957 (1966).

¹¹³ *Supra* note 111, at 1130.

the circulatory system made of them, and so broke down therefrom), courts are faced with a major problem because this design area is still a highly experimental art. Even though these valve designs are commercially produced and sold, they are subject to constant evaluation and modification by the medical profession. Where safe valve design is so uncertain, and where potential complications are understandably not always foreseen, the medical profession is understandably loath to claim that defective heart valve design is anything worse than a mistake of judgment. In those states where the plaintiff must recover against the manufacturer on a negligence theory, his chances of success are probably slight. In those states which have imposed strict liability, the defective or defectively designed heart valve should theoretically, in most cases, fall within the framework of cases where plaintiff is permitted recovery against the manufacturer. The attorney arguing such a case in a strict liability state must, more than in most medical instruments cases, emphasize to the court that recovery is based not on fault, but solely on the existence of the defect. The fact that the designers have made a significant advance in medical science, and that they have designed as best they could, given their knowledge at the time, is not enough to relieve them of liability. More than in any other area of products liability, perhaps, the heart valve case dramatizes the legal requirement that manufacturers be held liable for defective but praiseworthy products. The rule which shifts the burden of responsibility for the injured patient must not be attenuated.¹¹⁴

The Bahnsen cusp is a prosthesis made of knitted Teflon fabric which is used to replace the individual cusps of the aortic valve. As will be seen with whole valve replacements, discussed below, present technical developments have not yet succeeded in producing a synthetic valve or valve cusp that will withstand the stresses of the blood stream indefinitely. The synthetic valve is inserted because the original natural valve is so diseased that it no longer functions effectively and is an immediate threat to life. Nevertheless long term follow-up indicates that the Bahnsen cusp is only a relative blessing. Studies have shown that the prostheses tend to become calcified, rupture, or become the source of infection.¹¹⁵ In one dramatic reported case, rupture occurred twenty-nine

¹¹⁴ For a general survey of developing heart valve technology, see Kay & Suzukia, *Evolution of Aortic Valvular Prosthesis*, 45 J. THORAC. CARDIOV. SURG. 372 (1963); PROSTHETIC VALVES FOR CARDIAC SURGERY (Meredito ed. 1961).

¹¹⁵ Bjork, Cullhed & Lodin, *Aortic Valve Prosthesis (Teflon): Two Year Follow-Up*, 45 J. THORAC. CARDIOV. SURG. 635 (1963).

months after surgery.¹¹⁶ The fragments of the Teflon cusp entered the coronary arteries, producing extensive myocardial damage resulting in death. This was, in effect, a case of Teflon coronary embolism.

Perhaps the most commonly used mitral valve prosthesis today is the Starr-Edwards valve, manufactured by Edwards Laboratories of California. The design of the valves includes a Teflon fixation cuff, a ring-shaped structure from which are suspended the four struts of the ball valve cage. Enclosed in the cage is the Silastic ball.¹¹⁷

The possible adverse effects of the Starr-Edwards valve are directly traceable to the valve design, and in particular the length of the struts which comprise the ball cage. The Starr-Edwards valve interferes with myocardial contraction, thus causing low cardiac output in patients with small left ventricles. The protrusion length of the Starr-Edwards cage struts is such that they frequently come in contact with the ventricular septum, causing chronic irritation and endocardial grooving which in turn causes arrhythmias, ventricular fibrillation and death in two reported cases.¹¹⁸ The Kay-Suzuki disc valve has been deliberately designed to eliminate this problem, its struts protruding roughly one-third as far. A high incidence of thromboembolism (blood clotting about the prosthesis) has been associated with the Starr-Edwards valve, and this in turn has caused stasis or pooling of blood in the left atrium. Once again this may be directly traceable to dangers of design and material. The Teflon fixation cuff appears to be the culprit, since chemically Teflon tends to precipitate fibrin, and the greater the turbulence about the valve, the greater the precipitate and resulting clot formation.¹¹⁹

We have mentioned three clearly established defects of design and manufacture which may cause serious complications and which are present in every Starr-Edwards valve, at the time it is first manufactured. The patient whose injuries are traceable to these design infirmities should, in theory, have a strong case in a strict liability state, if the defense does not succeed in beclouding the issue with the "error in judgment" argument imported from malpractice cases.

Let us now consider design defects which manifest themselves in the

¹¹⁶ Aquino & Skinsnes, *Teflon Embolism of Coronary Arteries*, 80 ARCH. PATH. 625 (1965).

¹¹⁷ Kay, Suzuki, Demaney & Zimmerman, *Comparison of Ball and Disc Valves for Mitral Valve Replacement*, 18 AMER. J. CARDIOL. 504 (1966).

¹¹⁸ *Id.* at 504.

¹¹⁹ *Id.* at 505.

mechanical failure of the valve after several months of use. Once again we must emphasize that the crucial question in such a case is whether the court will be persuaded to treat the defect as caused by the manufacturer's failure to make his product durable, or by the destructive effects of the blood stream, well after the product has left the manufacturer's hands. Surely a product must be considered defective which breaks down when subjected to the very use for which it was intended. The fact that the manufacturer expected it to break down because it could design no better can hardly be a serious defense.

The most dramatic problem involves the expulsion and fracture of the Starr-Edwards valve ball. Several cases have been reported:

(1) Ablaza et al. reported the extrusion of the Starr-Edwards ball, which lodged in the bifurcation of the aorta eleven months after implantation, and caused embolism of the aorta. The extruded ball was found to be lighter and smaller than an unused aortic prosthesis ball.¹²⁰

(2) Attar et al. reported a case where cardiac massage performed at the end of the implantation procedure forced the expulsion of the ball from the valve chamber.¹²¹

(3) Mackenzie et al. reported a case of death approximately three months after implantation, in which the ball was expelled from the prosthesis and found at the aortic bifurcation. The ball had lost twenty-eight per cent of its original weight.¹²²

(4) Newman et al. reported a case in which death was caused by the escape of the ball from the valve chamber approximately thirty-three months after implantation. The ball was fractured through ninety per cent of its diameter.¹²³

Several causes have been advanced for ball expulsion, and all can be traced to design and material defects. The reports have emphasized weight loss of the Silastic ball, discoloration, and irregular erosions on the ball surface. Silastic is a silicone elastomer, and current laboratory investigations indicate that the choice of this product may have been

¹²⁰ Ablaza, Blanco, Maranhao & Goldberg, *Fatal Extrusion of the Ball from a Starr-Edwards Aortic Valve Prosthesis: Report of a Case*, 50 J. THORAC. CARDIOV. SURG. 401 (1965).

¹²¹ Attar, Saunders & McLaughlin, *Prosthetic Heart Valve Surgery*, 2 ANN. THORAC. SURG. 52 (1966).

¹²² Mackenzie & Almond, *Expulsion of Ball from Aortic Valve Prosthesis*, 2 ANN. THORAC. SURG. 435 (1966).

¹²³ Newman, Hoffman & Gesink, *Mechanical Failure of Starr-Edwards Aortic Prosthesis Due to Ball Fracture*, 53 J. THORAC. CARDIOV. SURG. 398 (1967).

unwise, since the elastomer tends to deteriorate due to absorption of lipid materials from the blood.¹²⁴ The deterioration of the ball material may explain the fracture reported by Newman. A second design defect is that the spacing between the four struts of the Starr-Edwards cage may be too wide. The ball may have escaped the cage by being driven through the gap between the struts by the force of ventricular systole.¹²⁵

Of course a possibility exists that the ball was defectively manufactured to begin with. The simplest proof of this would appear in a case where the ball was too small when the valve was first inserted, although decrease in the size after implantation is more likely. It has been suggested that the balls be measured at the time of insertion, and that they be impregnated with contrast material to allow radiographic detection of excessive wear or distortion.¹²⁶

One of the principal competitors to the Starr-Edwards ball valve is the Kay-Suzuki disc valve, manufactured by Valve Research Corporation of Cleveland. This valve has incorporated several safety features not found in the Starr-Edwards design. We have previously discussed the shorter strut length. Another safety feature is the presence within the valve orifice of four protrusions which give the disc greater support when closed and prevent dislodging of the disc caused by wear and tear.¹²⁷ The authors' claim that their disc valve, because of its low profile, is a safer design which interferes less with myocardial function and is less likely to develop complications, especially thromboembolism development.

Experimental evaluation of the Kay-Suzuki disc valve has not fully supported these claimed design improvements.¹²⁸ Although the designers claim that the four protrusions prevent cocking of the disc, thus leaving the orifice partly open, laboratory testing indicated that the disc closing was somewhat erratic nonetheless. Turbulence and blood stasis immediately after passing through the disc valve was greater than that seen with the Starr-Edwards ball valve.¹²⁹

¹²⁴ *Id.* at 400.

¹²⁵ *Id.*

¹²⁶ *Supra* note 122, at 436-47.

¹²⁷ *Supra* note 117, at 510.

¹²⁸ Smeloff, Huntley, Davey, Kaufman, & Gerboder, *Comparative Study of Prosthetic Heart Valves*, 52 J. THORAC. CARDIOV. SURG. 841 (1966).

¹²⁹ *Id.* at 844.

The Kay-Suzuki disc valve has proven as defective as its competitor's when subjected to the wear and tear of the blood stream. A case of acute mitral insufficiency due to jamming of the disc valve prosthesis twenty-nine days after implantation has been reported.¹³⁰ The findings on reoperation showed extensive deterioration of the silicone rubber disc. The valve disc was found to be fixed in an oblique position—it had been pierced by one of the prongs at the base of the valve. Eight points of wear, corresponding to the four metal cage struts and the four projections on the valve base, were seen. The authors concluded that: "The early appearance of the notchings shows the vulnerability of a silicone rubber disc to repeated mechanical stress at fixed points. This was probably due to the inability of this disc to turn freely in the cage."¹³¹ Apparently the design and manufacture of truly durable and defect-free heart valves must await the development of a substance more resistant to wear than the silicone rubber elastomers now in use.

PACEMAKERS

This final section will consider some of the hazards of design, manufacture, and use associated with in-dwelling cardiac pacemakers. Because the pacemaker is an electrical device (the natural pacemaker operates on electro-chemical principles), electrical hazards, such as ventricular fibrillation caused by electric shock, must be given equal prominence with mechanical defects.

The design of pacemakers is barely emerging from the experimental stage, where poor engineering caused major difficulties leading to pacemaker failures. Chief among these difficulties are failure of the pulse generator (*i.e.*, the pacemaker battery failed) and breakage of myocardial electrodes which had been constructed of inferior materials. In such cases the success of a suit based on defective manufacture of the pacemaker components would appear quite likely, because medical opinion acknowledges that much of the pacemaker equipment manufactured before 1962 was faultily designed and used unsuitable materials which increased the breakdown risk.¹³²

Among the significant problems which plague pacemaker design to-

¹³⁰ Low & Lefemine, *Acute Mitral Insufficiency Due to Jamming of a Disc-Valve Prosthesis*, 4 ANN. THORAC. SURG. 71 (1967).

¹³¹ *Id.* at 73.

¹³² Hellerstein, Hornstein & Ankeney, *The Runaway Artificial Pacemaker*, 62 OHIO MED. J. 907 (1966).

day, battery failure must still rank high. In one series,¹³³ where mercury batteries were used to power fixed rate implantable pacemakers, battery failure occurred in three of twenty-two patients. The batteries in use in the mid-1960's were not able to function indefinitely, and the risk of battery failure is very high after eighteen months have past. And again, in a defective manufacture lawsuit, it is no answer to claim that the patient, but for the defective device, would have died months before.

Although manufacturers at present appear to be incapable of designing a pacemaker battery that will last indefinitely, the standard of due care in pacemaker design must make provision for the early detection and effective replacement of batteries which fail. The following suggestions have been made which, if adopted, should make pacemaker failure somewhat less of a threat to human life:¹³⁴

(1) Patients with internal pacemakers should be supplied with wiring diagrams and other design information, which they should be instructed to carry with them at all times, so that physicians will be able to attempt battery replacement and other repair of the many different pacemaker designs intelligently rather than blindly.

(2) Adequate warning devices of impending pacemaker battery failure should be perfected. Pacemakers should be equipped with an audio signal which would produce a warning sound when one battery fails. With current pacemakers, the failure of one battery will not increase or decrease heart rate (three battery failures are usually needed), so that pulse taking is not an accurate indication of battery failure. This audible warning device is an inexpensive precaution.

(3) The parts used in the many varieties of pacemakers, manufactured by competing companies, should be standardized so that hospitals will be able to make replacements easily. Interchangeable parts would permit hospitals to purchase and stock pacemaker components, and they would not have to lose time writing to the manufacturer for parts, which may no longer be held in stock.

Dr. Hellerstein has further reported two cases involving defective pacemaker parts,¹³⁵ both of which would be considered examples of defective manufacture even under experimental conditions. In one case the output voltage of a pacemaker of a patient who died from heart

¹³³ Bartley & Wheat, Jr., *Pacemaker Problems*, 53 J. FLORIDA MED. ASS. 498 (1966).

¹³⁴ *Supra* note 132, at 910.

¹³⁵ *Supra* note 132, at 910.

block was found to be only 150 millivolts as opposed to a normal output near 8000 millivolts. The manufacturer examined the pacemaker and ascribed its premature failure to the failure of the oscillator transistor, causing rundown of the battery. The ineffective low voltage discharge of the pacemaker caused the heart block to reoccur.

Dr. Hellerstein's principal reported case involves a "runaway" pacemaker, in which the pacing rate increased rapidly due to battery failure. The physicians were forced to operate blind because the manufacturers had not furnished wiring diagrams.¹³⁶ A new pacemaker was successfully installed, but it was discovered that the runaway pacemaker was defective in five different parts: one soldered connection had broken, the pigtail safety wire broke, and the batteries, timing circuit and endplate all failed.¹³⁷ Two of these failures were due to electrode breakdown, which had been made of inferior quality material. Today the development of the platinum coil electrode has reduced the problem of myocardial electrode failure to the point where failure must be considered evidence of defective or negligent manufacture.¹³⁸

Another serious pacemaker complication may also be traced to unsafe design at least in part. In both temporary and permanent indwelling cardiac pacing, the electrode catheter may perforate the myocardial wall of the right ventricle. In temporary pacing this untoward effect has occurred from one day to two weeks after implantation, and this complication increases in frequency with more prolonged pacing.¹³⁹ Several such cases have been reported,¹⁴⁰ in which pacing was interrupted, remained the same, or ceased entirely depending on the degree of tip contact with the ventricular myocardial wall.

The pacemaker electrode catheter is simply a length of polyethylene tubing surrounding the electrode wire and culminating in a metal tip.

¹³⁶ Although such a diagram may be used and furnished to the purchaser of the original pacemaker device, it would seem to be negligent failure to instruct not to distribute such diagrams to major hospitals, since the manufacturer knows that battery failure and breakdown is a likely occurrence.

¹³⁷ *Supra* note 132, at 907-09.

¹³⁸ Chardack, *Heart Block Treated with an Implantable Pacemaker*, 6 *PROGR. CARDIOV. DIS.* 507 (1964).

¹³⁹ Nathan, Center, & Ping, *Perforation During Indwelling Catheter Pacing*, 33 *CIRCULATION* 124, 128-30 (1966).

¹⁴⁰ *Id.*; Cosby, Penido & Cotten, *Catheter Perforation of the Ventricle after Intracardiac Pacing*, 22 *GERIATRICS* 182 (1967); Crow, *Myocardial Perforation*, 67 *J. KANSAS MED. SOC.* 309, 340 (1966).

Temporary pacing has generally used a No. 5 or No. 6 Cournand catheter, which is not very flexible, and which has a rounded but somewhat bullet-nosed tip. The permanent Chardack electrode is designed specifically for permanent lasting capabilities. It is larger in diameter, approximately a 12 Fr. Cournand, but its very blunt end should theoretically be less likely to perforate the myocardium. However, cases of perforation with this catheter have been reported.¹⁴¹ In fact only minimal progress has been made in electrode catheter design, particularly with regard to flexibility. The presence of the electrode wire decreases flexibility, as does the increased width of the catheters designed for permanent indwelling.¹⁴²

Some brief comments on electrical dangers associated with cardiac pacemakers will show that the battery powered pacemaker (in spite of potential battery failure) has advantages over its externally connected counterpart. The principal danger is that of inducing ventricular fibrillation when a pacemaker and another electric instrument using a common power source (*e.g.*, wall outlets connected to the same electrical line in a hospital room) are connected to a patient. The use of the line-powered pacemaker alone provides little danger; it is the use in combination with other pieces of electrical apparatus which may deliver the fibrillation-causing electric shock.¹⁴³ If the two pieces of equipment have different electrical potentials relative to the common power line ground, they may deliver fibrillatory currents to the heart. Because of the high protective resistance of the skin and body tissues, small voltages caused by improper grounding of equipment rarely caused significant injury in the past. But now the intracardiac electrode furnishes a low-resistance pathway direct to the heart.¹⁴⁴ Under such conditions even low voltages can be lethal.

The electrocardiograph used to monitor the patient on a line-powered pacemaker is a frequent source of electric shock. It is possible, if the electrocardiograph has a two-prong plug, to reverse the plugs when connecting the EKG to the line outlet. The ground plug can be placed in

¹⁴¹ Meckstroth, Schoenfeld & Wardwell, *Myocardial Perforation from a Permanent Endocardial Electrode*, 54 J. THORAC. CARDIOV. SURG. 16 (1967); Jensen, Schmidt, Garamella, Lynch, & Peterson, *Intracavitary Cardiac Pacing*, 195 J. AMER. MED. ASS. 916 (1966).

¹⁴² *Supra* note 140, at 185.

¹⁴³ Starmer, Whalen & McIntosh, *Hazards of Electric Shock in Cardiology*, 14 AMER. J. CARDIOL. 537 (1964).

¹⁴⁴ Whalen, Starmer & McIntosh, *Electrical Hazards Associated with Cardiac Pacing*, 111 ANN. N.Y. ACAD. SCI. 922 (1964).

the "hot" slot of the outlet, and because the plug has been reversed, a difference in electrical potential exists between the EKG right leg electrode and the intracardiac catheter. The current generated by the electrical potential difference between the right leg electrode and the intracardiac electrode is delivered straight to the heart.¹⁴⁵ This danger is not confined to the electrocardiograph, but exists for any machine that carries a higher potential than the pacemaker, electrocautery equipment, for example.¹⁴⁶

The dangers of fibrillatory electric shock may be traced directly to manufacturer's refusal to institute certain basic design changes and provide conspicuous and unequivocal warnings. It should be remembered that, although these electrical devices are used by physicians, they are often set up by nurses or hospital orderlies, who can not be expected to understand the complexities of electric shock hazards, and must be given unequivocal warnings as well as devices so designed as to make the safe method of installation the only possible method.

Even physicians often fail to realize that potential differences may exist between electric devices which come in contact with the patient. The use of clearly coded or three-prong plugs, correctly wired (something manufacturers have not always done), will go far to make sure that all equipment is at the same ground potential. However the use of the three-prong plug is limited because many hospital rooms still have only two-prong receptacles.¹⁴⁷ This is why the use of a battery operated pacemaker is ideal in conjunction with other electrical apparatus. The danger of electric shock to the heart is eliminated because the battery-operated pacemaker is totally independent of the line outlet on the wall.¹⁴⁸

CONCLUSION

The evolution and expansion of theories of recovery in products liability litigation has come at a time when commercial products have mul-

¹⁴⁵ *Supra* note 143, at 540-41.

¹⁴⁶ Fein, *Transurethral Electrocautery Procedures in Patients with Cardiac Pacemakers*, 202 J. AMER. MED. ASS. 7 (1967).

¹⁴⁷ *Supra* note 143, at 542.

¹⁴⁸ Care must still be taken to ground the electrocardiograph or other electrical apparatus. If it is ungrounded, and a grounded person or apparatus comes in contact with the intracardiac electrode terminal, current will flow from the EKG to the EKG electrode on the patient, through the heart, and thence out the pacemaker electrode to the grounded person or apparatus. Fibrillatory current to the heart will result. *Supra* note 143, at 542.

tiplied in number and variety and have greatly increased in technical complexity. Nowhere is this more clearly the case than in litigation involving defective and negligently designed medical and surgical instruments. As the development of strict liability in tort continues, the emphasis of products litigation must shift towards effective and knowledgeable presentation of the facts upon which recovery is claimed.

The attorney's best approach to such litigation is an interdisciplinary one which emphasizes the need for thorough understanding of medicine and design technology, an understanding which can best be acquired through constructive working contact with the medical profession in joint efforts to promote instrument design safety. There is a crying need for new cooperation between the physician and the attorney in this area, an attitude which may begin to replace the old antagonisms of the malpractice suit. Both the physician and the trial attorney seek the development of more safely designed, defect-free medical devices. Their community of interest is undeniable.

APPENDIX

REPRESENTATIVE COMPENDIUM OF CASES INVOLVING DEFECTIVE MEDICAL AND SURGICAL INSTRUMENTS

ANESTHETIC AGENTS AND APPARATUS

Dierman v. Providence Hospital, 31 Cal. 2d 290, 188 P.2d 12 (1947):

Possibly contaminated nitrous oxide caused explosion when electrocautery needle used within oral and nasal passages of plaintiff—action against physician and hospital—*res ipsa loquitur* applied—defendant's failure to show gas was free from contamination.

Moehlenbrock v. Parke, Davis & Co., 169 N.W. 541 (Minn. 1918):

Plaintiff became cyanotic and died during tonsillectomy operation—malpractice action against physicians and negligence action against ether manufacturer—manufacturer allegedly negligent in placing ether on the market which had impurities caused by oxidation due to negligent sealing of the ether container—verdict for plaintiff affirmed.

Wilt v. McCallum, 214 Mo. App. 321, 253 S.W. 156 (1923):

Plaintiff was being administered a nitrous oxide-oxygen mixture through a Heidbrink gas apparatus, with a gas mask over her face, at the time a Wappler electrocautery machine was also in use—gas mask had been washed with alcohol causing possible impurity, since N_2O-O_2 not explosive—explosion inside the mask caused injuries to plaintiff's eyes and facial burns—action against surgeons—no liability if explosion caused by impurities added by manufacturer—*res ipsa loquitur* inapplicable—verdict for plaintiff reversed.

Andrepoint v. Ochsner, 84 So.2d 63 (La. App. 1955):

Plaintiff injured by explosion and fire caused by static electricity coming in contact with explosive gas in anesthetic machine—no defect in anesthetic machine—recovery for plaintiff allowed—hospital negligent in failing to ground machine and take precautions against static electricity.

APPLICATORS

Payne v. Santa Barbara Cottage Hospital, 2 Cal. App. 2d 270, 37 P.2d 1061 (1934):

Nurses employed by plaintiff used toothpick applicators furnished by hospital together with surgical dressings to bandage plaintiff's wounds—applicator worked its way into wound—hospital not liable, because negligence of nurses, plaintiff's agents, in using such applicators contrary to safe practice was sufficient intervening cause—foreseeability of such use not raised.

BONE DRILL

Kaplan v. State, 198 Misc. 62, 95 N.Y.S.2d 890 (Ct. Claims 1950):

Bone drill point broke while defendant physician was drilling hole in head of plaintiff's humerus—*res ipsa loquitur* no applicable to breaking of drill point—malpractice recovery against physician denied—plaintiff could prove no negligent cause for the breaking of the drill point—decision to continue operation nonnegligent.

Zanzon v. Whittaker, 310 Mich. 340, 17 N.W.2d 206 (1945):

Steel bone drill tip, about 1½ inches long, broke off and became imbedded through graft bone in plaintiff's humerus—malpractice action against physician for leaving portion of drill in plaintiff's arm—directed verdict for defendant.

Van Skike v. Potter, 53 Neb. 28, 73 N.W. 295 (1897):

Defendant physician performed surgery on plaintiff's fractured kneecap while attempting to wire it with silver wire—drill point broke off and left imbedded in plaintiff's bone—verdict for defendant—no negligence in leaving broken drill point in bone.

CATHETER

Dickerson v. St. Peter's Hospital, 432 P.2d 293 (Wash. 1967):

Catheter used for intravenous blood transfusion to hip was sequestered—plaintiff recovered against the hospital on negligent failure to properly tape the catheter.

Taylor v. Milton, 353 Mich. 421, 92 N.W.2d 57 (1958):

Filiform tip of catheter inserted in plaintiff's urethra broke off and traveled to plaintiff's bladder—malpractice action based on physician's negligent failure to inform plaintiff of complication and failure to operate to remove filiform tip—verdict for plaintiff sustained.

CONTRAST AGENTS

Ball v. Mallinkrodt Chemical Works, 53 Tenn. App. 218, 381 S.W.2d 563 (1964):

Plaintiff was paralyzed during translumbar aortography when part of an injection of Urokon reached her spinal cord—malpractice action against physician in selecting Urokon and in failing to take scout film—jury verdict for physician—action against Urokon manufacturer based on negligence and breach of implied warranty of fitness—jury verdict for manufacturer—refusal to permit jury to consider

representations of "low toxicity" in sales brochure which relates to breach of express warranty.

DENTAL EQUIPMENT

Thomas v. Leary, 15 App. Div. 2d 438, 225 N.Y.S.2d 137 (1962):

Employee of dentist purchaser was injured when dental chair collapsed—action against seller of dental chair—action based on breach of express and implied warranty maintainable even though employee not purchaser of chair.

Higdon v. Carlebach, 348 Mich. 363, 83 N.W.2d 296 (1957):

Plaintiff's tongue was lacerated when a separator disk on a dentist's drill slipped—malpractice action against dentist—no need for expert testimony.

DERMATOME

South Highlands Infirmary v. Camp, 279 Ala. 1, 180 So.2d 904, 14 A.L.R.3d 1245 (1965):

Hospital furnished a Stryker Dermatome, on which the springs controlling the depth setting adjustment were bent, so that physician removed too thick skin patches from plaintiff's thigh—hospital negligent in failing to examine for patent defects and in supplying defective instrument.

ELECTRO-SURGICAL EQUIPMENT

Smith v. American Cystoscope Makers, 44 Wash. 2d 202, 266 P.2d 792 (1954):

Defective insulation on wiring of electrocautery instrument caused burns on plaintiff's thighs during prostate resection—surgeon and vendor of Wappler Electro-Surgical Unit sued—judgment for defendants affirmed—vendor made no negligent misrepresentations—no duty to inspect for dangerous but hidden latent defects—no proof instrument defective when sold, since it performed properly in fifteen prior operations—suit against manufacturer dismissed for want of jurisdiction.

Hine v. Fox, 89 So. 2d 13 (Fla. 1956):

Electrocautery instrument broke during operation to remove moles from patient's face, causing facial burns—recovery against physician denied—no evidence of negligent handling—no physician duty to inspect for latent defect—dictum that duty to inspect for latent defect rests on manufacturer.

Clary v. Christiansen, 83 N.E.2d 644 (Ohio 1948):

Malpractice action against surgeon—surgeon requested Davis Bovie machine to drain pleural abscess and remove paraffin packing—hospital substituted a Fisher machine—judgment for surgeon affirmed—no negligence in failing to recognize change of machines—plaintiff suffered third degree burns where electrode rested on right thigh.

Delling v. Lake View Hospital Ass'n, 310 Ill. App. 155, 33 N.E.2d 915 (1941):

Electrocauterizing pencil, used in uterine operation, had defective insulation which caused electrical burns about plaintiff's vaginal orifice—negligence action against hospital and physician—verdict for \$2000 sustained—negligence in furnishing defective equipment.

Pariser v. Wappler Electric Co., 145 Misc. 315, 260 N.Y.S. 35 (1932):

Plaintiff suffered burns from electrosurgical instrument designed to remove surplus hair—action against manufacturer—complaint allegations were sufficient to allege defendant marketed inherently dangerous product.

HEART VALVE

Gill v. Surgitool, Inc., 256 Cal. App. 2d 583, 64 Cal. Rptr. 207 (1967):

Death allegedly resulted from myocardial infarction due to defective #3 Magovern aortic valve—service of summons on foreign manufacturer quashed, because manufacturer was not doing business in California.

HEAT BLOCKS

McLaughlin v. Mine Safety Appliances Co., 11 N.Y. 2d 62, 226 N.Y.S.2d 407, 181 N.E.2d 430 (1962):

Nurse applied chemical heat blocks to unconscious child rescued from lake—action against defendant manufacturer, based on failure to warn against use of heat blocks without insulating materials.

HYPODERMIC NEEDLE

Magrine v. Krasnica, 94 N.J. Super. 228, 227 A.2d 539, *aff'd*, 100 N.J. Super. 223, 241 A.2d 637 (1968):

Hypodermic needle stylus broke in plaintiff's jaw—recovery against dentist denied—no strict liability against user of article for injuries caused by latent defect—mandibular block anesthetic injection.

Shoumatoff v. Wiltbank, 226 N.Y.S.2d 576 (1962):

Short one-inch hypodermic needle for mandibular block anesthesia broke in plaintiff's jaw—recovery against dentist denied—no malpractice in failure to use longer needle—broken stylus no basis for *res ipsa loquitur*.

Mandelbaum v. Weil, 208 App. Div. 409, 203 N.Y.S. 289 (1924):

Hypodermic needle broke during tonsillectomy and lodged in throat—recovery against physician denied—no malpractice negligence in breaking of needle or inability to locate and remove stylus.

Tennant v. Barton, 164 Wash. 279, 2 P.2d 735 (1931):

Hypodermic needle stylus, used in local anesthesia during tonsillectomy, broke off in plaintiff's throat—duty of physician and hospital to inspect for patent defects and test for latent defects prior to operation—verdict for plaintiff sustained.

Bernstein v. Greenfield, 281 N.Y. 77, 22 N.E.2d 242 (1939):

Hypodermic needle stylus, used for local anesthesia during tonsillectomy, broke in plaintiff's throat and imbedded there—malpractice verdict for plaintiff against physician sustained—negligence in proceeding with operation and failure to retrieve stylus fragment.

Ribando v. American Cyanamid Co., 37 Misc. 2d 603, 235 N.Y.S.2d 110 (Sup. Ct. 1962):

Hypodermic needle broke off in plaintiff's buttock—action against physician and manufacturer—physician negligent in excessive re-use of needle—recovery against manufacturer denied—physician's subsequent excessive use negated claim based on breach of warranty of fitness—\$10,000 verdict reduced to \$7,500 against physician—dictum that patient is direct intended user, as are household members, so that privity no bar to action against manufacturer.

Cooke-Waite Laboratories, Inc. v. Napier, 166 So.2d 675 (Fla. 1964):

Hypodermic needle used by dentist for anesthesia broke in plaintiff's jaw—tort action for negligent manufacture of defective needle against manufacturer—jurisdiction over foreign corporation denied—not doing business within state.

INCUBATORS—WARMING BOXES

Woodhouse v. Knickerbocker Hospital, 39 N.Y.S.2d 671, *aff'd*, 266 App. Div. 839, 43 N.Y.S.2d 518 (1943):

Broken and defective asbestos pad used in shielding above warming light bulbs in warming box caused burns to newly born baby—hospital held liable for supplying defective heat cradle.

Chadwick v. Air Reduction Co., Inc., 239 F. Supp. 247 (N.D. Ohio 1965):

Right foot of premature infant became lodged in heating element of incubator, causing burns—suit against dissolved corporate manufacturer and purchaser of corporate assets, based on negligent design and failure to warn of dangerous design—subsequent corporation under no duty to warn of prior negligent design—suit against dissolved corporation allowed.

Emory University v. Porter, 103 Ga. App. 752, 120 S.E.2d 668 (1961):

Infant plaintiff was burned by unshielded light bulb in incubator, which had no thermostat control mechanism—action against hospital—no negligence, since alleged incubator was defective, and hospital was under no duty to furnish modern equipment.

Medical & Surgical Memorial Hospital v. Cauthorn, 229 S.W.2d 932 (Tex. Civ. App. 1949):

Light on improvised heat cradle was weighted down on plaintiff's foot, causing burns—recovery for plaintiff against hospital based on negligence allowed.

Cornell v. United States Fidelity & Guaranty Co., 8 So. 2d 364 (La. App. 1942):

Infant plaintiff was burned when he was placed on hot water bottle in incubator whose normal electrical heating equipment was not working—recovery against hospital denied—because use of hot water bottle was nonnegligent accepted practice—defective electrical system of incubator was not proximate cause of accident.

LAMPS

Crowe v. McBride, 25 Cal. 2d 318, 149 P.2d 69, *rev'd*, 153 P.2d 727 (1944):

Infrared deep therapy lamp exploded—no patent defect, and inspection by defendant impossible—jury question on negligence of physician in failing to install protective screen.

Stafford v. St. Clair's Hospital, 19 Misc. 2d 710, 189 N.Y.S.2d 351, *aff'd*, 11 App. Div. 2d 1055, 208 N.Y.S.2d 437 (1959):

Plaintiff suffered second degree burns about his left wrist, caused by defective surgical lamp immediately above operating area, because a light resistor, a heat diffusing device, was removed from the lamp—negligence action against the hospital for failure to correct defective condition—verdict for plaintiff.

See also Annot., 72 A.L.R.2d 413: "Hospital's liability for injury to patient from heat lamp, pad or hot water bottle."

ORTHOPEDIC PROSTHESES

Orthopedic Equipment Co. v. Eutsler, 276 F.2d 455, 79 A.L.R.2d 390 (4th Cir. 1960):

Intramedullary nail with reported diameter of 9mm. actually had diameter of 9.27mm. to 10.12mm.—it was partly driven into the medullary canal of plain-

tiff's femur, where it lodged and could not be withdrawn—Osteomyelitis developed, and plaintiff lost the use of his leg—verdict for plaintiff against manufacturer of Kunstler cloverleaf intramedullary nail sustained, on the grounds of negligent misbranding in violation of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C.A. § 352 (1968).

Bowles v. Zimmer Mfg. Co., 277 F.2d 868, 76 A.L.R.2d 120 (7th Cir. 1960):

Intramedullary pin inserted in plaintiff's left femur bent because it had a crack running the length of the pin—\$45,000 verdict for plaintiff sustained against manufacturer on theory of breach of implied warranty of fitness, Michigan law permitting recovery even in the absence of privity of contract—release to original automobile tortfeasor no bar to action.

Mitchner v. Wright Manufacturing Co. (W.D.D.C. Ind. 1959). Unreported, but summarized in 6 *LAWYERS' MEDICAL CYCLOPEDIA* § 42.33 (1961):

Plaintiff sued manufacturer for injuries caused by breakage of Naden-Reith hip prosthesis, based on improper testing and design—refusal to charge jury on *res ipsa loquitur*—fact of breakage not evidence of negligence by manufacturer.

Clark v. Zimmer Mfg. Co., 290 F.2d 849 (1st Cir. 1961):

Intramedullary nail inserted in plaintiff's right femur snapped or broke—action against manufacturer based on negligent manufacture and implied warranty of fitness—release of original tortfeasor who caused fracture operated as release of claim against nail manufacturer.

Trieschman v. Eaton, 224 Md. 111, 166 A.2d 892 (1961):

Orthopedic steel plate, used in fixation of fracture of left leg, broke at the fracture site—negligence and malpractice action against hospital and physician, and breach of warranty action against hospital for sale of orthopedic plate—release to automobile driver, original tortfeasor, not a bar to suit against physician and hospital.

Cheshire v. Southampton Hospital Ass'n., 53 Misc. 2d 355, 278 N.Y.S.2d 531 (Sup. Ct. 1967):

Intramedullary pin broke when inserted in plaintiff's leg—action against hospital based on breach of implied warranty that pin free from defects—necessity that plaintiff prove sale of pin rather than general services contract in order to recover on warranty theory against hospital.

Inouye v. Black, 238 Cal. App. 2d 31, 47 Cal. Rptr. 313, 14 A.L.R.3d 967 (1967):

Neurosurgeon used stainless steel wire to wire together first and second cervical vertebrae of plaintiff—the wire after remaining in plaintiff's body for two years broke into unusually small fragments and one fragment lodged itself in the lower spine requiring surgical removal—malpractice action against surgeon—recovery denied—*res ipsa loquitur* inapplicable—possibility of negligence of manufacturer or hospital-supplier, neither of which were sued—no evidence of surgeon's negligence.

See also Annot., 14 A.L.R.3d 967 (1967): "Malpractice: liability in connection with injection of prosthetic or other corrective devices in patient's body."

OXYGEN CYLINDER

Liberatore v. National Cylinder Gas Co., 193 F.2d 429 (2d Cir. 1951):

Plaintiff oxygen therapist was injured by explosion through valve at top of pressure oxygen cylinder—suit against manufacturer on negligent manufacture for failure to

tighten a packing nut—judgment for plaintiff affirmed—jury questions properly submitted on proximate cause and contributory negligence.

PAPER CUP

Bernstein v. Lily-Tulip Cup Corporation, 177 So. 2d 362 (Fla. 1965):

Paper cup came apart at handle causing plaintiff to be scalded by hot contents—plaintiff, a hospital patient, was served a drink in paper cup manufactured by defendant—implied warranty suit allowed, lack of privity no bar—defective product manufactured for human consumption or other intimate bodily use.

PROCTOCLYSIS APPARATUS

Ratliffe v. Wesley Hospital, 135 Kan. 306, 10 P.2d 859 (1932):

Patient was severely scalded by hot water when string on Murphy drip proctoclysis apparatus broke, pouring water on bed—negligence action against hospital—failure of nurse to inspect equipment for latent defects is not negligence.

Butler v. Northwestern Hospital of Minneapolis, 202 Minn. 282, 278 N.W. 37 (1938):

Plaintiff was burned by hot water when spring clamp holding water back on Murphy drip proctoclysis apparatus broke, allowing water to drain onto bed—action against hospital for furnishing defective spring clamp, based on negligence and implied warranty of fitness for use—\$5,140 verdict for plaintiff sustained.

PULMOTOR

Huffman v. Lindquist, 37 Cal. 2d 465, 234 P.2d 34, 29 A.L.R.2d 485 (1951):

Plaintiff died from pulmonary embolism—first two pulmotors ordered by attending physicians from hospital did not function—recovery against hospital denied—although failure to have functioning pulmotors was negligence, plaintiff failed to show that such negligence was the proximate cause of death—*res ipsa loquitur* inapplicable.

RECTAL BALLOON AND TUBE

Hoffman v. Nashund, 274 Minn. 521, 144 N.W.2d 580 (1966):

Radiologist's assistant inserted Bar-Dex amphetamine rectal tube with attached balloon for barium enema rectal X-ray study—plaintiff alleged tear in colon caused by negligent use of Bar-Dex tube—recovery against radiologist denied—no causal relationship proven by expert testimony between use of Bar-Dex tube and the colon perforation.

SCALPEL

Phillips v. Powell, 210 Cal. 39, 290 P. 441 (1930):

Blade of scalpel used by physician in performing tracheotomy, a Baird-Parker instrument, broke and imbedded in plaintiff's neck, becoming encysted—malpractice action against surgeon—negligence predicated on using a noncrystallized blade in the operation—new trial ordered after plaintiff's \$25,000 verdict.

SILVER NITRATE PENCIL

Hurt v. Susnow, 192 P.2d 771 (Cal. App. 1948):

Defendant physician outlined plaintiff's varicose veins with a silver nitrate pencil, causing inflammation and blisters where silver nitrate applied—*res ipsa loquitur*

doctrine applied—physician should have ascertained whether plaintiff unusually susceptible to silver nitrate.

STERILIZED PRODUCTS—DISPOSABLES

Cohran v. Harper, 115 Ga. App. 277, 154 S.E.2d 461 (1967):

Plaintiff contracted osteomyelitis from use of contaminated hypodermic in penicillin injection—recovery against physician denied—contamination not discoverable by exercise of ordinary care, nor did physician or nurse cause contamination.

Peck v. Charles B. Towns Hospital, 275 App. Div. 302, 89 N.Y.S.2d 190 (1949):

Plaintiff developed a skin infection when injected by improperly sterilized hypodermic needle—action against hospital—evidence of hospital negligence, in not using closed steam pressure sterilization and in not boiling the instruments long enough, sufficient to take case to jury.

Brown v. Shannon West Texas Memorial Hospital, 222 S.W.2d 248 (Tex. Civ. App. 1949):

Plaintiff suffered infection because needle used for withdrawing blood from her arm during phlebotomy operation was improperly sterilized—recovery against hospital denied—evidence insufficient to show that needle was contaminated or that infection was result of operation—no proof of hospital negligence.

SUTURES

Shepherd v. McGinnis, 257 Iowa 35, 131 N.W.2d 475 (1964):

Plaintiff suffered infection of the wound site of an ovarian cyst operation due to use of contaminated sutures furnished by hospital—negligence action against physician and hospital—verdict for plaintiff against physician and hospital of \$20,000 reversed for new trial as excessive.

THERMOMETER

Payne v. Garvey, 264 N.C. 593, 142 S.E.2d 159 (1965):

Patient was injured by mercury and glass fragments from thermometer which broke when shaken—recovery against physician denied, not responsible for negligence of nurse—recovery against hospital denied—hospital's only duty to make reasonable inspection and remedy patent defects.

UTERINE PACKER

Wharton v. Warner, 75 Wash. 470, 135 P. 235 (1913):

Spring contained in uterine packer, used to absorb blood during uterine curettement, came loose and was forced with the gauze into plaintiff's uterus—malpractice liability imposed for failure to observe broken surgical instrument and inspect for broken parts in the surgical field.

WHEELCHAIR

Holtfoth v. Rochester General Hospital, 304 N.Y. 27, 105 N.E.2d 610 (1952):

Right leg rest of wheelchair in which plaintiff was seated collapsed when she tried to adjust her position, causing refracture of right femur, right hip socket and dislodging of surgical nail—action based on negligent maintenance of equipment by hospital, because foot rest snapped down on very little pressure—duty to provide safe wheelchair a jury question.

Putman v. Erie City Manufacturing Co., 338 F.2d 911 (5th Cir. 1964):

Wheelchair collapsed when wheel came off because of defective fork stem connecting the wheel to the chair, causing plaintiff to break both his previously fractured legs—plaintiff had rented wheelchair from druggist who purchased it from defendant—recovery against manufacturer permitted on strict liability, in absence of privity and jury finding of no manufacturer's negligence.

Martin v. Aetna Casualty & Surety Co., 239 Ark. 95, 387 S.W.2d 334 (1965):

Leg rest of wheelchair in which plaintiff was seated collapsed, throwing plaintiff to floor and causing refracture of left femur and breaking of metal plate attached to femur—negligence action against hospital—*res ipsa loquitur* applied.

See also Annot., 31 A.L.R.2d 1118 (1953): "Liability of hospital for defective wheelchair or similar furniture or appliance."

X-RAY AND FLUOROSCOPIC EQUIPMENT

Nelson v. Swedish Hospital, 241 Minn. 551, 64 N.W.2d 38 (1954):

Plaintiff was struck by the head of a General Electric KX-10 X-ray machine, which had come loose—third party action by hospital against manufacturer—directed verdict for manufacturer sustained, no evidence of negligence in inspection—missing clamp attributed to three years of use—manufacturer's disclaimer effective against breach of warranty claim—hospital and physician negligent in failure to inspect and maintain.

Sinatra v. National X-Ray Products Corp., 26 N.J. 546, 141 A.2d 28 (1958):

Defective insulation of overhead electric cable of X-ray machine—recovery for plaintiff against manufacturer and distributor allowed—manufacturer responsible for inspection of latent and patent defects—recovery based on negligent manufacture and failure to inspect—distributor liable for failure to exercise reasonable care in inspecting for defects.

Thomas v. Pugh, 6 S.W.2d 202 (Tex. Civ. App. 1928):

Improperly insulated electric wire injured plaintiff, a dental nurse—release of manufacturer from liability did not bar suit against seller of X-ray machine for negligent demonstration.

O'Connell v. Westinghouse X-Ray Co., 261 App. Div. 8, 24 N.Y.S.2d 268, *rev'd*, 288 N.Y. 486, 41 N.E.2d 177 (1940):

Plaintiff physician suffered X-ray burns on his hands when he operated under fluoroscopy, without knowledge of radiation hazards or operative techniques—suit against manufacturer of fluoroscope—jury question as to contributory negligence and proximate cause of injuries—manufacturer's negligent design in failing to furnish guard shield, amperage governor, and improperly fitting protective filter.

Johnston v. Black Co., 33 Cal. App. 2d 363, 91 P.2d 921 (1933):

Fluoroscope table broke, throwing plaintiff to the ground—recovery against doctor and nurse denied—*res ipsa loquitur* inapplicable—no negligence for failure to inspect.

Bence v. Denbo, 98 Ind. App. 52, 183 N.E. 326 (1934):

Worn bolt caused dental X-ray machine to fall upon plaintiff's face—*res ipsa loquitur* applied—verdict against dentist sustained.

Repass v. Keleket X-Ray Corp., 212 F. Supp. 406 (N.J. 1962):

Physician purchaser received radiation injuries to hands—suit against seller of fluoroscope based on negligence and breach of warranty—cone of machine not lined with shield of lead coating—action barred by statute of limitations.

Taylor v. Beekman Hospital, 270 App. Div. 1020, 62 N.Y.S.2d 637 (1946):

Action against hospital for injuries caused by electrical shock while plaintiff's foot was X-rayed—negligent maintenance of equipment—discovery of hospital records permitted.

Heberle v. P.R.O. Liquidating Co., 186 So. 2d 280 (Fla. 1966):

Action by osteopath-purchaser of X-ray therapy machine, against manufacturer and seller of machine, based on negligence and implied warranty—defective shielding in control booth of machine—no jurisdiction over Illinois manufacturer not doing business in Florida.

Gross v. Robinson, 203 Mo. App. 118, 218 S.W. 924 (1920):

Plaintiff suffered radiation burns from exposure to X-ray machine, not equipped with filter, over a dozen times within two weeks—malpractice action against physician, based on excessive use of diagnostic X-rays—\$7,500 verdict for plaintiff. See also Annot., 41 A.L.R.2d 329 (1955): "Liability of hospital for injury by X-ray", and Charles E. Dunlap, *Medicolegal Aspects of Injuries from Exposure to Roentgen Rays and Radioactive Substances*, 1 OCCUP. MED. 237 (1946).