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DEFECTIVE PROSTHETIC DEVICES: STRICT TORT LIABILITY FOR THE HOSPITAL?

Hospitals which supply defective medical products—blood, medical instruments, drugs—to patients in the course of treatment have traditionally been liable only for negligent administration of those products, not for defects in the products themselves. This Note examines whether a similar standard should inhere for hospitals which supply defective prosthetic devices. With the increasing use and sophistication of such devices, the issue will assume greater importance. The Model Uniform Product Liability Act precludes strict products liability against hospitals except in limited situations. Because the primary function of a hospital is the supplying of services, not the sale of products, and because the supplying of prosthetic devices is integrally linked to professional medical judgment and opinion, this Note asserts that the UPLA standard is the proper one, and should be used in defective prosthetic device litigation.

INTRODUCTION

JUDICIAL RECOGNITION of a strict liability standard¹ for injuries arising from defectively produced products is a relatively recent development.² Strict products liability extends to manufacturers, wholesalers, and retailers of defective products.³ Traditionally, however, hospitals and the medical profession have been liable for negligent conduct only.⁴

1. See Prosser, *The Assault Upon the Citadel (Strict Liability to the Consumer)*, 69 YALE L.J. 1099 (1960); Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)*, 50 MINN. L. REV. 791 (1966).

2. See W. PROSSER, *HANDBOOK OF THE LAW OF TORTS* § 98, at 657 (4th ed. 1971) (citing *Greenman v. Yuma Power Prods., Inc.*, 59 Cal. 2d 57, 377 P.2d 897, 27 Cal. Rptr. 697 (1963) (first judicial decision to hold a manufacturer of a defective product strictly liable for the resulting injuries)).

3. See W. PROSSER, *supra* note 2, § 100, at 664-65 (4th ed. 1971). California has been one of the more progressive states in applying strict liability. See *Price v. Shell Oil Co.*, 2 Cal. 3d 245, 466 P.2d 722, 85 Cal. Rptr. 178 (1970) (bailors and lessors of personal property); *Vandermark v. Ford Motor Co.*, 61 Cal. 2d 256, 391 P.2d 168, 37 Cal. Rptr. 896 (1964) (retailer); *Garcia v. Halsett*, 3 Cal. App. 3d 319, 82 Cal. Rptr. 420 (1970) (licensor of chattels); *McClaffin v. Bayshore Equip. Rental Co.*, 274 Cal. App. 2d 446, 79 Cal. Rptr. 337 (1969) (commercial lessors of property); *Kriegler v. Eichler Homes, Inc.*, 269 Cal. App. 2d 224, 74 Cal. Rptr. 749 (1969) (housing developer); *Barth v. B.F. Goodrich Tire Co.*, 265 Cal. App. 2d 228, 71 Cal. Rptr. 306 (1968), *modified*, 15 Cal. App. 3d 137, 92 Cal. Rptr. 809 (1971) (wholesale and retail distributor).

4. See Rubin, *Manufacturer and Professional User's Liability for Defective Medical Equipment*, 8 AKRON L. REV. 99, 99-104 (1974); Note, *Products and the Professional: Strict Liability in the Sale-Service Hybrid Transaction*, 24 HASTINGS L.J. 111, 120-32 (1972); Note, *The Medical Profession and Strict Liability for Defective Products—A Limited Extension*, 17 HASTINGS L.J. 359, 365-66 (1965).

Historically, hospitals were protected from all tort liability under the doctrine of charitable immunity. See D. WARREN, *PROBLEMS IN HOSPITAL LAW* 9 (3d ed. 1978). A loss of

Section 402A of the *Restatement (Second) of Torts*⁵ imposes a strict liability standard on "sellers" of defective products. Hospitals and the medical profession, under a traditional common law approach, are not considered to be product "sellers." Rather, most courts reason that transactions between hospitals or members of the medical profession and their patients are primarily contracts for services.⁶ These jurisdictions have held that incidental and secondary transfers of medical products and devices during the performance of services do not qualify as sales.⁷

The service exception to strict products liability, however, is not absolute. Some jurisdictions hold that if the service element is of a routine, commercial nature and the sales aspect predominates, strict liability will attach.⁸

Other courts, however, have reasoned that a patient's contract with a hospital is divisible into separate service and sales ele-

assets intended for charitable purposes was considered to be against public policy. *Id.* With the present availability of liability insurance for charitable institutions, however, nearly every state abandoned this doctrine, recognizing that charitable institutions are obligated to compensate injured persons. *See id.* Today nongovernmental hospitals, thus, are liable for the acts of their employees operating within the scope of their employment.

Liability against governmental hospitals is somewhat uncertain. Federal hospitals face limited liability under the Federal Torts Claims Act, and governmental immunity exists only in approximately one-half of the states for officers, agents, and employees of state hospitals. Moreover, liability of county and municipal hospitals is determined by several factors which vary by jurisdiction. *Id.* at 10-13.

5. RESTATEMENT (SECOND) OF TORTS § 402A (1965). Section 402A states:

(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

(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.

Id. A manufacturer, distributor, wholesaler, or retailer is held strictly liable in tort, without regard to fault, when an article is placed on the market which has not been inspected for a defect, and which later proves to have an unreasonably dangerous defect which causes injury. Defects usually arise in design, manufacturing, warning, or labeling. *See W. PROSER, supra* note 2, § 99, at 659.

6. *E.g.*, *Perlmutter v. Beth David Hosp.*, 308 N.Y. 100, 104-06, 123 N.E.2d 792, 794-95 (1954); *see also infra* notes 56-85 and accompanying text.

7. *See infra* notes 56-71, 79-85 & 100-05 and accompanying text.

8. *See Newmark v. Gimbel's, Inc.*, 54 N.J. 585, 258 A.2d 697 (1969) (extending strict liability to the commercial service area by holding a beauty operator strictly liable for a defective product applied to a customer's hair). *See generally supra* note 3 and accompanying text.

ments, and that the hospital may be strictly liable for product defects under the sales aspect.⁹ Moreover, a minority of jurisdictions have spurned the sales/service distinction completely, determining the applicability of a strict products liability standard on an ad hoc basis.¹⁰

The courts have not conclusively determined the applicability of strict products liability standards to hospitals which supply defective prosthetic devices.¹¹ The drastic increase in the use, complexity, and development of prosthetic devices¹² will undoubtedly result in greater numbers of injuries to patients, thus presenting new questions concerning hospital liability.¹³ This Note examines the possible application of a strict products liability standard to

9. See *Silverhart v. Mount Zion Hosp.*, 20 Cal. App. 3d 1022, 98 Cal. Rptr. 187 (1971); *Cunningham v. MacNeal Memorial Hosp.*, 47 Ill. 2d 443, 266 N.E.2d 897 (1970); *Cheshire v. Southampton Hosp. Ass'n*, 52 Misc. 2d 355, 278 N.Y.S.2d 531 (Sup. Ct. 1967) (mem.); see also *infra* notes 72-79, 86-102 & 118-24 and accompanying text. Transactions involving both services and products are considered "hybrid" transactions. The sales/service transaction has created difficulty for many courts in determining the applicability of products liability. It is argued that a hybrid transaction occurs when a hospital implants a prosthetic device since the patient receives both professional service and a product.

10. See *Johnson v. Sears Roebuck & Co.*, 355 F. Supp. 1065 (E.D. Wis. 1973); see also *infra* notes 125-36 and accompanying text.

11. A prosthetic device is an artificial device used to replace a bodily part. Artificial organs and devices are now used in virtually every aspect of human medicine. Examples include devices which replace the breast, ureter, heart, lungs, kidneys, limbs, teeth, liver, eyes, nose, and ears. Metcalf, *Legal Problems in Medical Device Development*, 44 INS. COUNSEL J. 408 (1977). Dramatic advances in the development of electronic chips and microprocessors have helped lead to the development of more advanced heart pacemakers and effective new artificial limbs and organs. Examples of recent advances include artificial hearts, electronic elbows, arms, knees, and ears and manmade blood and skin. See Flaherty, *A Delicate Legal Operation*, NAT'L L.J., Dec. 20, 1982, at 3, col. 1; Marbach, *Building the Bionic Man*, NEWSWEEK, July 12, 1982, at 78-79; Kucheroy, *More Spare Parts for the Human Body*, U.S. NEWS & WORLD REPORT, Dec. 28, 1981/Jan. 4, 1982, at 76-77.

12. The variety of products offered for medical treatment increased exponentially in the last twenty years as 2000 companies produced over 12,000 different devices totaling five billion dollars in annual retail sales. Between 1960 and 1970, these devices caused an estimated 10,000 injuries—including 731 deaths. Shaffer & Gordon, *Clinical Engineering Liability in the Hospital*, 9 LAW. MED. J. 2d 273, 288-89 (1981).

13. It is possible that under certain circumstances a plaintiff injured by a defective prosthetic device will seek recovery directly from the hospital. These circumstances are present when jurisdictional problems preclude the plaintiff's chosen forum from exercising jurisdiction over the manufacturer or, when the manufacturer is insolvent. See *infra* note 176 and accompanying text. Insolvency is a very real possibility since the medical device industry is composed of many small companies dependent for survival on technology and innovation. See Rogers, *Medical Device Law—Intent and Implementation*, 36 FOOD, DRUG COSM. L.J. 4, 7-8 (1981). Furthermore, if one of these small companies produced or designed a defective device, the lawsuits arising from the defective product would quickly render the company insolvent.

hospitals supplying prosthetic devices¹⁴ by focusing on the sales/service hybrid transaction and determining whether hospitals should be classified as sellers of prosthetic devices or merely as providers of services.¹⁵ Judicial decisions regarding blood transfusions,¹⁶ medical instruments,¹⁷ drugs,¹⁸ and other products¹⁹ will be analyzed and analogized to defective prosthetic devices.

This Note examines the traditional policy rationales underlying imposition of a strict products liability standard²⁰ and concludes that they do not support its application to hospitals in this context. Moreover, the Note discusses the use by hospitals of the defenses of assumption of the risk,²¹ product misuse,²² and the unavoidably unsafe product doctrine.²³ The Note concludes by examining the Model Uniform Products Liability Act (UPLA) and its application to the hospital supplying defective prostheses.²⁴

I. POLICY JUSTIFICATIONS FOR IMPOSING STRICT LIABILITY

Although it might appear inequitable to impose liability on an individual who is not at fault in a traditional sense and who has exercised all possible care, this is the end result of the doctrine of strict products liability. Four policy rationales are utilized to justify imposition of a strict products liability standard.²⁵

14. This Note will examine only those injuries which are caused by implanted or attached devices and does not discuss injuries caused by external machines and devices. Injuries caused by implanted or attached prosthetic devices are arguably more susceptible to a strict products liability standard than injuries caused by external machines. A prosthetic device leaves the hospital's (retailer's) possession and is received by the patient (consumer). This transfer of possession creates the implication that a sale has occurred. With external devices there is no such transfer of property.

15. *See infra* notes 52-64, 71-102 & 111-24 and accompanying text. It is assumed that an unreasonably dangerous defect or condition exists. Products liability exposure exists, therefore, if the transaction is characterized as a sale and the hospital is deemed a seller of the prosthetic device.

16. *See infra* notes 57-64 and accompanying text.

17. *See infra* notes 65-78 and accompanying text.

18. *See infra* notes 100-11 and accompanying text.

19. *See infra* notes 112-24 and accompanying text.

20. *See infra* notes 28-41 and accompanying text.

21. *See infra* notes 138-39 and accompanying text.

22. *See infra* notes 140-45 and accompanying text.

23. *See infra* notes 146-50 and accompanying text.

24. *See infra* notes 151-65 and accompanying text.

25. For an examination of various policy rationales supporting strict products liability, see *Escola v. Coca Cola Bottling Co.*, 24 Cal. 2d 453, 461-68, 150 P.2d 436, 440-44 (1944) (Traynor, J., concurring); *see also* Comment, *Dubin v. Michael Reese Hosp. & Medical Center: The Application of Strict Liability to Hospital-Supplied X-Radiation Treatments*,

The first policy rationale advanced is the "loss spreading" theory, which advocates the spreading of costs associated with injuries caused by defective products throughout the community, rather than forcing the injured party to bear the entire loss.²⁶ The product manufacturer or retailer is in a better position vis-a-vis the consumer to spread the costs associated with defective products and resultant liability by either increasing the product's price or purchasing liability insurance.²⁷

This theory only supports imposition of a strict liability standard on a large hospital performing a substantial volume of surgery involving a particular prosthetic device. A large hospital in this situation would be in a position to spread compensation costs by either raising its medical care costs or by purchasing additional liability insurance. The smaller hospital, however, may have neither sufficient patient volume nor sufficient income to spread compensation costs to its patients.²⁸ Moreover, an increase in the present high cost of medical liability insurance would create a significant burden for the smaller hospital.²⁹ The validity of the loss spreading theory, therefore, is primarily dependent on the size of the hospital involved.

The second policy justification for imposition of a strict liability standard is the "resource allocation" theory.³⁰ Under this theory the purchase price of a product should incorporate the cost of compensation payments to consumers injured by the defective product.³¹ The failure to internalize these costs in the product's purchase price creates artificially low prices and overproduction. Once product costs are internalized, the "true" cost of those products which cause injuries to consumers would be greater than

13 J. MAR. L. REV. 485, 500 (1980) (social policy now requires imposition of a products liability standard on a seller of professional services who also transfers title to the goods).

26. See Franklin, *Tort Liability for Hepatitis: An Analysis and a Proposal*, 24 STAN. L. REV. 439, 463 (1972).

27. See Calabresi, *Some Thoughts on Risk Distribution and the Law of Torts*, 70 YALE L.J. 499, 520 (1961).

28. A total of 47.17% of the 5830 community hospitals reporting to the 1980 Annual Survey of the American Hospital Association had fewer than 100 beds, and the average hospital size was only 169 beds. AMERICAN HOSPITAL ASSOCIATION, *1980 Annual Survey*, at xiv-xv (1981 ed.) [hereinafter cited as ANNUAL SURVEY].

29. The average cost per inpatient day in community hospitals was \$284.96 in 1980, a 14.1% increase over 1979. ANNUAL SURVEY, *supra* note 28, at xviii. Thus, any increase in a hospital's fixed costs, such as liability insurance premiums, would result in still higher costs to its patients.

30. Franklin, *supra* note 26, at 463.

31. Calabresi, *The Decision for Accidents: An Approach to Nonfault Allocation of Costs*, 78 HARV. L. REV. 713, 718 (1965).

those products which cause less injuries. The result would be increased sales of the safer product and decreased sales of the dangerous product. This shift in resources away from the more dangerous product would therefore reduce the number of injuries, since there would be economic inducement to purchase safer products.³²

Resource allocation theory assumes that the manufacturer is in the best position to allocate compensation costs as a component of the product's purchase price.³³ When compensation costs are internalized at the manufacturer level, the "true" cost of a particular product is accurately reflected. The manufacturer can internalize cost through a slight price increase in all products it produces. Hospitals, however, would be required to increase dramatically the purchase price of the small number of products it supplies. In other words, imposing compensation costs on hospitals creates artificially high product prices resulting in underproduction due to decreased consumer demand. The hospital in this situation is merely a product distributor, supplying a small, geographically distinct market. The manufacturer, however, can allocate compensation costs equally among all of the products it produces, creating a uniform product price. Resource allocation theory, therefore, does not support the application of a strict liability standard on the hospital.

The third major policy rationale advanced is the "least cost preventer theory," which states that the party with the greatest control and knowledge of the product should bear ultimate responsibility for product defects.³⁴ A party, realizing it will be held strictly liable for injuries caused by its defective products, ideally will exercise greater control over product production, thereby producing a safer product. The least cost preventer theory imposes liability on the party with the greatest control over the product because corrective measures can be implemented with the least cost. A prosthetic device manufacturer who exercises ultimate control over product design, testing, and production fits within this policy rationale. But a hospital, because of its overall lack of control over prosthetic device production, is not a least cost preventer.

It is conceivable that a hospital, if designated by the manufac-

32. See Franklin, *supra* note 26, at 463.

33. See Calabresi, *supra* note 27, at 506-07.

34. See Franklin, *supra* note 26, at 462 (citing *Escola v. Coca Cola Bottling Co.*, 24 Cal. 2d 453, 462, 150 P.2d 436, 440-41 (1944) (Traynor, J., concurring)).

turer as a distributor and authorized to adjust, inspect, or maintain the prosthetic device, would be in a least cost preventer position.³⁵ A hospital, however, could merely inventory the devices prior to implantation without performing any significant inspection or maintenance functions. Moreover, some products may have latent defects which are impossible to detect without disassembly or sophisticated testing. Furthermore, the doctors or hospital employees responsible for product inspection arguably lack sufficient mechanical or engineering knowledge to detect latent design or construction defects.³⁶ Thus, latent defects in design or material would not be apparent in a pre-operation inspection.³⁷ Under the least cost preventer theory, therefore, unless the hospital has significant maintenance and inspection duties, there is insufficient control and knowledge of the device to justify imposition of strict liability.

A hospital may be in a position to exert indirect control over product production by applying economic pressure on the manufacturer. If a manufacturer's product proves to be unreliable, the hospital may threaten to switch product lines unless product safety increases. This economic threat would force the manufacturer to produce safer products. For some prosthetic devices, however, there may be no alternative product. The hospital is then placed in the difficult position of continuing to use the unreliable product or to discontinue its use altogether.

The final policy justification for imposition of a strict liability standard occurs when the defendant's complete control over and knowledge of the product's production process makes it difficult for the plaintiff to prove lack of due care.³⁸ Liability is imputed

35. Since a hospital is liable for negligence in inspection, maintenance, or care of prosthetic devices within its control, imposing products liability arguably would have little or no impact on this already high standard of care.

36. Mechanical failures of implants fall into three main categories: plastic failure, brittle failure, and fatigue failure. R. Wirquist & V. Frankel, *Complications of Implant Use*, in 1 *COMPLICATIONS IN ORTHOPAEDIC SURGERY* 100 (G. Epps, Jr., ed. 1978). Detection of improper or defective plastics or metals used in implants would require sophisticated testing of material stress capabilities.

37. When contemplating surgery the implanting surgeon should ask three questions: (1) what kinematic function the implant must serve; (2) what is the expected load on the implant; and (3) what is the expected life of the implant. *Id.* at 99. The implanting surgeon, therefore, is primarily concerned with choosing the appropriate implant for the purpose needed rather than detecting latent product defects.

38. See Franklin, *supra* note 26, at 461. The author asserts that the defendant's complete control and expert knowledge of the production process can overcome the plaintiff's initial advantage obtained under the doctrine of *res ipsa loquitur* through a showing of the defendant's due care. *Id.*

upon the showing of a product defect and exclusive control by the defendant over the production of the product. Strict liability is imposed to avoid a wasteful trial with potentially erroneous results.³⁹ But the factual circumstances which result in imposition of a strict liability standard upon a manufacturer are not applicable to a hospital. The mere existence of a defect does not implicitly require finding the hospital negligent. It is quite possible that the defect occurred during the design or manufacturing process. Furthermore, the factual circumstances surrounding the handling and implantation of prosthetic devices by hospitals will not preclude plaintiffs from establishing negligence. The defendant hospital is, increasingly, a local hospital,⁴⁰ making access to records and witnesses relatively easy. Finally, hospitals often lack the substantial control and knowledge of the product⁴¹ which might hinder a plaintiff attempting to establish negligence.

The traditional policy justifications for imposing strict liability, therefore, are of limited effectiveness when applied to the hospital-patient transaction. Loss spreading is only effective in a large hospital setting where the particular prosthetic device is used in a number of operations.⁴² Neither the resource allocation⁴³ nor the probable negligence theories⁴⁴ have much applicability to a hospital providing implantation services. Finally, the least cost prevention theory⁴⁵ mandates imposition of a strict liability standard only if the hospital performs significant product maintenance or inspection functions.

Most jurisdictions refuse to impose a strict liability standard on a transaction unless it involves a sale,⁴⁶ reasoning that the traditional policy rationales are not applicable to a service transaction.⁴⁷ The critical legal issue, therefore, is whether a hospital

39. *Id.*

40. Traditionally the implantation of complicated experimental devices is centered in a few large research hospitals. As the use of the device becomes accepted within the medical community, the knowledge and technology needed to implant these devices filters down to the local hospital level.

41. *See supra* notes 34-37 and accompanying text.

42. *See supra* notes 27-29 and accompanying text.

43. *See supra* notes 30-32 and accompanying text.

44. *See supra* notes 38-40 and accompanying text.

45. *See supra* notes 34-37 and accompanying text.

46. *See* W. PROSSER, *supra* note 2, § 104, at 679-80.

47. *See, e.g.,* Gagne v. Bertraine, 43 Cal. 2d 481, 489, 275 P.2d 15, 20-21 (1954); Board of Trustees of Union College v. Kennerly, Slomanson & Smith, 167 N.J. Super. 311, 317-18, 400 A.2d 850, 853-54 (Law Div. 1979) (citing *City of Mounds View v. Waljarvi*, 263 N.W.2d 420, 424 (Minn. 1978)). *But see* Hoven v. Kelble, 79 Wis. 2d 444, 468, 256

should be deemed a seller of products rather than solely a provider of professional services. This Note will analyze those cases which involve the sales/service distinction and which are analogous to the situation where a hospital provides implantation services involving a defective prosthetic device.

II. HOSPITAL LIABILITY UNDER SECTION 402A

Section 402A of the *Restatement (Second) of Torts*⁴⁸ is the embodiment of strict products liability case law.⁴⁹ Section 402A imposes strict liability on "sellers," *i.e.*, those "engaged in the business of selling such a product."⁵⁰ Although strict products liability has also been imposed upon persons who provide only commercial services,⁵¹ it has not been imposed upon those who provide *professional services*. Consequently, it must be determined whether the transfer of a prosthetic device from hospital to patient constitutes a sale (to which strict liability or warranties can apply) or is an inseparable part of the professional medical services provided (to which strict liability has not been applied). Since few courts have faced this issue,⁵² other hospital product cases will be analyzed to determine the ultimate analytical approach.

A. Development of the Sales/Service Distinction

Most jurisdictions have consistently held that a sale does not take place when a hospital provides a product during the rendition of medical services.⁵³ A few recent decisions, however, have held hospitals strictly liable by finding the existence of sales elements in the transaction.⁵⁴ These latter cases rarely are followed by other jurisdictions and have stimulated legislative actions limit-

N.W.2d 379, 391 (1977) ("[I]t may be admitted that many of the justifications for strict liability have force regarding professional medical services.")

48. RESTATEMENT (SECOND) OF TORTS § 402A (1965); see *supra* notes 5 & 8.

49. W. PROSSER, *supra* note 2, § 102, at 657-58.

50. See *supra* note 8.

51. See *Newmark v. Gimbel's, Inc.*, 54 N.J. 585, 258 A.2d 697 (1969).

52. See *Cheshire v. Southampton Hosp. Ass'n*, 53 Misc. 2d 355, 278 N.Y.S.2d 531 (Sup. Ct. 1967) (mem.); *Cutler v. General Elec. Co.*, 4 U.C.C. Rep. Serv. 300 (Callaghan) (N.Y. Sup. Ct. 1967); *Dorfman v. Austenal, Inc.*, 3 U.C.C. Rep. Serv. 856 (Callaghan) (N.Y. Sup. Ct. 1966); see also *infra* notes 104-16 and accompanying text for a discussion of these cases.

53. See *infra* notes 56-89 and accompanying text.

54. See *Cunningham v. MacNeal Memorial Hosp.*, 47 Ill. 2d 443, 266 N.E.2d 897 (1970); *Providence Hosp. v. Truly*, 611 S.W.2d 127 (Tex. Civ. App. 1980); see also *infra* notes 91-102, 118-24 and accompanying text for a discussion of these cases.

ing their effectiveness.⁵⁵

1. *Majority Rule: Existence of a Service*

In the leading case of *Perlmutter v. Beth David Hospital*,⁵⁶ the plaintiff, a hospital patient, contracted hepatitis after receiving a transfusion of contaminated blood.⁵⁷ The complaint alleged that when the hospital supplied the blood, the transaction constituted a sale⁵⁸ within the Sales Act.⁵⁹ The plaintiff argued that since a sale had occurred, the hospital, in supplying contaminated blood, had breached the implied warranty of quality.⁶⁰ The court rejected

55. See *infra* notes 104-16 and accompanying text.

56. 308 N.Y. 100, 123 N.E.2d 792 (1954).

57. In the typical blood transfusion transaction, the hospital purchases blood from a blood bank and then provides this blood for patient use. In some instances the blood is contaminated, thereby causing a possible fatal case of serum hepatitis. This is a similar situation to when hospitals purchase defective prosthetic devices which cause injury after implantation. In both circumstances the hospital is playing an intermediate role between the blood bank or manufacturer and patient.

58. The hospital charged the patient sixty dollars for the blood. 308 N.Y. at 103, 123 N.E.2d at 793.

59. N.Y. PERSONAL PROPERTY LAW § 96 (McKinney 1949) (repealed in 1964 by the Uniform Commercial Code).

60. 308 N.Y. at 103, 123 N.E.2d at 793. Although this case was argued as a breach of an implied warranty of quality the key issue in this and a products liability action is whether a sale occurred. Section 15 of the Sales Act provided for an "implied warranty or condition . . . of goods supplied under a contract to sell or a sale." *Id.* The successor to the Sales Act, the Uniform Commercial Code, now provides greater protection to purchasers. However, the fundamental restriction—the existence of a sale of goods—remains. Section 2-314 of the U.C.C., covering implied warranties of merchantability, states that: "Unless excluded or modified . . . a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." U.C.C. § 2-314 (1978). In addition, § 2-315, which covers implied warranties of fitness for a particular purpose, states:

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified . . . an implied warranty that the goods shall be fit for such purpose.

U.C.C. § 2-315 (1978). In an action for breach of a U.C.C. implied warranty three defenses may be raised which are not applicable to a strict tort products liability action: (1) that the plaintiff and defendant were not in privity, U.C.C. § 2-318; (2) that the plaintiff did not give timely notice of the breach to the defendant, U.C.C. § 2-607(3)(a); (3) that defendant effectively disclaimed such warranties. U.C.C. § 2-316. 1 R. HURSH & H. BAILEY, AMERICAN LAW OF PRODUCTS LIABILITY § 4:8 (2d ed. 1974). For a comparison of breach of warranty and products liability actions, see generally Rapson, *Products Liability Under Parallel Doctrines: Contrasts Between the Uniform Commercial Code and Strict Liability in Tort*, 19 RUTGERS L. REV. 692 (1965); Shanker, *Strict Tort Theory of Products Liability and the Uniform Commercial Code: A Commentary on Judicial Eclipses, Pigeonholes and Communication Barriers*, 17 W. RES. L. REV. 5 (1965); Shanker, *A Case of Judicial Chutzpah (The Judicial Adoption of Strict Tort Products Liability Theory)*, 11 AKRON L. REV. 697 (1978); Shanker, *A Re-examination of Prosser's Products Liability Crossword Game: The*

this contention, reasoning that the transaction between the plaintiff and the hospital was essentially a contract for services and was not divisible into separate sale and service components.⁶¹ The court stated that "[i]t has long been recognized that, when service predominates, and transfer of personal property is but an incidental feature of the transaction, the transaction is not deemed a sale within the Sales Act."⁶² The court deemed the supplying of blood a minor act, subordinate to the hospital's primary function of providing a trained staff and specialized facilities to restore a patient's health.⁶³ Finally, the court noted that there existed no means of detecting or treating those with contaminated blood, thus implying that it would be inequitable to hold a hospital liable if it was unable to detect a defect.⁶⁴

Silverhart v. Mount Zion Hospital,⁶⁵ a leading medical instrument case,⁶⁶ involved a patient injured when a surgical needle broke during an operation and lodged in the patient's pelvic area.⁶⁷ The patient alleged that the hospital was strictly liable because it was the supplier of a defective product.⁶⁸ The court noted, however, that strict liability applies only to defendants who either play an integral part in production and marketing of the

Strict or Stricter Liability of Commercial Code Sales Warranty, 29 CASE W. RES. L. REV. 550 (1979).

61. *Perlmutter*, 308 N.Y. at 104, 123 N.E.2d at 794. A minority of New York cases indicate that the existence of a sale is dependent upon whether the warranty of blood quality is expressed or implied. See *Napoli v. St. Peter's Hosp. of Brooklyn*, 213 N.Y.S.2d 6 (1961) (cause of action alleged the existence of an express warranty; *Perlmutter*, however, was decided on an implied warranty theory); cf. *Payton v. Brooklyn Hosp.*, 21 A.D.2d 898, 252 N.Y.S.2d 419 (1967) (Kleinfeld, J., dissenting).

62. *Perlmutter*, 308 N.Y. at 104, 123 N.E.2d at 794.

63. *Id.* at 106, 123 N.E.2d at 795.

64. *Id.* at 106-07, 123 N.E.2d at 795. The inability to detect a defect, however, is irrelevant in an implied warranty or products liability action. Absolute liability is imposed whenever a defect is discovered. RESTATEMENT (SECOND) OF TORTS § 402A (1965) ("although . . . the seller has exercised all possible care in the preparation and sale of his product."); see *infra* note 97 and accompanying text. But cf. *infra* notes 154-58 and accompanying text for a discussion of the unavoidably unsafe product doctrine in which the seller's ability to detect a defect is a relevant consideration.

65. 20 Cal. App. 3d 1022, 98 Cal. Rptr. 187 (1971).

66. Injuries caused by defective medical instruments provides an interesting comparison to the defective implanted device problem. Defective medical instruments do not present all of the problems encountered by defective prosthetic devices and impure blood or drugs. Medical instruments are not intended to be implanted or introduced into a patient's body as are blood, drugs, and prosthetic devices, thus, there is no intended transfer of personalty from hospital to patient. See *supra* note 57. The medical instrument cases do, however, provide valuable insights into the sales/service distinction in medical care.

67. 20 Cal. App. 3d at 1025, 98 Cal. Rptr. 189.

68. *Id.* at 1026, 98 Cal. Rptr. 190.

product or who are a link in the chain of distribution from manufacturer to consumer.⁶⁹ The court observed that the chain of distribution ended with the hospital, the ultimate user of the needle.⁷⁰ Furthermore, the hospital was not in the business of selling needles, nor did it intend to transfer the needle to the patient during the rendition of medical services.⁷¹

Although the *Silverhart* case rejects strict liability in the medical instrument situation, the opinion⁷² arguably would support holding the hospital strictly liable when it supplies a defective prosthetic device. A hospital could easily be considered an integral part of the marketing of a prosthetic device. Moreover, the hospital is certainly a link in the chain of distribution from manufacturer to consumer. Finally, the chain of distribution of a prosthetic device does not end with the hospital. The ultimate consumer of a prosthetic device is the patient. These factors point to imposing strict liability under the preliminary *Silverhart* analysis.

The *Silverhart* court, however, relied heavily on *Carmichael v. Reitz*,⁷³ which held that strict liability is not applicable to a prescribing doctor whose patient suffered adverse side effects from an impure drug.⁷⁴ The *Carmichael* court reasoned that the physician was not a product seller but merely provided services utilizing skill and judgment derived from specialized training and knowl-

69. *Id.* at 1028, 98 Cal. Rptr. 191.

70. *Id.*

71. See *Magrine v. Krasnica*, 94 N.J. Super. 228, 227 A.2d 539 (Law Div. 1967), *aff'd sub nom. Magrine v. Spector*, 100 N.J. Super. 223, 241 A.2d 637 (App. Div. 1968), *aff'd per curiam* 53 N.J. 259, 250 A.2d 129 (1969) (similar rationale applied to dentists using a defective instrument in rendering professional services); *Barbee v. Rogers*, 425 S.W.2d 342 (Tex. 1968) (optometrists). *But see Newmark v. Gimbel's, Inc.*, 54 N.J. 585, 258 A.2d 697 (1969) (beauty operator who provides a routine commercial service is subject to products liability standard when using defective products). For an interesting variation of the *Silverhart* rule, see *Anderson v. Somberg*, 134 N.J. Super. 1, 338 A.2d 35 (App. Div.) *aff'd* 67 N.J. 291, 338 A.2d 1 (1973) (suit against surgeon, hospital, manufacturer, and supplier of defective forceps that broke and remained in patient's body after surgery; the court held that the mere occurrence of accident indicated liability of one or more of the defendants and thus, shifting the burden of proof to defendants and requiring them to come forward with explanatory and exculpatory evidence).

72. See *supra* notes 69-71 and accompanying text.

73. 17 Cal. App. 3d 958, 95 Cal. Rptr. 381 (1971).

74. *Id. But cf. Mouran v. Mary Fletcher Hosp.*, 318 F. Supp. 297 (D. Utah 1970), (dictum that the U.C.C.'s warranty sections could apply to a hospital which provides anesthesia; the court stated that since implied warranties have been extended to sales of new houses, to be consistent with that rationale, they also should apply to hospitals which provide anesthesia).

edge.⁷⁵ The *Carmichael* court approvingly quoted *Perlmutter v. Beth David Hospital*⁷⁶: "The art of healing frequently calls for a balancing of risks and dangers to the patient. Consequently, if injury results from the course adopted where no negligence or fault is present, liability should not be imposed on [a professional] seeking to save or otherwise assist the patient."⁷⁷ Thus, although *Silverhart* contains language that could arguably point to strict liability for suppliers of defective prosthetic devices,⁷⁸ that reading would be conceivable only if the prosthetic devices, unlike medical instruments used in an operation, were found to have been "sold."

Three lower court opinions from New York, following *Perlmutter*,⁷⁹ specifically address the issue of whether hospitals which provide defective prosthetic devices are sellers of those products. In *Dorfman v. Austenal Inc.*,⁸⁰ and *Cutler v. General Electric Co.*,⁸¹ warranty principles were held inapplicable to hospitals or physicians because neither sells prosthetic devices. In *Dorfman*, the hospital was sued for breaching an implied warranty of fitness for a particular purpose⁸² by implanting a defective surgical pin into a patient's hip. The court, following *Perlmutter*, held that the hospital's primary activity was not the selling of surgical pins,⁸³ stating: "The incidental furnishings of medicines and supplies in the treatment and care of the patient—granted the patient is charged for them—does not create a separate and additional relationship be-

75. 17 Cal. App. 3d at 979, 95 Cal. Rptr. at 393. The court stated:

[T]here is a difference in status or classification between those upon whom the courts have heretofore imposed the doctrine of strict liability and a physician who prescribes an ethical drug to achieve a cure of the disorders for which the patient has sought his professional services. The former act basically as mere conduits to the distribution of the product to the consumer; the latter sells or furnishes his services as a healer of illnesses.

Id.; see also *Osborn v. Kelley*, 61 A.D.2d 367, 402 N.Y.S.2d 463 (1978); *Batiste v. American Home Prods. Corp.*, 32 N.C. App. 1, 231 S.E.2d 269, cert. denied, 292 N.C. 466, 233 S.E.2d 921 (1977) (products liability standard not applicable to a doctor who provides drugs to his patients; doctor was rendering services not selling products).

76. 308 N.Y. 100, 123 N.E.2d 792 (1954). For a discussion of *Perlmutter*, see *supra* notes 56-64 and accompanying text.

77. 17 Cal. App. 3d at 979, 95 Cal. Rptr. at 393 (quoting *Perlmutter*, 308 N.Y. at 107, 123 N.E.2d at 795).

78. See *supra* notes 69-72 and accompanying text.

79. 308 N.Y. 100, 123 N.E.2d 792 (1954); see *supra* notes 56-64 and accompanying text for a discussion of this case.

80. 3 U.C.C. Rep. Serv. 856 (Callaghan) (N.Y. Sup. Ct. 1966).

81. 4 U.C.C. Rep. Serv. 300 (Callaghan) (N.Y. Sup. Ct. 1967).

82. See *supra* note 60.

83. 3 U.C.C. Rep. Serv. at 857.

tween them of seller and purchaser for those items."⁸⁴ The court in *Cutler* similarly held that supplying a pacemaker is a secondary function of the hospital's rendition of medical services and is therefore not within the provisions of Article II of the Uniform Commercial Code.⁸⁵

*Cheshire v. Southampton Hospital Association*⁸⁶ acknowledges that a patient may successfully sue a hospital by showing that a sale occurred, but the holding offers little additional aid to plaintiffs.⁸⁷ The court interpreted *Perlmutter* not as an outright prohibition on classifying the hospital-patient transaction as a sale but as indicating the difficulties a patient would encounter in distinguishing a sale from the overall transaction for services.⁸⁸ The court reasoned that "[s]ince it *may be possible* to prove a sale here somewhere, as opposed to an overall services contract, we cannot dismiss the complaint on grounds of presumptive insufficiency."⁸⁹ Of these three cases, then, *Dorfman* and *Cutler* completely reject sales status for the supplying of prosthetic devices, while *Cheshire* holds out only the mere possibility that a plaintiff might establish a sale.

2. *Minority Rule: Existence of a Sale*

a. *Strict Liability in Tort: Cunningham v. MacNeal Memorial Hospital.*⁹⁰ The *Perlmutter* rationale was followed throughout the 1950's and 1960's.⁹¹ In 1970, however, the Illinois Supreme

84. *Id.*

85. 4 U.C.C. Rep. Serv. at 301; *see also* *Ruybe v. Gordon*, 18 U.C.C. Rep. Serv. 889 (Callaghan) (N.Y. Sup. Ct. 1976); *Schuchman v. Johns Hopkins Hosp.*, 9 U.C.C. Rep. Serv. 637 (Callaghan) (Md. Super. Ct. 1971). In *Ruybe* a doctor who supplied a defective intrauterine device was held not liable for breach of an implied warranty of merchantability. The court held that U.C.C. § 2-314 attaches neither to a doctor's professional services nor to surgical or therapeutic devices employed incidentally to the treatment. *Schuchman* was a blood transfusion case, but the court stated in dictum that a hospital is not a merchant in a vendor-vendee relationship if it furnishes medical supplies ranging from "alcohol and aspirin, to Ace bandages, Fleet's enemas, Nembutal, as well as braces, crutches, and canes." 9 U.C.C. Rep. Serv. at 647.

86. 53 Misc. 2d 355, 278 N.Y.S.2d 531 (Sup. Ct. 1967) (mem.).

87. *Cheshire* involved a defective intramedullary pin supplied by a hospital. *Id.* at 355, 278 N.Y.S.2d at 532.

88. *Id.* at 356, 278 N.Y.S.2d at 533.

89. *Id.* (emphasis added).

90. 47 Ill. 2d 443, 266 N.E.2d 897 (1970).

91. *Cf.* W. PROSSER, *supra* note 2, § 95, at 638, § 104 at 679-80. Three cases often cited as conflicting with *Perlmutter*, are *Community Blood Bank, Inc. v. Russell*, 196 So. 2d 115 (Fla. 1967) (complaint charging a blood bank with liability under an implied warranty for sale of blood to hospital patient did state a cause of action); *Jackson v. Muhlenberg Hosp.*, 53 N.J. 138, 249 A.2d 5 (1969) (*per curiam*) (summary judgment denying the use of

Court in *Cunningham v. MacNeal Memorial Hospital*,⁹² facing a sales/service issue similar to that in *Perlmutter*, held that a hospital's liability for contaminated blood could be established under the strict liability standard expressed in section 402A of the *Restatement (Second) of Torts*. The *Cunningham* court reasoned that human blood was a "product" under section 402A⁹³ the "sale" of which was distinct from the services provided by the hospital.⁹⁴ Holding it irrelevant that selling blood was not the hospital's principal function, the court stated: "It is not necessary that the seller be engaged solely in the business of selling such products" for section 402A to apply.⁹⁵ Thus, if the hospital was "within the distribution chain of the product involved,"⁹⁶ a strict products liability standard would apply.

The *Cunningham* court rejected every defense asserted by the hospital. That contaminated blood is impossible to detect was not dispositive because recognition of this defense would "emasculate the [strict liability] doctrine and in a very real sense would signal a return to a negligence theory."⁹⁷ Moreover, the "unavoidably unsafe product" doctrine⁹⁸ was inapplicable because the plaintiff had alleged that the blood was impure.⁹⁹ The court reasoned that the unsafe product doctrine "relates only to products which are not impure and which, even when properly prepared, inherently involve substantial risk of injury to the user."¹⁰⁰

Blood, a product not impure or harmful when properly pre-

a products liability standard and an implied warranty action in blood transfusion cases reversed; trial record was deemed to be inadequate on the issue of holding hospitals liable under implied warranty or products liability standards for supplying contaminated blood); *Hoffman v. Misericordia Hosp.*, 439 Pa. 501, 267 A.2d 867 (1970) (recovery under implied warranties of merchantability or fitness for a particular purpose may arise from transfer of blood; decision should rest on technical existence of a sale).

92. 47 Ill. 2d 443, 266 N.E.2d 897 (1970).

93. *Id.* at 447, 266 N.E.2d at 899.

94. *Id.* at 451, 266 N.E.2d at 901.

95. *Id.* at 451, 266 N.E.2d at 901 (quoting RESTATEMENT (SECOND) OF TORTS § 402A comment f (1965)).

96. *Id.* at 452, 266 N.E.2d at 901.

97. *Id.* at 453, 266 N.E.2d at 902. The court noted that a strict liability has been applied when detection of a defect is impossible, such as in a tin of canned meat, a sealed candy bar, or in a bottle drink. *Id.* at 454, 266 N.E.2d at 902 (quoting *Community Blood Bank, Inc. v. Russell*, 196 So. 2d 115, 119-20 (Fla. 1967) (Roberts, J., specially concurring)).

98. *See infra* notes 165-78 and accompanying text.

99. 47 Ill. 2d at 456, 266 N.E.2d at 904. *But cf.* *Brody v. Overlook Hosp.*, 127 N.J. Super. 331, 317 A.2d 392 (App. Div. 1974), *aff'd per curiam*, 66 N.J. 448, 332 A.2d 596 (1975) (products liability inapplicable absent tests to detect contaminated blood).

100. 47 Ill. 2d at 456, 266 N.E.2d at 904.

pared, is not unavoidably unsafe.¹⁰¹ *Cunningham's* reasoning conceivably could hold a hospital strictly liable for supplying defective prosthetic devices—but that reasoning is faulty. Some products provided for patient care are clearly separable from the professional services rendered;¹⁰² blood and prosthetic devices clearly are not. When the hospital provides blood and medical devices, those products become integrally linked to the professional judgment, opinion, expertise, and service rendered by physicians or other trained staff personnel. Provision of prosthetic devices similarly are linked, and cannot be broken into separate sales and service elements. Thus, strict liability should not apply.¹⁰³

The result reached in *Cunningham* contradicted existing legislation in twenty-five states.¹⁰⁴ After the *Cunningham* decision, twenty additional states enacted legislation which statutorily exempts those who provide blood from liability under either implied warranty or strict tort liability standards.¹⁰⁵ The Illinois legislature, one of those twenty,¹⁰⁶ made an implied warranty or strict liability standard inapplicable by legislatively mandating that the furnishing and processing of blood is not a sale.¹⁰⁷

The Illinois statute, however, is inapplicable to prosthetic devices. The statute's declaration of public policy was restricted in scope to the availability of scientific knowledge concerning blood products, human tissue and other natural organs.¹⁰⁸ This restric-

101. *Id.*

102. See *infra* notes 127-36 and accompanying text.

103. The hospital, of course, can still be held liable for any negligent handling of the device by its employees.

104. 47 Ill. 2d at 453, 266 N.E.2d at 902.

105. See Wiest, *Pricing Bad Blood: Reassessing Liability for Post-Transfusion Hepatitis*, 15 HARV. J. ON LEGIS. 557, 559 (1978).

106. Liability Relating to Use of Human Blood, Organs or Tissue, P.A. 77-184 § 2, ILL. ANN. STAT. ch. 111½, ¶ 5102 § 2 (Smith-Hurd Supp. 1981).

The procuring, furnishing, donating, processing, distributing or using human whole blood, plasma, blood products and products, corneas, bones, and organs or other human tissue . . . is declared for purposes of liability in tort or contract to be the rendition of a service . . . and is declared not to be a sale of any such items and no warranties of any kind or description nor strict tort liability shall be applicable

Id. The statutes sheltering hospitals from liability under an implied warranty or strict tort liability standard apply to human organs and blood products but do not encompass artificial products such as prosthetic devices.

107. *Id.* The Illinois statute followed most jurisdictions. Thirty-three state legislatures have declared the procurement of blood for transfusions to be definitionally not a sale. However, few states exempt blood suppliers from liability because of the suppliers' inability to detect and eliminate hepatitis carriers. Wiest, *supra* note 105, at 588-89.

108. P.A. 77-184 § 1, ILL. ANN. STAT. ch. 111½, ¶ 5101 § 1.

tion indicates the legislature's intent not to eliminate hospital liability in all situations, but only with respect to the specifically mentioned products involved. Consequently, the *Cunningham* principle of separating the hospital-patient relationship into distinct sales and service elements still survives.¹⁰⁹

The *Cunningham* rationale was subsequently applied to a different medical situation in *Dubin v. Michael Reese Hospital & Medical Center*.¹¹⁰ The *Dubin* court held a hospital strictly liable for supplying and selling x-radiation which subsequently caused cancer.¹¹¹ The appellate court determined that x-radiation is a product as defined under section 402A¹¹² which was unreasonably dangerous due to inadequate warnings of radiation dangers.¹¹³ The court, applying the *Cunningham* rationale, held that the patient had stated a cause of action under a strict liability standard even though supplying x-radiation was ancillary to the hospital's regular business.¹¹⁴

The Illinois Supreme Court reversed *Dubin* without overruling or modifying *Cunningham*. The court instead reasoned that the dangerous condition was caused by a misapplication of the x-radiation and not by inherent defects in the product.¹¹⁵ The transaction, therefore, involved an error in professional judgment to which strict liability does not apply.¹¹⁶ Since *Dubin* did not overrule *Cunningham*, Illinois hospitals are still subject to liability under implied warranty or strict liability standards for selling defective products.

It is possible that if *Cunningham* is widely adopted as applica-

109. P.A. 77-184 § 4, ILL. ANN. STAT. ch. 111½, ¶ 5104 § 4. In initially limiting the statute's life span to ten years, the legislature may have believed that by 1981, scientific advancements in detecting blood contaminants would eliminate lawsuits like *Cunningham*. Between *Cunningham* and the planned termination of the Illinois statute in 1981, technological advances were made: the counterelectrophoresis (CEP) detection test, which is 40% effective in detecting blood contaminants, was developed in the late 1960's. By early 1973, however, the radioimmunoassay (RIA) technique was developed which is approximately 80% effective. Elser, *Medical Products: An Area of Growing Concern*, INS. L.J. 539 (1974). Apparently these technological advances were insufficient to obviate concern, because on June 19, 1981, the Illinois legislature repealed the automatic repealing provision. P.A. 82-16, § 1 (1981). Thus, the statutory exemptions are still effective.

110. 74 Ill. App. 3d 932, 393 N.E.2d 588 (1979), *rev'd*, 83 Ill. 2d 277, 415 N.E.2d 350 (1980).

111. *Id.* at 945, 393 N.E.2d at 597.

112. *Id.* at 942, 393 N.E.2d at 595.

113. *Id.* at 945, 393 N.E.2d at 598.

114. *Id.* at 944, 393 N.E.2d at 596-97.

115. 83 Ill. 2d 277, 415 N.E.2d 350 (1980).

116. *Id.* at 280-81, 415 N.E.2d at 352.

ble to hospital provision of prosthetic devices, state legislatures would act to exempt hospitals from liability under implied warranty or strict products liability. This result could easily occur given the contextual similarity between blood and prosthetic devices. Detection of defective prosthetic devices is as difficult today as was detecting contaminated blood in the late 1960's, since detection of latent defects in the device would be almost impossible from a pre-operation inspection.¹¹⁷ Moreover, both products are often involved in life-saving procedures which promote public health and welfare. The various legislatures would also have an incentive to create statutory immunity because the *Cunningham* rationale exposes hospitals to extensive liability.

b. *Breach of Implied Warranty*: *Providence Hospital v. Truly*. *Providence Hospital v. Truly*¹¹⁸ supports the imposition of an implied warranty or strict liability standard on a hospital which provides a defective prosthetic device. In *Truly*, a patient was injured when a contaminated drug from the hospital's pharmacy was injected into the patient's eye.¹¹⁹ The hospital, citing *Perlmutter*, argued that the mere supplying of drugs while rendering medical service does not constitute a sale under warranty or strict liability theories.¹²⁰ The court held, however, that a sale had occurred when the patient paid for the drug.¹²¹ The court then noted that the implied warranties of merchantability and fitness for a particular purpose—where applicable—inhere in every sale except those statutorily excepted as medical services.¹²² Implied warranties attached to this transaction because the statutory exemption was not broad enough to cover drugs.¹²³ Under this analysis, implied warranties would attach to the provision of prosthetic devices (which are not exempted statutorily) whenever the hospital is reimbursed for the cost of those devices.¹²⁴

The *Truly* court's restriction of the medical services immunity

117. See *supra* note 109.

118. 611 S.W.2d 127 (Tex. Civ. App. 1980).

119. *Id.* at 129.

120. *Id.* at 132.

121. *Id.* at 131.

122. *Id.* at 133. The court noted that the Texas statute only exempted providers of blood, plasma, and human tissue. *Id.*

123. *Id.*

124. Although not discussed, a strict liability action would also be successful, since the hospital would also be considered a seller under § 402A. In *Mueller & Co. v. Corley*, 570 S.W.2d 140 (Tex. Civ. App. 1978), the court held both the manufacturer and distributor of a silicone breast implant strictly liable for the defect. Although the hospital in *Corley* was

to only those services specifically enumerated in the statute conflicts with the case law of almost all other jurisdictions.¹²⁵ Adoption of the *Truly* rationale would place hospitals on the same level as retail stores, since they would be liable under either implied warranty or strict liability theories for every product included on the patient's bill. This is inequitable treatment; it ignores the essential purpose and function of a hospital. The selection and administration of medical products is only one ancillary aspect of the hospital's primary function—the rendering of medical services. A retail store's sole purpose and means of existence is selling products at a profit, but a hospital, whether it provides medical products at cost or at a profit, exists primarily to provide services. This essential difference justifies dissimilar treatment.

B. *Abandonment of the Sales/Service Distinction*

Throughout this Note, the question of whether to classify the hospital as a seller of products or as solely a provider of services has been analyzed. Some jurisdictions,¹²⁶ however, hold that the sales/service distinction is not dispositive of the strict liability issue.

In *Johnson v. Sears Roebuck & Co.*,¹²⁷ defendants, being sued for improper installation of a tire, impleaded a hospital under the theory that the hospital had provided the plaintiff deficient "mechanical and administrative services."¹²⁸ The court, abandoning what it saw as the untenable sales/service dichotomy,¹²⁹ examined the underlying policy rationales¹³⁰ and found that three considerations supported strict liability for mechanical and administrative services: the potentially serious consequences of defective services, the inability of laymen to control defective services, and the doctor's need for accurate information when

not joined, a court following the *Truly* rationale might consider a hospital to be a distributor of prosthetic devices, and thus, liable under § 402A.

125. See *supra* notes 56–89 and accompanying text.

126. See *infra* notes 127–37 and accompanying text.

127. 355 F. Supp. 1065 (E.D. Wis. 1973).

128. *Id.* The court does not indicate what mechanical or administrative services were provided, merely that they were nonprofessional services. *Id.* at 1067. See *infra* text accompanying notes 133–37 for an example of what the *Johnson* court would consider a nonprofessional service.

129. 355 F. Supp. at 1066 (citing *Newmark v. Gimbel's, Inc.*, 54 N.J. 585, 594, 258 A.2d 697, 700 (1969) (difference between sale and rendition of services is highly artificial); *Hoffman v. Misericordia Hosp.*, 439 Pa. 501, 507, 267 A.2d 867, 870 (1970) (court was not required to hinge resolution of important issues on the existence of a technical sale)).

130. 355 F. Supp. at 1067; see also *supra* notes 26–47 and accompanying text.

treating patients.¹³¹ The court, therefore, held that strict liability would arise for performance of such services—while emphasizing that professional *medical* services could not be subject to strict liability.¹³²

*Thomas v. St. Joseph Hospital*¹³³ similarly held that a hospital could be strictly liable for supplying an unreasonably dangerous hospital gown.¹³⁴ The hospital disclaimed strict liability since it was not in the business of selling hospital gowns or other medical products.¹³⁵ The court held, however, that although only sellers are usually held strictly liable, lessors and bailors are similarly liable since they also introduce products into the stream of commerce.¹³⁶ Hospitals which supply products unrelated to professional medical services, therefore, are strictly liable because they have introduced the product into the stream of commerce.¹³⁷

Both *Johnson* and *Thomas* abandon the sales/service distinction as it applies to hospitals which supply professional and non-professional services. Strict liability attaches to nonprofessional administrative services but not to professional medical services. Under this analysis, a hospital could be found strictly liable for supplying defective prosthetic devices only if the devices were provided as an “administrative” function. The more rational position, however, would be to classify the supplying of prosthetic devices as a professional medical service, since the selection, implantation, and maintenance of the devices requires professional *medical* opinions and expertise.

C. *Defenses to Strict Liability*

If a hospital's liability for supplying a defective prosthetic device is to be determined under a strict liability standard, then it is necessary to explore the available defenses. Assumption of risk,¹³⁸

131. 355 F. Supp. at 1067.

132. *Id.* at 1066–67.

133. 618 S.W.2d 791 (Tex. Civ. App. 1981).

134. *Id.* at 798.

135. *Id.* at 796. It is unclear whether the court considered the hospital a seller or lessor of gowns. The court constantly stated the gowns were “supplied,” although noting that overhead included the cost of the gowns. *See id.* at 796–97.

136. *Id.* (citing *Rourke v. Gorza*, 530 S.W.2d 794 (Tex. 1975) (lessor of unreasonably dangerous scaffolding held liable under a products liability standard); and *Freitas v. Twin Cities Fisherman's Coop. Ass'n*, 452 S.W.2d 931 (Tex. Civ. App. 1970) (products liability standard not applicable to lessee of oil tank with unsafe ladder)).

137. *Id.* at 796–97.

138. *See infra* notes 146–47 and accompanying text.

product misuse,¹³⁹ and the unavoidably unsafe product doctrine¹⁴⁰ are all available defenses in defective prosthetic device cases.¹⁴¹ A consumer's contributory negligence in failing to discover or guard against product defects, however, has not been judicially accepted as a defense to strict liability.¹⁴² Moreover, disclaimers of liability, allowable under the Uniform Commercial Code,¹⁴³ are not generally applicable to strict tort liability claims.¹⁴⁴ An attempt by a hospital to waive strict tort liability for sales of a defective prosthetic device, therefore, arguably would be unenforceable.¹⁴⁵

1. *Assumption of Risk*

Assumption of risk occurs when one voluntarily and unreasonably accepts a known danger.¹⁴⁶ The viability of this defense to defective prosthetic devices depends upon an examination of the particular circumstances in each case. This defense is unavailable, for example, when the patient requires a prosthetic device to survive or to relieve pain. Under these circumstances, the patient's choice to have the device implanted is neither voluntary nor unreasonable. Furthermore, it is unlikely that every danger of a complicated prosthetic device could be adequately explained by the hospital or appreciated by the patient.¹⁴⁷ The assumption of

139. See *infra* notes 148-53 and accompanying text.

140. See *infra* notes 154-58 and accompanying text.

141. Product alteration by the consumer is another traditional defense. However, patients would not tamper with a prosthetic device prior to installation.

142. 1 R. HURSH & H. BAILEY, *supra* note 60, at 737; see also RESTATEMENT (SECOND) OF TORTS § 402A (1965).

143. U.C.C. § 2-316 (1978) provides for limited or total waiver of all express or implied warranties. Any attempt, however, to eliminate the U.C.C. imposed warranties in the case of injured consumers would be governed by U.C.C. § 2-719(3), which declares prima facie unconscionable any attempt to limit consequential damages for injury.

144. RESTATEMENT (SECOND) OF TORTS § 402A (1965) states:

The rule stated in this Section is not governed by the provisions of the Uniform Sales Act, or those of the Uniform Commercial Code, as to warranties; and it is not affected by limitations on the scope and content of warranties, or by limitations to the "buyer" and "seller" in those statutes.

But see *Keystone Aeronautics Corp. v. R.J. Enstrom Corp.*, 499 F.2d 146 (3d Cir. 1974) (courts have allowed for contractual waiver of products liability protection between business entities of equal bargaining strength).

145. If liability disclaimers are enforceable in products liability claims involving prosthetic devices, they would be difficult to sustain considering the coercive circumstances surrounding the medical services provided, including possible emergency surgery. See *Franklin, supra* note 26, at 473.

146. 1 R. HURSH & H. BAILEY, *supra* note 60, at 739. A subjective test is applied to determine voluntariness, unreasonableness, and knowledge. *Id.* at 742.

147. *Cf.* Comment, *The Knowledge Element of Assumption of Risk as a Defense to Strict*

risk defense, however, may be viable when the procedure undertaken is a nonessential, elective operation using a relatively simple prosthetic device. A voluntary and informed choice is more likely in that situation, since medical treatment is presumably possible without utilizing a prosthetic device. The assumption of risk defense, therefore, has limited applicability to defective prosthetic devices since voluntary, reasonable, and informed choices cannot occur except in restricted circumstances.

2. *Misuse of Product*

A seller is not liable if the product is used for an unintended purpose unforeseeable to the seller.¹⁴⁸ In *Stewart v. Von Solbrig Hospital, Inc.*,¹⁴⁹ a defective, hospital-manufactured surgical pin was implanted into the patient's tibia.¹⁵⁰ The pin was designed merely to align the leg fracture, not for skeletal support.¹⁵¹ Contrary to the doctor's express direction, however, the plaintiff walked on his leg and broke the pin.¹⁵² The court held that although the pin was defective, the plaintiff's misuse precluded application of strict liability, since walking would cause even a nondefective pin to fail.¹⁵³ The product misuse defense, therefore, may be available if the patient uses the device for an unintended purpose unforeseeable to the seller.

3. *The Unavoidably Unsafe Product*

A hospital or manufacturer can avoid the imposition of strict liability if the prosthetic device is unavoidably unsafe.¹⁵⁴ The unavoidably unsafe product is not considered defective or unreasonably dangerous and therefore, may exempt the seller from liability.¹⁵⁵ Section 402A of the *Restatement (Second) of Torts de-*

Products Liability, 10 J. MAR. J. PRAC. & PROC. 243 (1977) (assumption of risk defense should not be permitted in products liability cases unless plaintiff is substantially aware of both the gravity of the harm and the probability of its occurrence).

148. 1 R. HURSH & H. BAILEY, *supra* note 60, at 754-58; W. PROSSER, *supra* note 2, § 102, at 668-69.

149. 24 Ill. App. 3d 599, 321 N.E.2d 428 (1974).

150. *Id.* at 600, 321 N.E.2d at 429.

151. *Id.* at 601-02, 321 N.E.2d at 430.

152. *Id.* at 602, 321 N.E.2d at 431.

153. *Id.* at 604, 321 N.E.2d at 432.

154. RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965).

155. A product can be classified as unavoidably unsafe and still be defective. Strict liability will be invoked if the product is defectively constructed, prepared, or without adequate warnings. Comment k of § 402A states:

The seller of such products, again with the qualification that they are properly

finer an unavoidably unsafe product as one which, given present human knowledge, is "incapable of being made safe for [its] intended and ordinary use."¹⁵⁶ This section has been applied to drug and vaccine products¹⁵⁷ because the public benefits outweigh the medical risks. A product's unavoidably unsafe status, however, is subject to change as knowledge, skill, and technology increase.¹⁵⁸ If technological developments refine the product sufficiently, the unavoidably unsafe label should be dropped. The unavoidably unsafe doctrine, therefore, should apply only to those properly prepared and labeled devices which still cannot be made completely safe, but whose benefits outweigh their risks.

Classifying a prosthetic device as unavoidably unsafe depends upon its intended use and complexity. A device used in critical situations where the patient's life is threatened could be classified as unavoidably unsafe because the device's benefits outweigh its possible detriments. However, a device that is easily designed and manufactured—a surgical pin or artificial joint—would not be classified as unavoidably unsafe. These products can be safely designed, and the benefits of the products do not justify unavoidably high probabilities of harm.

D. Conclusion

Although strict products liability is applicable to an increasing number of transactions,¹⁵⁹ it has yet to be imposed on professional medical services or to products provided by hospitals or physicians. Hospitals and physicians may be held strictly liable for

prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND) OF TORTS § 402A comment k (1965); *see also, e.g.*, *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121, 131 (9th Cir. 1968) (Sabin polio vaccine was an unavoidably unsafe product, but unreasonably dangerous from inadequate warnings).

156. *Id.*

157. *Id.* The example given in comment k is the Pasteur treatment for rabies.

158. The Illinois legislature, for example, declared blood an unavoidably unsafe product because there was no adequate test for detecting impure human blood when the statute was enacted. *See supra* notes 26-45 and accompanying text. The legislators weighed the benefits and detriments of blood products and concluded: "The imposition of legal liability without fault upon the persons and organizations engaged in such scientific procedures inhibits the exercise of sound medical judgment and restricts the availability of important scientific knowledge, skills and materials."

159. *See supra* note 3.

products¹⁶⁰ and services¹⁶¹ unrelated to professional medical services. The majority of cases,¹⁶² however, advocate immunity from strict liability for products and services integrally related to professional medical expertise. In most jurisdictions, prosthetic implants would be considered integrally linked to medical services, thus, precluding strict liability.¹⁶³

III. THE MODEL UNIFORM PRODUCT LIABILITY ACT

The Department of Commerce published the Model Uniform Product Liability Act (UPLA)¹⁶⁴ as an attempt to eliminate the contradictions¹⁶⁵ and uncertainties¹⁶⁶ in products liability cases. The UPLA has not been enacted by any state, but its provisions are used by states to guide promulgation of their own codes. Under the UPLA, a hospital providing a defective prosthetic device will not be subject to strict tort liability.

The UPLA defines a product seller as "any person or entity that is engaged in the business of selling products" including a manufacturer, wholesaler, distributor, or retailer.¹⁶⁷ Professionals

160. See *supra* notes 133-36 and accompanying text.

161. See *supra* notes 127-32 and accompanying text.

162. See *supra* notes 56-89 and accompanying text.

163. See *supra* notes 79-89 and accompanying text for cases involving hospital liability and medical implants. These cases, however, were breach of warranty actions.

164. MODEL UNIFORM PRODUCT LIABILITY ACT, 44 Fed Reg. 62,714 (1979) [hereinafter cited as UPLA].

165. The Model law, if enacted by the states, would introduce uniformity and stability into the law of product liability. . . .

The current system of having individual state courts develop product liability law on a case-by-case basis is not consistent with commercial necessity. Product sellers and insurers need uniformity in product liability law so they will know the rules by which they are judged. At the same time, product users are entitled to the assurance that their rights will be protected and will not be restricted by "reform" legislation formulated in a crisis atmosphere. Thus, the Model Law meets the needs of product users, sellers and insurers.

Id. Introduction.

166. The criteria utilized in evaluating the provisions of the UPLA were:

(6) *To use language that is comparatively clear and concise.* Many product liability proposals that appear sound when stated in a broad and general manner break down when one focuses on the practicality of their implementation. In drafting the Act, practicality, together with conciseness and clarity of language, were important goals. The Act was drafted as a guideline for courts, not as a detailed legal contract between product seller and user.

Id. (emphasis in original).

167. (A) *Product Seller.* "Product seller" means any person or entity that is engaged in the business of selling products, whether the sale is for resale, or for use or consumption. The term includes a manufacturer, wholesaler, distributor, or retailer of the relevant product. The term also includes a party who is in the business of leasing or bailing such products.

Id. § 102(A).

who use, provide, or sell products within the legally authorized scope of their practice, however, are expressly excluded from this definition.¹⁶⁸ The UPLA notes that absent any product preparation or modification, the courts generally have not applied products liability doctrines to professional judgments.¹⁶⁹ The UPLA's official analysis states that professionals, such as pharmacists, physicians, optometrists, and opticians should not be considered product sellers; nor should such professionals working within the scope of their employment.¹⁷⁰

Although hospitals are not expressly mentioned in the official analysis, they are arguably within the product seller exclusion. The drafters' intent was to exclude all parties exercising professional judgment or skills.¹⁷¹ This conclusion is supported by the drafters' findings which suggest that the imposition of strict liability creates serious "disincentives for innovation and for the development of high-risk but potentially beneficial products."¹⁷² Imposing strict liability on hospitals for defective prosthetic devices would discourage hospitals from using the devices, thus curtailing their development. Hospitals, therefore, likely would fall within the product seller exclusion.

Even if hospitals are considered product sellers of prosthetic devices, several UPLA provisions would prevent imposition of

168. "The term 'product seller' does not include . . . [a] provider of professional services who utilizes or sells products within the legally authorized scope of its professional practice." *Id.* § 102(A)(2).

169. The majority of current decisions look to the factual circumstances of each case and generally exclude persons exercising professional judgment within their legally authorized scope of practice. Thus, in the absence of product preparation or modification, or any representation by service providers that the products are their own, or of warranty, the courts have generally not applied products liability doctrine." *Id.* § 102(A) (Analysis).

170. The UPLA provides:

[P]rofessionals, such as pharmacists, physicians, optometrists and opticians, should *not* be considered product sellers in those circumstances where they are selling a product while within their legally authorized scope of professional practice. In addition, pharmacists or other professionals, employed by and working within the scope of their employment for a hospital or other health-related facility, would *not* be considered product sellers within this context since they would be rendering a part of the overall services of such facilities.

Id. (emphasis in original) (citations omitted). Such professionals, however, are considered product sellers when "the sale of a product is the principal part of the transaction and when the essence of the relationship between buyer and seller is *not* the furnishing of a professional skill or service." *Id.* (emphasis in original). A pharmacist selling perfume or photographic film is given as an example in which the professional is considered a product seller. *Id.*

171. The drafters noted that the vast majority of cases involving professional skill or judgment are not resolved by resort to a strict liability standard. *Id.* See *supra* note 155.

172. UPLA § 101.

strict liability. Section 105(A) states that nonmanufacturing product sellers are liable only for negligence.¹⁷³ Since a hospital is often a nonmanufacturer, it would be liable only for its negligence¹⁷⁴—the very standard currently imposed on hospitals in most jurisdictions. A hospital would be subject to strict liability only if it expressly warrants a material fact concerning the product,¹⁷⁵ or where the manufacturer is not subject to service of process, is insolvent, or is judgment proof.¹⁷⁶ If the hospital were considered a product seller,¹⁷⁷ strict liability would be imposed

173. A product seller, other than a manufacturer, is subject to liability to a claimant who provides by a preponderance of the evidence that the claimant's harm was proximately caused by such product seller's failure to use reasonable care with respect to the product. . . .

Unless Subsection (B) or (C) is applicable, product sellers shall not be subject to liability in circumstances in which they did not have a reasonable opportunity to inspect the product in a manner which would or should, in the exercise of reasonable care, reveal the existence of the defective condition.

Id. § 105(A).

174. In determining whether a product seller other than a manufacturer, is subject to liability under Subsection (A), the trier of fact:

shall consider the effect of such product seller's own conduct with respect to the design, construction, inspection, or condition of the product, and any failure of such product seller to transmit adequate warnings or instructions about the dangers and proper use of the product.

Id.

175. A product seller, other than a manufacturer, who makes an express warranty about a material fact or facts concerning a product is subject to the standards of liability set forth in Subsection 104(D).

Id. § 105(B).

In order to determine that the product was unreasonably unsafe because it did not conform to an express warranty, the trier of fact must find that the claimant, or one acting on the claimant's behalf, relief on an express warranty made by the manufacturer or its agent about a material fact or facts concerning the product and the express warranty proved to be untrue.

A "material fact" is any specific characteristic or quality of the product. It does not include a general opinion about, or praise of, the product.

The product seller may be subject to liability under Subsection (D) although it did not engage in negligent or fraudulent conduct in making the express warranty.

Id. § 104(D).

176. A product seller, other than a manufacturer, is also subject to the liability of a manufacturer . . . if:

- (1) The manufacturer is not subject to service of process under the laws of the claimant's domicile; or
- (2) The manufacturer has been judicially declared insolvent in that the manufacturer is unable to pay its debts as they become due in the ordinary course of business; or
- (3) The court determines that it is highly probable that the claimant would be unable to enforce a judgment against the product manufacturer.

Id. § 105(C); *see also generally* C. WRIGHT, HANDBOOK OF THE LAW OF FEDERAL COURTS § 64, at 301-04 (3d ed. 1976) (discussion of in personam jurisdiction over nonresident corporations).

177. The product manufacturer is held liable for construction defects, UPLA § 104(A), and failure to conform to express warranties, *id.* § 104(D); and is held to a negligence

only under limited circumstances.¹⁷⁸

IV. CONCLUSION

Analysis of the traditional policy rationales for imposing strict liability¹⁷⁹ reveals that only the loss spreading theory applies to hospitals supplying defective prosthetic devices.¹⁸⁰ Even this justification is weakened when applied to small hospitals supplying an insignificant number of prosthetic implants.¹⁸¹ The key issue in determining the imposition of strict products liability is whether the hospital is a seller of products.¹⁸² Since there are few reported cases involving defective prosthetic devices,¹⁸³ it is necessary to examine other hospital product cases and analogize them to potential prosthetic devices cases.

Courts gradually have expanded the strict liability doctrine beyond transactions involving the mere sale of products;¹⁸⁴ nevertheless, section 402A has been generally held inapplicable to professional medical services. The courts consider a hospital as primarily providing medical services, with the transfer of goods in the hospital-patient relationship as merely ancillary to this primary function.¹⁸⁵ Those few jurisdictions which treat a hospital as a seller or retailer of products¹⁸⁶ are clearly in error. A hospital is essentially a service oriented facility which supplies products only incidentally, whereas a retailer's primary activity is selling. Some jurisdictions have abandoned the sales/service distinction, recognizing that hospitals primarily provide services, but they classify these services as either professional or administrative.¹⁸⁷ If the defective product is associated with an administrative service, these jurisdictions conclude that basic policy considerations

standard for design defects, *id.* § 104(B)(1), and defects from inadequate warnings. *Id.* § 104(C)(3)-(5). The UPLA's primary purpose is to assure adequate compensation for those injured by unreasonably unsafe products. *Id.* Preamble. The UPLA guarantees recovery by imposing a products liability standard on the wholesaler and retailer if the manufacturer cannot be sued.

178. Furthermore, the hospital could assert the products liability defense doctrines of assumption of risk, *id.* § 112(B), misuse, *id.* § 112(C), product alteration, *id.* § 112(D), and the unavoidably dangerous product. *Id.* § 106.

179. *See supra* notes 16-51 and accompanying text.

180. *See supra* notes 26-29 and accompanying text.

181. *See supra* notes 27-29 and accompanying text.

182. *See supra* notes 46-55 and accompanying text.

183. *See supra* notes 79-89 and accompanying text.

184. *See supra* notes 3, 49-64 and accompanying text.

185. *See supra* notes 56-89 and accompanying text.

186. *See supra* notes 91-125 and accompanying text.

187. *See supra* notes 126-37 and accompanying text.

justify imposition of liability. Under either analysis, however, the hospital should not be held strictly liable because the selection, implantation, and maintenance of prosthetic devices involve professional medical services and judgment rather than administrative conduct. Finally, if a hospital were to be held liable, the defense doctrines of assumption of risk,¹⁸⁸ product misuse,¹⁸⁹ and unavoidably unsafe product¹⁹⁰ would be available. Their availability varies with the complexity and intended use of the device.

In addition, the Model Uniform Product Liability Act¹⁹¹ would exempt hospitals from strict liability. The UPLA apparently prohibits strict liability when professional judgment and skill are a necessary element of the transaction, and only holds such professionals liable for negligence. Under the UPLA, the injured patient has recourse against the hospital for negligence and is compensated by the manufacturer through strict liability for device defects. In the interest of lower medical costs brought about by reduced insurance expenses and damage claims, the UPLA offers the best solution.

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188. *See supra* notes 146-47 and accompanying text.

189. *See supra* notes 148-53 and accompanying text.

190. *See supra* notes 154-58 and accompanying text.

191. *See supra* notes 165-78 and accompanying text.