

Winter 1999

Passing the Essence Test: Health Care Providers Escape Strict Liability for Medical Devices

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NOTE

PASSING THE ESSENCE TEST: HEALTH CARE PROVIDERS ESCAPE STRICT LIABILITY FOR MEDICAL DEVICES

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I. INTRODUCTION

Traditionally, courts have not imposed strict liability on doctors and hospitals for either defective instruments used during medical treatment or defective, surgically implanted devices. This general rule rests on the finding that health care providers are not “sellers” under section 402A of the Restatement (Second) of Torts,¹ a version of which most states have either statutorily or judicially adopted.² Courts instead treat doctors and hospitals as primarily professional “service providers” and, therefore, generally hold them exempt from strict liability statutes.³ Likewise, health care providers are typically not held liable for defective medical instruments and devices under breach of statutory warranty or common-law implied warranty, both of which apply exclusively to the “sale of goods.”⁴

Defining health care providers as sellers of hypodermic needles and other instruments used during medical procedures seems ludicrous, as clearly no “sale” is involved—the patient neither bargains for the instrument nor assumes possession of it. However, commentators have recently called into question judicial reluctance to treat doctors and hospitals as sellers in cases involving defective medical devices implanted or otherwise transferred during surgery.⁵ Critics of the majority rule against strict liability for health care providers argue that patients in fact purchase these devices through actual sale transactions.⁶

This Note examines the implications of the South Carolina Supreme Court’s recent adoption of the majority rule that health care providers are not strictly liable for defective medical devices or instruments, regardless of their

1. See RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 20 cmts. a, d & f (Proposed Final Draft 1997) (explaining that despite the historical trend of courts to extend strict liability beyond the manufacturer under section 402A, hospitals and doctors generally are not considered sellers under section 402A).

2. See W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS § 98, at 694 n.11.5 (5th ed. 1984 & Supp. 1988).

3. *Id.* § 104, at 720.

4. 61 AM. JUR. 2D *Physicians, Surgeons, and Other Healers* § 204 (1981).

5. See discussion *infra* Part IV.

6. See discussion *infra* Part IV.

nature. The court's June 1998 decision, *In re Breast Implant Product Liability Litigation (In re Breast Implant)*,⁷ rejects the contention that doctors and hospitals sell the medical devices they surgically implant into patients, holding that health care providers are not subject to South Carolina's strict tort liability statute,⁸ to its expressed⁹ and implied warranty¹⁰ statutes, or to a common-law warranty of soundness and quality.¹¹ Part II of this Note summarizes the holding of *In re Breast Implant*; Part III details the national development of the majority rule; and Part IV considers criticism of the rule's application to transferred medical devices, with special attention to policy concerns. Finally, Part V revisits the South Carolina decision in light of these criticisms.¹²

II. IN RE BREAST IMPLANT PRODUCT LIABILITY LITIGATION

In June of 1998, the South Carolina Supreme Court reversed a circuit court order and held that "health care providers are not strictly liable under S.C. Code Ann. § 15-73-10 for medical devices or instruments used in the course of treatment of patients."¹³ The court further found that health care providers are not liable under South Carolina's statutory adaptations of Uniform Commercial Code Article Two warranties or under a common-law warranty of soundness and quality.¹⁴ In March 1997, the court granted a petition for writ of certiorari from the health care providers—referred to by the court as Healthcare Defendants—despite the court's general practice of denying such writs for matters that can be resolved at trial or on appeal.¹⁵ The South Carolina Supreme

7. 331 S.C. 540, 503 S.E.2d 445 (1998).

8. S.C. CODE ANN. § 15-73-10 (Law. Co-op. 1976).

9. *Id.* § 36-2-313.

10. *Id.* §§ 36-2-314 to -315.

11. *In re Breast Implant*, 331 S.C. at 553, 503 S.E.2d at 452. The *In re Breast Implant* court indicated that South Carolina does not recognize a common-law warranty of soundness and quality in the medical context. *See id.*

12. The application of comment k of section 402A, which deals with unavoidably unsafe products, to breast implants is outside the scope of this Note. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (1965). For discussions of application of comment k, see Richard L. Cupp, Jr., *Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Product Transactions*, 21 FLA. ST. U. L. REV. 873, 909-11 (1994); Rachel B. Adler, Comment, *Device Dilemma: Should Hospitals Be Strictly Liable for Retailing Defective Surgical Devices?*, 5 ALB. L.J. SCI. & TECH. 95, 116-21 (1994); Emily C. Aschinger, Note, *The Selling of the Perfect Breast: Silicone, Surgeons, and Strict Liability*, 61 UMKC L. REV. 399, 414-15 (1992).

Likewise, this Note does not consider federal preemption of claims involving class III medical devices under the Medical Devices Amendments to the Federal Food, Drug & Cosmetic Act of 1938. For discussion of preemption, see Adler, *supra*, at 112-16; Beverly L. Jacklin, Annotation, *Federal Pre-emption of State Common-Law Products Liability Claims Pertaining to Drugs, Medical Devices, and Other Health-Related Items*, 98 A.L.R. FED. 124 (1990 & Supp. 1998). The South Carolina Supreme Court did not address these issues in *In re Breast Implant*.

13. *In re Breast Implant*, 331 S.C. at 553, 503 S.E.2d at 452.

14. *Id.*

15. *Id.* at 543-44 & 543 n.2, 503 S.E.2d at 447 & n.2.

Court agreed with the circuit court judge that the issues involved presented “[n]ovel questions of law concerning issues of significant public interest that are contained in numerous state and federal actions,” and that a state supreme court decision “would serve the interests of judicial economy by eliminating numerous inevitable appeals raising these issues.”¹⁶

The opinion, written by Associate Justice Jean H. Toal, is perhaps better understood when read against the backdrop of similar cases that preceded and informed the court’s decision. By examining the line of cases that came before *In re Breast Implant*, one can more fully comprehend the history of the court’s “essence of the transaction” test¹⁷ and can better appreciate arguments of critics who believe the majority-rule test yields unacceptable results when applied to implanted medical devices.¹⁸

III. DEVELOPMENT OF THE MAJORITY RULE

In the landmark decision of *Greenman v. Yuba Power Products, Inc.*,¹⁹ the California Supreme Court unanimously adopted an alternative to negligence and breach of warranty actions for holding manufacturers and merchants liable—a new theory that imposed less stringent requirements on the plaintiff.²⁰ The court held the defendant manufacturer liable for injuries its defective product caused, despite the plaintiff’s failure to meet the notice requirement for a breach of warranty action, by finding the manufacturer accountable under the theory of strict liability in tort.²¹

Soon after *Greenman*, the American Law Institute adopted section 402A

16. *Id.* at 543-44 n.2, 503 S.E.2d at 447 n.2.

17. *See infra* notes 48-76 and accompanying text.

18. *See* discussion *infra* Part IV.A.

19. 377 P.2d 897, 900 (Cal. 1962) (“A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.”).

20. *See KEETON ET AL., supra* note 2, § 98, at 692 (“It gradually became apparent that strict liability on ‘warranty’ concepts . . . carries far too much luggage in the way of undesirable complications, and is more trouble than it is worth.”).

21. *Greenman*, 377 P.2d at 900 (“The notice requirement . . . is not an appropriate one for the court to adopt in actions by injured consumers against manufacturers with whom they have not dealt.”). The doctrine of strict liability in tort for defective products was first articulated in Justice Traynor’s concurring opinion in *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 440 (Cal. 1944) (Traynor, J., concurring). In *Escola* Justice Traynor stated:

I believe the manufacturer’s negligence should no longer be singled out as the basis of a plaintiff’s right to recover in cases like the present one. In my opinion it should now be recognized that a manufacturer incurs an absolute liability when an article that he has placed on the market, knowing that it is to be used without inspection, proves to have a defect that causes injury to human beings.

Id.

of the Restatement (Second) of Torts.²² Section 402A describes a method by which plaintiffs may recover damages from manufacturers and sellers. Plaintiffs may plead this cause of action in conjunction with or as an alternative to actions for negligence or breach of warranty.²³

The policy justifications for strict products liability underlying section 402A revolve around several core propositions.²⁴ First, strict liability proponents argue that those who manufacture and sell defective products can best spread the costs of liability for defective goods through their ability to raise prices, which allows consumers and sellers to share the costs of risk of injury or damages.²⁵ Second, manufacturers and sellers are best positioned to discover and prevent defects, and the threat of strict liability deters them from creating and marketing defective products.²⁶ Third, the consumer often relies on the reputation, care, and skill of the manufacturers and sellers.²⁷ And fourth, negligence is often so difficult to establish that it results in wasteful litigation, or is so costly to prove that it discourages plaintiffs from pursuing

22. 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.

RESTATEMENT (SECOND) OF TORTS § 402A (1965).

23. KEETON ET AL., *supra* note 2, § 98, at 694.

24. See *Porter v. Rosenberg*, 650 So. 2d 79, 81 (Fla. Dist. Ct. App. 1995); RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (1965); KEETON ET AL., *supra* note 2, § 98, at 692-93; Cupp, *supra* note 12, at 876 n.20; John E. Montgomery & David G. Owen, *Reflections on the Theory and Administration of Strict Tort Liability for Defective Products*, 27 S.C. L. REV. 803, 809-10 (1976); David G. Owen, *Rethinking the Policies of Strict Products Liability*, 33 VAND. L. REV. 681, 684-85 (1980).

25. *Porter*, 650 So. 2d at 81; KEETON ET AL., *supra* note 2, § 98, at 692-93; Cupp, *supra* note 12, at 876 n.20; Montgomery & Owen, *supra* note 24, at 809.

26. *Porter*, 650 So. 2d at 81; Cupp, *supra* note 12, at 876 n.20; Montgomery & Owen, *supra* note 24, at 809.

27. RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (1965); Cupp, *supra* note 12, at 876 n.20; Montgomery & Owen, *supra* note 24, at 809.

compensation at all.²⁸ Justice Traynor later elucidated the justification for extending strict liability from manufacturers to distributors and sellers in *Vandermark v. Ford Motor Co.*,²⁹ where the court held that “[r]etailers like manufacturers are engaged in the business of distributing goods to the public. They are an integral part of the overall producing and marketing enterprise that should bear the cost of injuries resulting from defective products.”³⁰

These policy arguments stem from “[t]he fundamental purpose underlying the doctrine of strict products liability”: the furtherance of “public safety in the use of consumer goods.”³¹ Each argument applies not only to strict liability in tort, but also to breach of implied warranty (the two products liability causes of action not requiring fault).

Almost immediately, courts nationwide began relying on *Greenman* and section 402A to apply strict products liability.³² South Carolina first recognized the doctrine in 1974, when the legislature passed the Defective Products Act.³³ Like the strict liability statutes of other jurisdictions, section 15-73-10 of the Act codifies section 402A nearly verbatim.³⁴

A. *Strict Liability in Tort and Breach of Implied Warranty Compared*

As noted above, practical differences between an action for breach of warranty and one for strict liability in tort exist.³⁵ Plaintiffs suing under strict

28. KEETON ET AL., *supra* note 2, § 98, at 693; Cupp, *supra* note 12, at 876 n.20; Montgomery & Owen, *supra* note 24, at 809. Cupp notes that “[a]nother often stated rationale for strict liability is that the price of a good should reflect its true cost to society, including the cost of injuries which it causes.” Cupp, *supra* note 12, at 876 n.20.

29. 391 P.2d 168 (Cal. 1964).

30. *Id.* at 171.

31. *Porter*, 650 So. 2d at 81.

32. KEETON ET AL., *supra* note 2, § 98, at 694.

33. S.C. CODE ANN. §§ 15-73-10 to -30 (Law. Co-op. 1976); see F. PATRICK HUBBARD & ROBERT L. FELIX, *THE SOUTH CAROLINA LAW OF TORTS* 265 (2d ed. 1997). Strict liability in tort was not part of South Carolina common law prior to the adoption of this section. *Hatfield v. Atlas Enter., Inc.*, 274 S.C. 247, 248, 262 S.E.2d 900, 901 (1980) (“[T]he doctrine of strict liability in tort, imposed as a result of a product’s defective condition, did not emerge until Code § 15-73-10—§ 15-73-30 (1976) were enacted.”); HUBBARD & FELIX, *supra*, at 266.

34. Section 15-73-10 deviates from section 402A only by omitting “thereby” in subsection one and substituting “shall apply” for “applies” in subsection two. Section 15-73-20 of the Defective Products Act is entitled “Situation in which recovery shall be barred,” and provides: “If the user or consumer discovers the defect and is aware of the danger, and nevertheless proceeds unreasonably to make use of the product and is injured by it, he is barred from recovery.” S.C. CODE ANN. § 15-73-20 (Law. Co-op. 1976). Section 15-73-30, entitled “Intent of chapter,” expressly incorporates the comments to section 402A as evidencing the legislative intent of the chapter. *Id.* § 15-73-20. Furthermore, “since most jurisdictions have judicially adopted some form of strict liability akin to section 402A, the decisions of their courts can be helpful in interpreting the statute.” HUBBARD & FELIX, *supra* note 33, at 266.

35. See Dana Shelhimer, Comment, *Sales-Service Hybrid Transactions and the Strict Liability Dilemma*, 43 Sw. L.J. 785, 789 (1989). This Note emphasizes the doctrine of strict liability in tort and its applicability to health care providers because the South Carolina Supreme

liability in tort need not prove reliance on the seller's judgment or representation, and they need not notify the seller within a reasonable time after injury.³⁶ However, while section 402A prohibits recovery for pure economic loss in the absence of personal injury or property damage, implied warranty statutes generally permit recovery.³⁷ On the other hand, plaintiffs suing under an implied warranty theory cannot recover damages for claims such as wrongful death. Also, claimants who merely suffer damage to their property may be able to sue only under strict liability in tort because under implied warranties sellers can disclaim liability for property damage.³⁸

Despite these differences, the two causes of action overlap in terms of theoretical justifications and goals. Although courts created strict products liability to provide an alternative or additional remedy to those of negligence and breach of warranty, most courts and commentators consider the theories behind strict liability in tort and breach of implied warranty to be interchangeable.³⁹ Liability based on breach of warranty is, after all, closely related to strict liability because it is based on contract; thus, fault need not be established.⁴⁰ Further, neither theory allows the manufacturer or merchant to disclaim liability for personal injuries.⁴¹ When both causes of action are claimed, courts almost always decide both claims the same way⁴² because the

Court's *In re Breast Implant* opinion clearly focuses on this issue. However, authority addressing warranty claims is included throughout to support arguments concerning both warranty and strict liability in tort. The *In re Breast Implant* decision includes warranty authority as support for strict tort liability arguments, as do the decisions of most cases cited in this Note. *But cf. infra* Part III.A (discussing the differences between warranty claims and claims for strict liability in tort).

36. RESTATEMENT (SECOND) OF TORTS § 402A cmt. m (1965).

37. Shelhimer, *supra* note 35, at 789.

38. Shelhimer, *supra* note 35, at 789 & n.38 ("Sellers of defective products cannot disclaim liability for personal injury under § 402A or under implied warranties." RESTATEMENT (SECOND) OF TORTS § 402A comment m (1965) (strict products liability is not affected by disclaimer . . .)).

39. *See, e.g.,* Herrick v. Monsanto Co., 874 F.2d 594, 598 (8th Cir. 1989) ("[T]here appears to be little difference between the [breach of warranty and strict liability] theories, apart from the warranty defenses of lack of notice, disclaimer, and perhaps lack of privity."); Kozup v. Georgetown Univ., 663 F. Supp. 1048, 1058 (D.D.C. 1987) (holding that "implied warranty and strict liability in tort are but two labels for the same legal right and remedy," and because their "governing principles are identical" . . . plaintiffs' two separate Counts may be viewed together.) (quoting Cotton v. McGuire Funeral Serv., Inc., 262 A.2d 807, 808 (D.C. Cir. 1970)), *modified*, 851 F.2d 437 (D.C. Cir. 1988), *aff'd*, 906 F.2d 783 (D.C. Cir. 1990); 63A AM. JUR. 2D *Products Liability* § 935 (1997) ("Under the law of some jurisdictions, warranty and strict liability are treated as similar or even identical concepts.").

40. *See* JAMES J. WHITE & ROBERT S. SUMMERS, UNIFORM COMMERCIAL CODE § 9-7, at 349-50 (4th ed. 1995) (calling the implied warranty of merchantability a "first cousin" of strict liability and outlining the elements of a merchantability claim).

41. *See supra* note 38.

42. *Cf.* Daniel F. Ryan, III & Timothy R. Lawn, *Strict Liability Claims Against Health Care Providers in Breast Implant Litigation*, 29 TORT & INS. L.J. 818, 824 (1994) (arguing that "appellate courts would not create a body of case law holding that those who furnish medical services are sellers of services under section 402A but merchants of goods under the Uniform

two theories share the same governing principles.⁴³

B. The Classic Seller/Service Provider Distinction and Hybrid Transactions

Courts typically do not apply strict products liability to service providers.⁴⁴ Services are not considered “products” or “goods” and thus generally fall outside the scope of Restatement (Second) of Torts section 402A and Uniform Commercial Code section 2-213.⁴⁵ Moreover, those who provide services are already subject to liability under negligence or theories of intentional misconduct.⁴⁶

However, a problem arises when the services involve the use or transfer of a defective product.⁴⁷ In these so-called “hybrid” sales/service transactions, the distinction between seller and service provider is not so clear. To facilitate this classification, most courts expressly or implicitly apply the “essence of the

Commercial Code”). *But see* *Denny v. Ford Motor Co.*, 662 N.E.2d 730, 734, 739 (N.Y. 1995) (stating that strict products liability claims and breach of implied warranty of merchantability claims are not correctly considered identical, and finding that a manufacturer may be held liable under warranty and not tort). In *Denny* the court explained: “It is th[e] negligence-like risk/benefit component of the defect element that differentiates strict products liability claims from U.C.C.-based breach of implied warranty claims in cases involving design defects.” *Id.* at 736.

43. *See supra* note 36 and accompanying text; *cf.* Morris G. Shanker, *Strict Tort Theory of Products Liability and the Uniform Commercial Code: A Commentary on Jurisprudential Eclipses, Pigeonholes and Communication Barriers*, 17 W. RESERVE L. REV. 5, 11 (1965) (comparing strict liability in tort with breach of warranty and arguing for a unified system of products liability).

44. *See* David B. Harrison, Annotation, *Application of Rule of Strict Liability in Tort to Person or Entity Rendering Medical Services*, 100 A.L.R. 3d 1205, 1208 (1980 & Supp. 1998) (noting the cases in which strict liability was held inapplicable to medical service providers).

45. *See* WHITE & SUMMERS, *supra* note 40, § 9-2, at 331 (“By its own terms, Article 2 applies only to ‘transactions in goods.’ Code warranty provisions do not govern contracts which are purely for services.”); William C. Powers, Jr., *Distinguishing Between Products and Services in Strict Liability*, 62 N.C. L. REV. 415, 419-20 (1984) (“[N]early all courts have refused to extend strict products liability to pure service transactions.”).

46. *See* Magrine v. Krasnica, 227 A.2d 539, 546 (Hudson County Ct., N.J. 1967) (stating that service providers “are not liable in the absence of negligence or intentional misconduct”) (quoting *Gagne v. Bertran*, 275 P.2d 15, 20 (Cal. 1954)), *aff’d sub nom.* Magrine v. Spector, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968) (per curiam), *aff’d*, 250 A.2d 129 (N.J. 1969) (per curiam); KEETON ET AL., *supra* note 2, § 104, at 719.

47. In such situations, parties often do not dispute that the item involved is a product for purposes of strict liability, and courts recognize causes of action against the product manufacturer and distributors. *See* *Porter v. Rosenberg*, 650 So. 2d 79, 81 (Fla. Dist. Ct. App. 1995) (breast implant); *E.R. Squibb & Sons, Inc. v. Stickney*, 274 So. 2d 898 (Fla. Dist. Ct. App. 1973) (bone graft material). Rather, the question is whether a *service provider* who supplies the product qualifies as a seller.

transaction” or “predominant factor” test (“Essence Test”).⁴⁸ In *Bonebrake v. Cox*⁴⁹ the Court of Appeals for the Eighth Circuit explained: “The test for inclusion or exclusion is not whether [goods and services] are mixed, but . . . whether their predominant factor, their thrust, their purpose, reasonably stated, is the rendition of service, with goods incidentally involved . . . or is a transaction of sale, with labor incidentally involved”⁵⁰ If the service is only incidental to the sale, the seller/service provider may be strictly liable because the sale was the predominant factor of the transaction.⁵¹

In the 1967 case *Magrine v. Krasnica*,⁵² a New Jersey county court declined to hold a dentist strictly liable for injuries caused by a defective hypodermic needle that broke in the patient’s jaw during treatment.⁵³ The court held that the situation’s novelty did not “justify a headlong leap to impose strict liability” on “a dentist, or any other ‘user’ of an article . . . for injuries caused by a latent defect therein.”⁵⁴ The court distinguished the dentist from a commercial salesman:

[T]he *essence* of the transaction between the retail seller and the consumer relates to the *article sold*. The seller is *in the business* of supplying the product to the consumer. It is that, and that alone, for which he is paid. A dentist or a physician offers, and is paid for, his professional services and skill. That is the *essence* of the relationship between him and his patient.⁵⁵

The New Jersey Supreme Court affirmed this ruling in 1969.⁵⁶ However, later in 1969 the same court held that when a *commercial* service is involved in a hybrid transaction, a court *may* hold the service provider strictly liable for a

48. The Essence Test was first applied in *Clay v. Yates*, 156 Eng. Rep. 1123 (1856). This case involved the printing of a book, which included the service of printing as well as the sale of paper and binding cloth. The court noted that “the true criterion is, whether work is the essence of the contract, or whether it is the materials supplied.” *Id.* at 1125. Other courts applying the Essence Test include: *Hoff v. Zimmer, Inc.*, 746 F. Supp. 872, 875 (W.D. Wis. 1990) (hip prosthesis); *Hector v. Cedars-Sinai Medical Center*, 225 Cal. Rptr. 595, 599 (Ct. App. 1986) (pacemaker); *Silverhart v. Mount Zion Hospital*, 98 Cal. Rptr. 187, 190-91 (Ct. App. 1971) (surgical needle); and *Ayyash v. Henry Ford Health Systems*, 533 N.W.2d 353, 355 (Mich. Ct. App. 1995) (temporomandibular joint implants).

49. 499 F.2d 951 (8th Cir. 1974).

50. *Id.* at 960.

51. *Id.*

52. 227 A.2d 539 (Hudson County Ct., N.J. 1967), *aff’d sub nom. Magrine v. Spector*, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968) (per curiam), *aff’d*, 250 A.2d 129 (N.J. 1969) (per curiam).

53. *Id.* at 547.

54. *Id.* at 540.

55. *Id.* at 543.

56. *Magrine v. Spector*, 250 A.2d 129 (N.J. 1969) (per curiam).

defective product used in rendering the service.⁵⁷ In that case, the court held a beauty parlor strictly liable for injuries to a patron caused by a defective permanent wave solution.⁵⁸ The court found that despite the hybrid nature of the transaction, the sale was still a sale, and an implied warranty of fitness existed.⁵⁹

Careful to distinguish its earlier affirmation of *Magrine v. Krasnica*, the New Jersey Supreme Court differentiated professional services—particularly medical services—from commercial services such as those offered by a beautician. The court noted the following: medical professionals cater to medical needs, not aesthetic desires; medical professionals are unable to advertise their services; medical professionals use their experienced judgment to diagnose the patient and to decide what treatment is necessary; medicine is not an exact science, so no implied warranty that treatment will be infallible can exist; and the importance of medical services outweighs the need to impose strict liability on health care providers.⁶⁰

C. Maintaining the Seller/Service Provider Distinction for Health Care Providers

The Essence Test is an adequate tool for determining whether a medical service provider is also a seller when the defective device is merely an instrument used during medical treatment. Applying the Essence Test, one can logically conclude that a health care provider is not a “seller” if the defective product in question is a hypodermic needle or scalpel used during surgery. A patient neither bargains for, nor obtains title to, such instruments. Therefore, these instruments are only incidentally involved in the service provided. However, the Essence Test is not as helpful when a medical device is surgically implanted or otherwise transferred. Is the transfer of an artificial pacemaker only incidentally involved in the surgical procedure by which it is implanted? Or is the labor of surgery only incidental to transferring the pacemaker? Despite the difficulty of resolving these questions, courts generally refuse to hold hospitals or doctors strictly liable even when the sole purpose of surgery

57. See *Newmark v. Gimbel's Inc.*, 258 A.2d 697, 702 (N.J. 1969) (stating that the seller is liable if the product in a sales/service hybrid transaction is in “a dangerously defective condition”).

58. *Id.* at 705.

59. *Id.* at 702. For more discussion on the applicability of the Uniform Commercial Code to commercial hybrid transactions, see *United States v. Southern Contracting of Charleston, Inc.*, 862 F. Supp. 107, 109-10 (D.S.C. 1994) (noting that courts typically use the “predominant factor” test to determine the applicability of the U.C.C. to hybrid transactions, and holding that a contract for provision and installation of an incinerator was predominantly a sale); WHITE & SUMMERS, *supra* note 40, § 9-2, at 331-32 (explaining that most courts use the predominant factor test in deciding whether the U.C.C. applies to a contract involving both a sale and a service).

60. *Newmark*, 258 A.2d at 702-03.

is the transfer of a medical device.⁶¹

The California Court of Appeals applied the Essence Test in *Hector v. Cedars-Sinai Medical Center*,⁶² where a former patient sued a hospital under strict liability in tort and breach of warranty for supplying him with a defective pacemaker. The court found that “[t]he essence of the relationship between hospital and patient is the provision of professional medical services necessary to effect the implantation of the pacemaker—the patient does not enter the hospital merely to purchase a pacemaker but to obtain a course of treatment which includes implantation of a pacemaker.”⁶³ The court posited that the hospital was not “‘engaged in the business of distributing [pacemakers],”’ but instead engaged in the business of providing health care services.⁶⁴

Similarly, in *Cafazzo v. Central Medical Health Services, Inc.*,⁶⁵ the Pennsylvania Supreme Court suggested that the application of strict liability to a health care provider who implanted a mandibular prosthesis⁶⁶ would ignore the “ancillary nature” of the device.⁶⁷ The court refused to view the skills required to implant prosthetic devices as “adjunct to the sale of the implants.”⁶⁸ The hospital’s charging the patient for the medical device separately did not, according to the court, support the contention that the health care provider was involved primarily as the seller of the implant.⁶⁹

The Florida District Court of Appeal applied the Essence Test to breast implants in *Porter v. Rosenberg*.⁷⁰ The court affirmed the trial court’s order dismissing the strict liability complaint against the plastic surgeon, finding strict liability inapplicable to “a physician who supplies a product to a patient where the medical services could not have been rendered without using the product and where the predominant purpose of the transaction is the provision of medical services.”⁷¹

Though courts typically use the Essence Test to exempt hospitals from strict liability for the defective products they supply, a Texas court in *Thomas*

61. See, e.g., *Porter v. Rosenberg*, 650 So. 2d 79, 82 (Fla. Dist. Ct. App. 1995) (noting the distinction between defective instruments that are used and defective implants that are transferred, but nevertheless finding medical services the essence of the transaction in breast implant surgery); KEETON ET AL., *supra* note 2, § 104, at 720; Ryan & Lawn, *supra* note 42, at 831-32.

62. 225 Cal. Rptr. 595 (Ct. App. 1986).

63. *Id.* at 599.

64. *Id.* (quoting *Vandermark v. Ford Motor Co.*, 391 P.2d 168, 171 (Cal. 1964)).

65. 668 A.2d 521 (Pa. 1995).

66. A mandibular (or temporomandibular) prosthesis is a jaw implant.

67. *Cafazzo*, 668 A.2d at 524.

68. *Id.*

69. *Id.*

70. 650 So. 2d 79, 83 (Fla. Dist. Ct. App. 1995).

71. *Id.* at 80.

*v. St. Joseph Hospital*⁷² reached the opposite result using the test.⁷³ However, the dispositive fact in *Thomas* was that the defective product was provided not during medical treatment but in the course of an administrative hospital procedure. A defective hospital gown had ignited and fatally burned the patient wearing it.⁷⁴ The court stated: “Where . . . a hospital apparently supplies a product unrelated to the essential professional relationship, we hold that it cannot be said that as a matter of law the hospital did not introduce the harmful product into the stream of commerce.”⁷⁵

Thus, despite judicial reluctance to apply strict liability to hospitals and doctors, some courts apply it when the services involved are not professional. Why do courts refuse to extend the application to professional medical services? The court in *Thomas* apparently was influenced by the plaintiff’s argument that “no public policy supports extension of immunity to a hospital that supplies a defective product not integrally related to the professional services it renders.”⁷⁶ The decision points to the main impetus behind judicial reluctance to hold health care providers strictly liable for medically transferred defective products—public policy.

1. *Professional vs. Commercial Services: Policy Justifications for Strict Liability Do Not Apply to Health Care Providers Because They Are Professionals*

Courts applying the Essence Test to defective medical devices almost always buttress their somewhat illogical results with policy justifications, perhaps realizing the arbitrary hairsplitting often involved in holding that one aspect of a hybrid transaction predominates over another. Most of the policy considerations, in turn, rest on the professional/commercial distinction elucidated in *Newmark*⁷⁷ and *Thomas*. These considerations consistently presuppose the existence of a wide chasm between the transfer of articles through skilled medical services and the sale of commercially marketed goods.

Many of these policy arguments are simply assertions that imposing strict liability on health care providers would not coincide with the goals of and justifications for strict liability in tort.⁷⁸ For example, courts and commentators

72. 618 S.W.2d 791 (Tex. Civ. App. 1981, writ ref’d n.r.e.).

73. *Id.* at 796-97; see also *Johnson v. Sears, Roebuck & Co.*, 355 F. Supp. 1065, 1067 (E.D. Wis. 1973) (holding that a hospital may be strictly liable for products supplied through administrative, but not professional, services).

74. *Thomas*, 618 S.W.2d at 793.

75. *Id.* at 796-97.

76. *Id.* at 796.

77. *Newmark v. Gimbel’s Inc.*, 258 A.2d 697 (N.J. 1969).

78. See, e.g., *Ayyash v. Henry Ford Health Sys.*, 533 N.W.2d 353, 355 (Mich. Ct. App. 1995) (“[T]hose economic theories that underlie the imposition of strict liability upon makers and sellers of products do not justify the extension of strict liability to those who provide medical services.”).

propose that applying the doctrine to health care providers, who have no control over, or input in, the manufacture of medical instruments or devices, would not serve the deterrence justification for strict liability.⁷⁹ In addition, majority rule proponents contend that health care providers, unlike manufacturers, cannot effectively distribute the risk of loss caused by defective products because of their relatively small client base.⁸⁰ When making this argument, courts and commentators frequently point to the individual practitioner or the small hospital.⁸¹ They also cite comment c to section 402A,⁸² which discusses the risk-spreading justifications for imposing strict liability on those who “market” products and can incorporate the “burden of accidental injuries caused by products” into the cost of their production.⁸³ Majority rule proponents contend that health care providers cannot further the risk-spreading purpose because they do not market or advertise medical devices and instruments.⁸⁴ Furthermore, any risk spreading they could accomplish would be so limited as to be inefficient.⁸⁵

Majority rule proponents argue that the cost of imposing strict liability on health care providers would far outweigh the benefits. Medical treatment would become prohibitively expensive, necessarily reflecting the cost of insurance that strict liability would force health care providers to obtain for defective products.⁸⁶ Costs would further increase if health care providers had to hire their own researchers to test products for defects.⁸⁷ Majority rule proponents also assert that imposing strict liability would hinder medical advances because doctors would refrain from using new devices, fearing liability for any defects

79. *Id.* at 356; David Crump & Larry A. Maxwell, *Should Health Service Providers Be Strictly Liable for Product-Related Injuries? A Legal and Economic Analysis*, 36 Sw. L.J. 831, 854-55 (1982).

80. *Cf. Magrine v. Krasnica*, 227 A.2d 539, 545-46 (Hudson County Ct., N.J. 1967) (noting that although a medical professional could effectively spread the risk by impleading the supplier or manufacturer, often the medical professional cannot do so because the supplier and manufacturer are unknown), *aff'd sub nom. Magrine v. Spector*, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968) (per curiam), *aff'd*, 250 A.2d 129 (N.J. 1969) (per curiam).

81. *See, e.g., Crump & Maxwell, supra* note 79, at 853 (small rural hospital).

82. *See, e.g., Cafazzo v. Central Med. Health Servs., Inc.*, 635 A.2d 151, 153 (Pa. Super. Ct. 1993), *aff'd*, 668 A.2d 521 (Pa. 1995); Crump & Maxwell, *supra* note 79, at 851-52.

83. RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (1965).

84. *See Crump & Maxwell, supra* note 79, at 852 (discussing the “widely accepted” interpretation that “medical professional[s] do[] not advertise, merchandise, or make medical products available for discrete sales to the public”).

85. *See id.* at 853-54 (explaining that increased legal and incidental costs of imposing strict liability on health care providers would create net losses to the public). In other words, if health care providers incorporated the cost of liability into the cost of providing the product, no one could afford the product.

86. *See Magrine v. Krasnica*, 227 A.2d 539, 545 (Hudson County Ct., N.J. 1967) (rhetorically questioning whether anyone could dispute that costs were already increasing in 1967, after explaining that dentists and patients would spread the cost of insurance for strict liability by increasing fees paid by patients), *aff'd sub nom. Magrine v. Spector*, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968) (per curiam), *aff'd*, 250 A.2d 129 (N.J. 1969) (per curiam).

87. *See Crump & Maxwell, supra* note 79, at 855.

they may contain.⁸⁸ Finally, proponents of the majority rule point to the alternative legal avenues through which patients can seek compensation, including strict liability actions against manufacturers or distributors⁸⁹ and negligence claims against health care providers.⁹⁰

2. *A Final Policy Justification for Not Imposing Strict Liability on Health Care Providers: Preserving the Availability of "Healing" Services*

A recurrent refrain in cases involving the imposition of strict liability on health care providers is that public policy demands courts preserve the availability of medical services.⁹¹ Courts often express fear that if they impose strict liability on health care providers, health care providers will cease providing services.⁹² Courts likewise worry that health care providers' new insurance costs will make treatment prohibitively expensive, as mentioned above.⁹³ Concern over treatment availability lies at the root of concerns about increased costs and the hindering of medical development. The concept of "healing" is emotionally more powerful and seems more sociologically significant than any economic analysis of risk spreading or abstract anxiety about scientific advancement.

The "treatment availability" argument ultimately subsumes the others; indeed, the other considerations all seem to flow from the desire to keep high-quality medical services publicly accessible. Courts frequently note the "special and essential role" that health care providers occupy in our society. This sentiment echoes dicta in the *Newmark* opinion:

[T]he nature of the [medical] services, the utility of and the need for them, involving as they do, the health and even survival of many people, are so important to the general welfare as to outweigh in the policy scale any need for the

88. See *Hoven v. Kelble*, 256 N.W.2d 379, 391 (Wis. 1977) (stating that "imposition of strict liability might hamper progress in developing new medicines and medical techniques"); see also Richard A. Epstein, *Legal Liability for Medical Innovation*, 8 CARDOZO L. REV. 1139, 1142 (1987) ("Where products are subject to more stringent standards than medical services, there is a risk that treatment (services) will be substituted for products (goods), even when the latter is more suited to the task.").

89. See *Magrine*, 227 A.2d at 546 (noting that health care providers can implead the manufacturer and that patients can reach suppliers through discovery).

90. See *id.* at 546; *Cafazzo v. Central Med. Health Servs., Inc.*, 668 A.2d 521, 525-26 (Pa. 1995) (noting that health care providers could presumably be held negligent in providing services for errors in choosing medical products).

91. See *Cupp*, *supra* note 12, at 879-80, 890-91; Frank J. Vandall, *Applying Strict Liability to Professionals: Economic and Legal Analysis*, 59 IND. L.J. 25, 27-28 (1983-1984).

92. *Newmark v. Gimbel's Inc.*, 258 A.2d 697, 703 (N.J. 1969); *Hoven*, 256 N.W.2d at 391.

93. See *supra* note 86 and accompanying text.

imposition on dentists and doctors of the rules of strict liability in tort.⁹⁴

Like the Essence Test itself, these frequently cited policy concerns make sense when applied to certain products, procedures, and circumstances, but are less persuasive when applied to others. Critics of the majority rule exempting health care providers from strict liability ask the following questions: Does the Essence Test adequately classify hybrid transactions in which a product is transferred and not merely used? Do the economic policy concerns behind the majority rule take into account the increasingly commercial nature of modern health care? Is the interest in preserving health care availability relevant in the context of cosmetic surgery?

IV. CRITICISM OF THE MAJORITY RULE

Few courts have imposed strict liability on health care providers for defective medical devices.⁹⁵ The most significant minority rule case is *Bell v. Poplar Bluff Physicians Group, Inc.*,⁹⁶ which the South Carolina Supreme Court has declined to follow.⁹⁷ Unfortunately for the plaintiffs, the *Bell* decision is not even from its state's highest court. Further, its holding that health care providers may be strictly liable in tort for defective temporomandibular implants applies only to hospitals; the court expressly declined to extend it to individual doctors.⁹⁸ Though plaintiffs lack a large amount of supportive case

94. *Newmark*, 258 A.2d at 703; *see also Hoven*, 256 N.W.2d at 391 ("Medical services are an absolute necessity to society, and they must be readily available to the people."). Even courts rejecting the majority rule have noted that strict liability should not be imposed lightly or carelessly on those that are vital to the maintenance of public health and life. *See Bell v. Poplar Bluff Physicians Group, Inc.*, 879 S.W.2d 618, 620 (Mo. Ct. App. 1994) ("[I]n cases which deal with the conduct of individuals or institutions which themselves are pledged to protect human life and health, precautions must be taken to avoid an ultimate diminution of protection.") (quoting *Greenberg v. Michael Reese Hosp.*, 415 N.E.2d 390, 394 (Ill. 1980)).

95. *See, e.g., Bell*, 879 S.W.2d 618; *see also Skelton v. Druid City Hosp. Bd.*, 459 So. 2d 818, 823-24 (Ala. 1984) (reversing summary judgment for the hospital on an implied warranty claim involving a defective suturing needle because a hospital is a "merchant" under the U.C.C.); *Garcia v. Edgewater Hosp.*, 613 N.E.2d 1243, 1249 (Ill. App. Ct. 1993) (holding the hospital liable for breach of implied warranty of a defective heart valve).

96. 879 S.W.2d at 621 (reversing summary judgment for the hospital on a strict liability claim for injuries caused by a defective temporomandibular implant).

97. *See In re Breast Implant Prod. Liab. Litig.*, 331 S.C. 540, 550-51, 503 S.E.2d 445, 450-51 (1998).

98. *Bell*, 879 S.W.2d at 619 ("We recognize that the Western District of this court in *Hershley v. Brown* held that strict liability is not a basis for recovery against medical physicians. Whether there is a distinction between physicians and hospitals in the present context we need not decide . . .") (citation omitted); *see also James W. Poppell, Comment, When Is a Sale a Sale, and a Product a Product? Missouri Health Care Providers and Strict Product Liability Claims*, 63 UMKC L. REV. 283, 283 (1994) ("Under Missouri law, physicians are not subject to strict liability in tort . . .").

law, they nonetheless have an abundance of critical commentary on their side.⁹⁹

A. Transferrable Medical Devices, Hybrid Transactions, and the Essence Test

Technological advancement has produced a new breed of medical products—those intended for transfer and not mere use. Examples of such products include pacemakers, artificial valves, mandibular implants, penile prosthetics, and intrauterine devices. Unlike a grounding pad or hypodermic needle, the patient actually leaves the hospital in physical possession of these implanted devices. Unfortunately, some argue, the law is lagging behind these scientific advancements by refusing to recognize this sort of transfer as a sale.¹⁰⁰

When presented with implant cases, many courts blindly follow the majority rule exempting health care providers from strict liability for defective products;¹⁰¹ a rule initially formulated in the context of hybrid transactions involving incidental use of medical instruments.¹⁰² Many of these courts even fail to note the distinction between the use of these instruments and the transfer of implanted medical devices.¹⁰³ Others mention the distinction but nevertheless proceed to follow the majority rule as though none exists.¹⁰⁴

Why do courts ignore or dismiss the distinction between used instruments and transferred devices? Perhaps they realize that truly conceding the difference would render the Essence Test ineffective, so they refuse to acknowledge the distinction in order to maintain the test's viability. These courts may want to rely on more than policy in exempting health care providers from strict liability, so they turn a blind eye to the instrument/implant dichotomy in order to preserve the analytical tool with which they can conclude that even implanted devices are not “sold.”¹⁰⁵ These courts fail to realize that

99. See articles cited *infra* Part IV.

100. See Adler, *supra* note 12, at 96.

101. See, e.g., *Hector v. Cedars-Sinai Med. Ctr.*, 225 Cal. Rptr. 595 (Ct. App. 1986); *Cafazzo v. Central Med. Health Servs., Inc.*, 668 A.2d 521 (Pa. 1995); *In re Breast Implant*, 331 S.C. 540, 503 S.E.2d 445 (1998).

102. *Silverhart v. Mount Zion Hosp.*, 98 Cal. Rptr. 187, 191 (Ct. App. 1971) (holding that the hospital is not strictly liable for the use of a defective needle); *Magrine v. Krasnica*, 227 A.2d 539, 547 (Hudson County Ct., N.J. 1967) (holding that a dentist who used a defective needle was not strictly liable), *aff'd sub nom. Magrine v. Spector*, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968) (per curiam), *aff'd*, 250 A.2d 129 (N.J. 1969) (per curiam); *Podrat v. Codman-Shurtleff, Inc.*, 558 A.2d 895, 898 (Pa. Super. Ct. 1989) (holding that a hospital is not liable for defective forceps used in surgery).

103. See Adler, *supra* note 12, at 107-08 (implying that courts misapply “surgical instrument analysis” to implant cases).

104. See, e.g., *Porter v. Rosenberg*, 650 So. 2d 79, 82 (Fla. Dist. Ct. App. 1995).

105. Poppell, *supra* note 98, at 300 (“In order to avoid arguing these conclusions strictly on policy grounds, the courts often resort to deciding that there is no ‘sale’ involved between patient and doctor because the essence of the transaction is services-oriented.”).

truly valid policy justifications can indeed stand alone and that the inappropriate Essence Test is an unstable and unnecessary foundation which actually weakens the claims it is meant to support.

Some majority rule critics do not question the viability of the Essence Test despite the instrument/implant distinction. However, these critics argue that a *proper* application of the Essence Test does not justify exempting health care providers from strict liability for defective medical implants. Implying that the test can nevertheless yield valid results when correctly implemented, these critics argue that the “essence of the transaction” in implant procedures is the implant itself, not the medical service of implanting it.¹⁰⁶ The *Bell* court achieved this result by applying the Essence Test in this manner.¹⁰⁷

A more defensible contention is that courts should not apply the Essence Test to implant procedures at all.¹⁰⁸ One cannot logically assert that the service by which a pacemaker is implanted, rather than the pacemaker itself, predominates a pacemaker operation. In seeking the procedure, patients do not desire the implantation services more than the implant, or vice versa; they necessarily desire both equally because they simply cannot have one without the other.

Despite the criticism directed at particular applications of the Essence Test, the South Carolina Supreme Court’s *In re Breast Implant* decision illustrates that courts continue to apply it, even in transferred medical device cases. Courts cling to the legal fiction that the services predominate implant surgery out of reluctance to base a decision solely on public policy. However, many critics argue that even the traditional policy justifications for refusing to extend strict liability to health care providers are not well founded, especially in the implant context.

B. Blurring the Professional/Commercial Distinction: Hospitals As Big Business

Many of the policy justifications that support the health care provider

106. See Adler, *supra* note 12, at 96 (arguing that the supply of surgical devices, not the services, can represent the essence of the transaction in many instances); Cupp, *supra* note 12, at 895-96 (arguing that at least in cases of cosmetic surgery, the consumer’s expectations focus more on the product than the services, and thus the sale of the implant is the predominant factor). However, Adler also points out that the Essence Test, as traditionally applied, “is no longer a viable option” with regard to some hybrid transactions. Adler, *supra* note 12, at 103-05.

107. The court distinguished between use and transfer but applied the Essence Test anyway, finding that the “sales aspect of the transaction may predominate over the service aspect and the policy of strict liability in tort is served by allowing this action.” *Bell v. Poplar Bluff Physicians Group, Inc.*, 879 S.W.2d 618, 620 (Mo. Ct. App. 1994).

108. Adler, *supra* note 12, at 103-05. Adler asserts that “[t]he essence test seems to fail in a health care arena so filled with transactions in essential goods.” *Id.* at 105. She criticizes the test and questions its viability but does not expressly argue that it should be rejected. Instead, she emphasizes that implanted or otherwise transferred goods often themselves “reflect the crux of the transaction.” *Id.*

exemption from strict liability relate to the distinction between professional and commercial services.¹⁰⁹ But the increasingly commercial nature of health care weakens the arguments that health care providers do not market goods, cannot spread the risk of loss, and cannot deter defects. To a lesser extent, the arguments that strict liability would prohibitively increase health care costs and hinder medical research also suffer in light of the health care industry's transformation into a big-business enterprise. Finally, the justification that patients already have enough avenues of recovery often fails, at least with respect to breast implants, because of the manufacturer's bankruptcy.

1. *Marketing Medical Devices*

Health care providers argue that because they do not market medical devices and are not in "the business of selling" them, they are outside the scope of section 402A.¹¹⁰ They likewise contend that breach of warranty actions should not apply to them because they are not merchants. Health care providers resist acknowledging their commercial nature, perhaps hoping no one will notice that "the hospital of just twenty years ago bears little resemblance to today's complex corporate entity."¹¹¹ However, the court in *Skelton v. Druid City Hospital Board*¹¹² did note:

We cannot ignore the fact that hospitals, whether profitable or not, are businesses.

... In the course of their competition, hospitals certainly hold themselves out to the public as having special knowledge regarding the provision of medical services to patients. Inherent in this presentment is a warranty that the hospital will sell, furnish, or supply patients with goods for use in the provision of medical services which are fit for their intended purpose. For that reason, Druid City is clearly a "merchant," within the Commercial Code's definition of that word.¹¹³

109. *See supra* Part III.C.1.

110. This argument is based on comments c and f of section 402A. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (1965) (emphasizing that strict liability should be imposed on those who market products); *id.* cmt. f (defining the "business of selling" and noting that "[i]t is not necessary that the seller be engaged solely in the business of selling such products").

111. Paul L. Scibetta, Note, *Restructuring Hospital-Physician Relations: Patient Care Quality Depends on the Health of Hospital Peer Review*, 51 U. PITT. L. REV. 1025, 1025 (1990).

112. 459 So. 2d 818 (Ala. 1984).

113. *Id.* at 822-23. The court further noted that even if it had determined that Druid City was not a merchant, the hospital "would still be liable under U.C.C. § 2-315 because of the nature of the patient's reliance on the skill and judgment of the hospital in the selection of medical supplies used for the care of the patient." *Id.* at 823.

As for section 402A, the court in *Bell* dismissed the defendant hospital's assertions that it was not in "the business of selling," holding that even if this contention was true, courts should allow plaintiffs to maintain strict liability claims "against a seller whether or not such sales are a substantial part of its operation or business."¹¹⁴ The *Bell* court believed that the incidental nature of such a sale "should not relieve [a hospital] of liability any more than if a hospital sells a defective toy at its gift shop or a hairdresser sells defective hair spray which may be incidental to her other services."¹¹⁵

These examples resemble the facts of *Thomas*,¹¹⁶ the case involving the defective hospital gown, and *Newmark*,¹¹⁷ the case involving the defective perm solution. The courts in both of those cases carefully distinguished between the commercial or administrative services of furnishing these items and the professional services involved in medical treatment. The *Bell* court refused to draw such a distinction. The *Bell* court also noted that the defendant hospital charged a \$129 mark-up for the temporomandibular implant.¹¹⁸ Although the court did not consider the mark-up greatly significant,¹¹⁹ such actions by health

114. *Bell v. Poplar Bluff Physicians Group, Inc.*, 879 S.W.2d 618, 619 (Mo. Ct. App. 1994).

115. *Id.* The court went on to note that "a sale of a product is not required to bring an action for strict liability. Liability is imposed on those placing a product in the stream of commerce." *Id.*; see also *Henderson v. Gould, Inc.*, 288 S.C. 261, 268, 341 S.E.2d 806, 810 (Ct. App. 1986) (holding that though a sale is required for a breach of warranty action, the use of the terms "sells" and "sellers" in section 402A and section 15-73-10 of the South Carolina Code is "merely descriptive and the doctrine of strict liability may be applied if the requirements for its application are otherwise met, even though no sale has occurred in the literal sense"). The *Henderson* court further noted that the South Carolina Supreme Court "has implicitly recognized that a sale is not required for the doctrine to be applied." *Id.* (citing *Schall v. Sturm, Ruger Co.*, 278 S.C. 646, 648, 300 S.E.2d 735, 736 (1983) ("Recovery under Section 15-73-10, Code, does not rest upon any rights or duties framed by some transaction, as in the case in a suit for breach of warranty, even where privity has been abolished.")).

116. *Thomas v. St. Joseph Hosp.*, 618 S.W.2d 791 (Tex. Civ. App. 1981, writ ref'd n.r.e.).

117. *Newmark v. Gimbel's Inc.*, 258 A.2d 697 (N.J. 1969).

118. See *Bell*, 879 S.W.2d at 619 n.1.

119. See *id.* Other majority rule decisions have dismissed such charges as irrelevant. See, e.g., *In re Breast Implant Prod. Liab. Litig.*, 331 S.C. 540, 548, 503 S.E.2d 445, 449 (1998) ("[T]he thrust of the inquiry is not whether a separate consideration is charged for the products used in the exercise of medical skill, but what service is performed to restore or maintain the patient's health.").

Section 20 of the proposed final draft of the Restatement (Third) of Torts: Products Liability, entitled "Definition of 'One Who Sells or Otherwise Distributes,'" includes a comment that contrasts the statements of these courts by emphasizing the significance of separately billing a consumer for a product. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 20 cmt. d (Proposed Final Draft 1997). Comment d, which discusses "sales-service combinations," states:

When the same person provides both products and services in a commercial transaction, whether a product has been sold may be difficult to determine. When the product and service components are kept separate by the parties to the transaction, as when a

care defendants nevertheless illustrate their commercial nature. One would think that if providers of pure professional services desired higher compensation, they would simply increase the cost of their services rather than marking up the product; that is, if they really believe their services overwhelmingly predominate over the product's sale.

Scholars maintain that because advertising may inspire consumers to exercise less caution in planning their purchases, the imposition of strict liability on those who advertise defective products is all the more justified.¹²⁰ Consumers rely on the representations made in advertisements. To support the argument that health care providers do not market their medical devices and are not in the business of selling, the *Newmark* and *Hoven* courts mentioned that health care providers do not advertise.¹²¹ This argument is simply no longer valid. Modern health care providers do in fact promote both their services and their medical devices through advertisements. Magazines and newspapers often contain ads for cosmetic surgery; in particular, ads that induce the consumer to rely on both the skill and expertise of a particular doctor and on the safety of the medical device involved.¹²² Emily Aschinger has researched the incredible lengths to which plastic surgeons have gone to promote their products:

In order to help create the demand for breast implants and get implants into the stream of commerce, the American Society of Plastic and Reconstructive Surgeons (ASPRS) created a new disease. This medical problem is called micromastia, small breasts, and it can be cured with breast implants. The ASPRS told the FDA that “[t]here is a substantial and enlarging body of medical information and opinion that these deformities (small breasts) are really a disease.” “In a petition to the FDA, ASPRS said that small breasts were ‘deformities’—‘really a disease’—causing ‘a total lack of well-being . . . in most patients.’” Now that small breasts are a bona fide problem confirmed by the medical

lawn-care firm bills separately for fertilizer applied to a customer's lawn or when a machinery repairer replaces a component part and bills separately for it, the firm will be held to be the seller of the product.

Id. Despite this assertion, the comment later warns of the double standard applied to hospitals: “It should be noted that, in a strong majority of jurisdictions, hospitals are held not to be sellers of products they supply in connection with the provision of medical care, regardless of the circumstances.” *Id.*

120. See, e.g., Cupp, *supra* note 12, at 898-99.

121. *Newmark v. Gimbel's Inc.*, 258 A.2d 697, 702 (N.J. 1969); *Hoven v. Kelble*, 256 N.W.2d 379, 391 n.15 (Wis. 1977) (“Although physicians do hold themselves out as experts deserving of reliance, they do not advertise, and it has been suggested that this factor is significant.”).

122. See Cupp, *supra* note 12, at 899 (stating that many magazines and newspapers contain ads for cosmetic surgery).

community, there are more than a few willing cosmetic surgeons to help the diseased find the way to a cure.¹²³

While Aschinger establishes the pattern and volume of advertisements for cosmetic breast implants, she also points out that “[t]he American Medical Association finds advertising to be an unprofessional practice.”¹²⁴ Although other types of medical devices are rarely promoted in this fashion, the categorical argument that doctors do not advertise can no longer be used to support the claim that health care providers, unlike sellers, do not market their products and should thus be exempt from strict liability.

2. *Spreading the Risk*

“A general purpose for imposing strict liability on businesses is that they are profiting from the sale of the product and thus, are in the best position to redistribute the cost of compensating the injured.”¹²⁵ Proponents of the majority rule argue that because health care providers consist of relatively small, charitable organizations and individual physicians, they cannot serve the risk-spreading function of strict liability. This argument ignores the fact that the typical modern hospital is not only a business driven by profits, but often a huge corporate enterprise.¹²⁶ More and more business-like, hospitals, if not individual doctors, are capable of compensating patients injured by defective medical devices. The Utah Supreme Court’s assertion that “hospitals are bourns of mercy and most physicians are unselfish disciples of relief and the cure of

123. Aschinger, *supra* note 12, at 407 (footnotes omitted) (quoting, respectively, Kate Dunn, *Why Do Women Remake Their Bodies to Fit the Fashion?*, THE GAZETTE (Montreal), Feb. 25, 1992, at A2, and Jan Gehorsam, *Women Feeling Pressured to Sculpt a Perfect Body*, ATLANTA J. & CONST., Mar. 29, 1992, at A1). After describing several specific ads for breast implants, Aschinger asserts that “[t]he most graphic depiction of promoting the sale of breast implants was in Tennessee in 1987. A radio station, in conjunction with a local plastic surgeon, offered a free breast enlargement surgery as a radio giveaway.” *Id.* at 409 (footnote omitted).

124. Aschinger, *supra* note 12, at 407; *but see* DAVE LINDORFF, MARKETPLACE MEDICINE: THE RISE OF THE FOR-PROFIT HOSPITAL CHAINS 27 (1992) (noting that, in 1989, hospitals spent \$687 million on advertising and \$853 million on other marketing).

125. Kristin B. Meyer, Comment, *Silicone Breast Implants and Hospital Liability: A New Forum for Hybrid Transactions*, 99 DICK. L. REV. 439, 464 (1995).

126. *See* LINDORFF, *supra* note 124, at 12 (“It’s hard to accept the idea that today hospitals are becoming just another business. But they are.”); *see also* Skelton v. Druid City Hosp. Bd., 459 So. 2d 818, 822 (Ala. 1984) (noting that even if a hospital does not make a profit, it is nevertheless a business); Meyer, *supra* note 125, at 465 (“Of course, it is recognized that all hospitals may not be as profitable as others, but the same inequity exists in the business world.”). In fact, as a result of studies showing that hospitals do not provide free medical treatment in proportion to the extent of their exemption, several states have challenged the tax-exempt status of their non-profit hospitals. *See* Alice A. Noble et al., *Charitable Hospital Accountability: A Review and Analysis of Legal and Policy Initiatives*, 26 J.L. MED. & ETHICS 116, 116-17 (1998).

human ills[, not] profit-seeking vendors in the market place”¹²⁷ seems clearly misplaced today, particularly with regard to plastic surgeons.

Comment c to section 402A states that “the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.”¹²⁸ Further, “public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained.”¹²⁹ Given the manner in which many hospitals and doctors market their services and the medical devices they provide, and given the fact that health care providers could obtain strict liability insurance, the rationale for risk-spreading stated in comment c applies to these health care providers just as it applies to commercial retailers and distributors. The court in *Hoven v. Kelble*¹³⁰ conceded that “[t]he hospital and doctor are in a better position than the patient to bear and distribute the risk of loss.”¹³¹ However, the court ultimately refused to impose strict liability on health care providers out of concern for the costs and availability of health care. Courts that have adopted the majority rule, like the *Hoven* court, argue that insurance costs would not be absorbed seamlessly into the production cost of medical devices, but would radically increase health care costs.¹³²

3. *Increasing the Costs of Health Care*

Minority rule proponents maintain that the concern over increasing health care costs is unwarranted.¹³³ Commentators have found the argument that costs would skyrocket unpersuasive because imposing strict liability on other products, including essential items such as food and drugs, has clearly not inspired prohibitive price increases.¹³⁴ As businesspeople, health care providers perhaps realize that if they raise prices too much, they will lose patients to the competition.

In sum, minority rule proponents claim no reason exists to suspect that the risk-spreading rationale would fail with respect to health care providers because

127. *Dibblee v. Dr. W. H. Groves Latter-Day Saints Hosp.*, 364 P.2d 1085, 1087 (Utah 1961).

128. RESTATEMENT (SECOND) OF TORTS § 402A cmt. c (1965).

129. *Id.*

130. 256 N.W.2d 379 (Wis. 1977).

131. *Id.* at 391.

132. *Id.*

133. See Adler, *supra* note 12, at 108-09.

134. See Michael M. Greenfield, *Consumer Protection in Service Transactions—Implied Warranties and Strict Liability in Tort*, 1974 UTAH L.REV. 661, 687 (1974), quoted in *Hoven*, 256 N.W.2d at 391 n.17; see also Cupp, *supra* note 12, at 891 (noting that if courts applied strict liability to health care providers for cosmetic devices, any resulting cost increase might even benefit society by discouraging consumers from purchasing them and, therefore, from being injured by them).

their purchase of insurance would lead to prohibitively expensive health care. Though David Crump and Larry Maxwell have argued that insurance of this sort would be more expensive than other kinds because of the range of products involved and the lack of claims history and precedent,¹³⁵ such initial insurance costs are not unusual when the insured subject matter is novel. If strict liability was applied only to those devices that are transferred during medical treatment, the amount of products would be manageable.

4. Deterrence

In response to the *Cafazzo* court's argument that "a hospital not involved in the development or manufacture of the product" is not best positioned to prevent a defective product's circulation,¹³⁶ the *Bell* court pointed out the ironic truth of this statement with regard "to most products sold by retailers."¹³⁷ The traditional justification for extending strict liability to retailers despite this argument is that a retailer's place in the distribution chain allows it to influence the manufacturer to produce safer products.¹³⁸ A retailer can simply refuse to buy a product that has not been thoroughly tested or that poses a known risk. In that sense, the retailer does have control over a product, even though it may not participate directly in its manufacture.

Health care providers enjoy even more control than most retailers because they provide the only avenue through which a patient can obtain a medical device; purchasing implants directly from manufacturers would do patients little good.¹³⁹ Also, because of the essential role health care providers play in the implantation and distribution of medical devices, patients rely completely on providers' judgment in selecting the devices, typically having no input in brand selection.¹⁴⁰ Manufacturers are surely aware of this reliance and of health care providers' resulting control over what they produce.

135. Crump & Maxwell, *supra* note 79, at 854.

136. *Cafazzo v. Central Med. Health Servs. Inc.*, 635 A.2d 151, 154 (Pa. Super. Ct. 1993), *aff'd*, 668 A.2d 521 (Pa. 1995).

137. *Bell v. Poplar Bluff Physicians Group, Inc.*, 879 S.W.2d 618, 620 (Mo. Ct. App. 1994). The arguments of Crump and Maxwell, like the *Cafazzo* court's argument, are applicable to all retailers. Therefore, such arguments do not credibly distinguish health care providers as a special class that should be immune from strict liability.

138. *See Vandermark v. Ford Motor Co.*, 391 P.2d 168, 171 (Cal. 1964); Meyer, *supra* note 125, at 461.

139. *See Adler*, *supra* note 12, at 109 ("[T]here may be *more* cause to apply strict liability to the hospital, as the hospital and the health care profession in general have a unique relationship with their consumers."); Meyer, *supra* note 125, at 462 ("[A]n individual's purchase of breast implants directly from the manufacturer would be utterly useless.").

140. *See Meyer*, *supra* note 125, at 463.

5. *Hindering Medical Advancements*

In *Johnson v. Sears, Roebuck & Co.*¹⁴¹ the court maintained that holding medical professionals strictly liable might discourage them from performing treatment that “involves a developing area of medicine,” remarking that this practice “would work a serious social disservice.”¹⁴² However, “the charge that the tort system undermines innovation, keeps valuable products out of the market, and halts research investment has never been documented.”¹⁴³ Research and development of prescription drugs, for example, have significantly increased since products liability suits have become common in that area.¹⁴⁴ Though the *Hoven* court declined to extend strict liability to a hospital, it did not find the argument that the “imposition of strict liability might hamper progress in developing new medicines and medical techniques” completely persuasive.¹⁴⁵

6. *Adequate Compensation from Manufacturer*

The contention that patients can recover adequate compensation from sources other than health care providers runs somewhat thin when the manufacturer has declared bankruptcy.¹⁴⁶ Manufacturer bankruptcy is often the sole reason plaintiffs sue health care providers under strict liability, a theory widely held inapplicable to doctors and hospitals.¹⁴⁷ When defects are discovered in popular devices like breast implants, which have been supplied to over two million women, the probability that the manufacturer will become bankrupt is very high.¹⁴⁸ Because plaintiffs cannot recover from health care providers for negligence when the defective nature of the product was the sole cause of the injury, they are left with no source of compensation when courts deny their strict liability claims. In these situations, if health care providers are not strictly liable, the risk-spreading function of strict liability is confounded; the party least able to bear the loss—the consumer—is forced to do so. However, majority rule proponents would likely counter this contention by

141. 355 F. Supp. 1065 (E.D. Wis. 1973).

142. *Id.* at 1067.

143. Adler, *supra* note 12, at 110; *see also id.* (“[R]esearch and development expenditures have more than doubled.”).

144. *Id.*

145. *Hoven v. Kelble*, 256 N.W.2d 379, 391 (Wis. 1977); *see id.* at 391 n.17.

146. *See generally* Cupp, *supra* note 12, at 903-06 (discussing how “Medical Professionals May Become the Only Parties Against Whom Recovery Is Available”). Dow Corning, the leading manufacturer of breast implants, declared bankruptcy in 1995. *See* Michael Higgins, *Mass Tort Makeover?*, 84 A.B.A. J., Nov. 1998, at 53, 54.

147. In *Ayyash v. Henry Ford Health Systems*, 533 N.W.2d 353 (Mich. App. 1995), the court recognized that imposing strict liability on the medical profession would only benefit the few who, for reasons such as bankruptcy, cannot obtain recovery from manufacturers. *Id.* at 355.

148. *See* Cupp, *supra* note 12, at 905 (discussing Dow Corning’s economic liability).

asking whether holding health care providers liable merely because the manufacturer's pockets are empty is really justifiable.

C. *Cosmetic Procedures: A "Healing" Service?*

Concern that the availability of medical treatment will suffer if courts impose strict liability on health care providers, because of either prohibitive cost or reluctance of doctors and hospitals to provide certain services, underlies all other policy considerations. But if courts imposed strict liability only when a health care provider implants or otherwise transfers a medical device to a patient, only these procedures would be affected. While anxiety over the accessibility of such procedures is perhaps warranted with regard to medically necessary devices, cosmetic devices such as breast implants hardly fall under the category of "healing" services in need of special protection. Even those implants provided to women who have had mastectomies are arguably not "medically necessary."¹⁴⁹

But should a court distinguish between cosmetic and medically necessary devices with regard to holding health care providers strictly liable for device defects? The court in *Weissman v. Dow Corning Corp.*¹⁵⁰ found the cosmetic, rather than the "healing," nature of the plaintiff's surgery legally insignificant, stating "[w]e are not even sure that the distinction between a cosmetic procedure and 'an act of healing' is susceptible to objective, legal articulation" because "[m]any legitimate medical procedures undoubtedly serve both purposes."¹⁵¹ Indeed, though policy considerations do not justify immunity from strict liability for health care providers supplying purely cosmetic devices, a court or legislature would not likely open that can of worms for practical reasons.

Without distinguishing between cosmetic and medically necessary surgery, concern over maintaining the availability of medical services is valid. However, if courts applied strict liability to health care providers, the nation's doctors would not likely give up medicine and begin selling used cars. Likewise, hospitals across the country would not suddenly shut their doors to the sick and infirm. Because of their commercial nature, and because they supply something that will always be in demand, hospitals would find a way to recover. Moreover, they would be forced to recover without increasing costs to a

149. See *id.* at 907 (explaining that the definition of "cosmetic" covers all breast implants, "regardless of whether they were purchased in response to a mastectomy or merely to make breasts larger"); but see *id.* at 906 ("Given the physical deformity caused by a mastectomy and the widely recognized psychological impact of such an operation, one might certainly question whether implanting a silicone breast following a mastectomy should be considered cosmetic as opposed to therapeutic.")

150. 892 F. Supp. 510 (S.D.N.Y. 1995).

151. *Id.* at 517 n.8; see also *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 383 (Ct. App. 1992) (involving penile implant designed to improve aesthetic appearance as well as to alleviate impotency).

prohibitive level in order to maintain their broad client base.

V. THE SOUTH CAROLINA DECISION

A. *Procedural Background*

The South Carolina Supreme Court heard oral arguments on matters relating to health care provider liability for defective breast implants in February of 1998 and issued its decision in June of that year. *In re Breast Implant Product Liability Litigation*¹⁵² reached the court in an unconventional fashion.¹⁵³ For expediency, manufacturers were set apart as one group of

152. 331 S.C. 540, 503 S.E.2d 445 (1998).

153. In its opinion, the court explained:

In August 1993, Chief Justice David W. Harwell assigned Judge Henry F. Floyd to dispose of all pre-trial motions and other matters arising out of the breast implant litigation then pending, and to be subsequently filed, in this state's court system. In April 1995, Chief Justice Ernest A. Finney, Jr. issued an order granting permission to Judge Floyd to promulgate a Case Management Order regulating pre-trial proceedings in the breast implant cases.

In November 1996, Judge Floyd issued an order addressing the defendants' motion to dismiss the master complaint. The circuit court dismissed certain of the causes of action in the master complaint. Among the causes of action not dismissed were those for strict liability, breach of implied warranties, and breach of express warranty. After Plaintiffs proposed an amended master complaint, adding a cause of action for the common law warranty of soundness and quality, the defendants again moved to dismiss the complaint. Judge Floyd denied the motion. The circuit court then, *sua sponte*, moved to certify to this Court two questions related to the applicability of S.C. Code Ann. § 15-73-10 (1976) and Restatement (Second) of Torts § 402A to Healthcare Defendants.

In addition, Healthcare Defendants petitioned this Court for a writ of certiorari to review Judge Floyd's orders regarding the applicability of strict liability and warranty causes of action to Healthcare Defendants. In March 1997, we issued an order granting Healthcare Defendants' petition. We found that there is no provision, under Rule 228(a), SCACR, for this Court to answer questions certified by a state circuit judge; however, we agreed with Judge Floyd that very important questions of law need to be answered at this time. Accordingly, the request for certification was denied, but the petition for a writ of certiorari was granted.

defendants, and hospitals and doctors together formed another defendant category (despite their differing roles in breast implant provision).

The court mentioned the unusual nature of this procedural background in a footnote, pointing out that the court generally will not grant certiorari for matters “that can be entertained in the trial court or on appeal.”¹⁵⁴ The court defined the breast implant litigation as presenting “exceptional circumstances,” explaining that the issuance of a writ of certiorari is in order when such circumstances are present.¹⁵⁵ Because the matter involved “[n]ovel questions of law concerning issues of significant public interest that are contained in numerous state and federal actions,” the court agreed to review the case to best “serve the interests of judicial economy.”¹⁵⁶

Perhaps the problems imposed by breast implant litigation in other jurisdictions influenced the court. Federal breast implant litigation in the Northern District of Alabama, for example, has dominated U.S. District Judge Sam Pointer Jr.’s docket for the past six years.¹⁵⁷ In 1992 Judge Pointer was chosen “to manage discovery in federal implant cases,” which so far have totaled about 27,000 cases.¹⁵⁸ Judge Pointer had to relinquish his criminal docket and establish an office to handle the administration of settlement claims.¹⁵⁹ By resolving some of the important issues involved in breast implant litigation, such as whether strict products liability applies to health care providers, the South Carolina Supreme Court has served judicial economy.

B. The Court’s Analysis

The court considered whether a health care provider who uses or provides a medical instrument or device is liable under the following: (1) South Carolina’s strict tort liability statute,¹⁶⁰ (2) South Carolina’s statutory versions of the Uniform Commercial Code’s express¹⁶¹ and implied warranties,¹⁶² and (3) a common-law warranty of soundness and quality.¹⁶³ The court noted that “[t]he determinative issue in this case is whether a health care provider . . . is a ‘seller’ within the meaning of section 15-73-10.”¹⁶⁴ Thus, most of the opinion

Id. at 542-43, 503 S.E.2d at 446-47 (footnote omitted).

154. *Id.* at 543 n.2, 503 S.E.2d at 447 n.2.

155. *Id.*

156. *Id.* at 543-44 n.2, 503 S.E.2d at 447 n.2.

157. See Higgins, *supra* note 146, at 54 (quoting Judge Pointer as saying that breast implant litigation “has probably, professionally, taken 80 percent of my time”).

158. *Id.*

159. *Id.* at 55.

160. S.C. CODE ANN. § 15-73-10 (Law. Co-op. 1976).

161. *Id.* § 36-2-313.

162. *Id.* §§ 36-2-314 to -315.

163. The *In re Breast Implant* court indicated that South Carolina does not recognize a common-law warranty of soundness and quality in the medical context. See *In re Breast Implant Prod. Liab. Litig.*, 331 S.C. 540, 553, 503 S.E.2d 445, 452 (1998).

164. *Id.* at 545, 503 S.E.2d at 448.

is devoted to strict liability in tort.

Reversing Judge Floyd's November 1996 ruling that South Carolina's Defective Products Act¹⁶⁵ applies to health care providers, rendering them strictly liable in tort for defective instruments or devices used in surgery, the court adopted the majority rule that health care providers are not "sellers" for strict liability purposes.¹⁶⁶ Perhaps in the interest of brevity, the court provided little original analysis, instead listing majority-rule cases and summarizing their holdings.¹⁶⁷ The court's failure to justify its decision with lengthy policy arguments ironically makes its ruling seem more justified, as if the court was so confident in the majority rule that it found policy-related rationalization simply unnecessary. By omitting reference to the policy arguments that so many commentators have criticized as weak and inapplicable to health care providers, the court effectively shielded its ruling from attack on these grounds.

1. *Blood Shield Statutes*

The court dismissed the plaintiffs' argument that implant providers are subject to strict tort liability under section 15-73-10 because they are not specifically exempted in the statute. The plaintiffs noted that section 44-43-10 exempts the providers of blood products from implied warranties of merchantability and fitness;¹⁶⁸ therefore, if the legislature had intended to exempt implant providers from liability under section 15-73-10, it would have done so in the same fashion—by expressly exempting them.¹⁶⁹ The court found the argument reasonable from the standpoint of statutory construction but held that the argument ignored relevant case law specifically addressing health care providers' immunity from strict liability for defective devices and instruments.¹⁷⁰

Section 44-43-10 is what is commonly known as a "blood shield statute." It states that blood and human tissues are not to be thought of as products or "commodities subject to sale or barter."¹⁷¹ The section further specifies that the transfer of these substances "shall be considered a medical service," not a sale.¹⁷² Forty-seven other states have enacted similar statutes.¹⁷³

"[B]lood shield statutes indicate a clear legislative intent to treat blood differently than other goods intended for human consumption."¹⁷⁴ Most of these statutes were enacted in the 1970s and 1980s in response to legislative fears of

165. S.C. CODE ANN. §§ 15-73-10 to -30 (Law. Co-op. 1976).

166. *In re Breast Implant*, 331 S.C. at 553, 503 S.E.2d at 452.

167. *Id.*

168. S.C. CODE ANN. § 44-43-10 (Law. Co-op. 1976).

169. *In re Breast Implant*, 331 S.C. at 545, 503 S.E.2d at 448.

170. *Id.*

171. S.C. CODE ANN. § 44-43-10 (Law. Co-op. 1976).

172. *Id.*

173. *See Adler, supra* note 12, at 124.

174. *Id.*

disease proliferation through infected blood.¹⁷⁵ The fundamental role blood transfusions play in countless medical procedures, in addition to anxiety over the spread of AIDS and hepatitis, led legislatures to separate blood from other products used or transferred during medical treatment.¹⁷⁶ The obvious fact that, unlike medical devices, blood and human tissue are not manufactured further sets these medically transferred articles apart from breast implants.

Because courts typically “resolve tainted blood claims simply by reviewing the applicable statute,”¹⁷⁷ blood cases decided after a jurisdiction has enacted a blood shield statute bear little relevance to medical device cases. However, a court could find cases decided before a blood shield statute’s enactment are still good law with respect to other products and that these cases remain valid precedent for medical device cases. In *Garcia v. Edgewater Hospital*¹⁷⁸ the Illinois Appellate Court recognized that Illinois’s enactment of a blood shield statute effectively overruled its decision in *Cunningham v. MacNeal Memorial Hospital*,¹⁷⁹ in which it held a hospital strictly liable for the transfer of defective blood. Nevertheless, the court found *Cunningham* “still controlling with respect to other sales,” relying on it to hold the defendant hospital liable under an implied warranty of merchantability for supplying the plaintiff with a defective heart valve.¹⁸⁰

Despite *Garcia*, the South Carolina Supreme Court rejected the idea that *Cunningham* could apply to medical device cases.¹⁸¹ The court repudiated *Cunningham* as a decision that had been “superseded by statute,”¹⁸² citing the Illinois post-blood-shield-statute case *Advincula v. United Blood Services*.¹⁸³ Perhaps because the plaintiffs failed to cite *Garcia* in their briefs,¹⁸⁴ the supreme court failed to acknowledge it. At any rate, *Garcia* is a minority rule decision based on another minority rule decision that has arguably become bad law. Therefore, even if the South Carolina Supreme Court had considered the

175. *See id.*

176. *See id.*

177. Ryan & Lawn, *supra* note 42, at 821.

178. 613 N.E.2d 1243, 1248 (Ill. App. Ct. 1993).

179. 266 N.E.2d 897 (Ill. 1970).

180. *Garcia*, 613 N.E.2d at 1248. Because the *Cunningham* decision followed the minority rule, most courts relying on pre-blood-shield-statute cases would arrive at the opposite conclusion. The leading pre-blood-shield-statute case is *Perlmutter v. Beth David Hospital*, 123 N.E.2d 792 (N.Y. 1954), in which the New York Court of Appeals opined that services were the essence of the transaction in a blood transfusion. *Id.* at 794.

181. *In re Breast Implant Prod. Liab. Litig.*, 331 S.C. 540, 551, 503 S.E.2d 445, 451 (1998).

182. *Id.*

183. 654 N.E.2d 644 (Ill. App. Ct. 1995), *rev’d on other grounds*, 678 N.E.2d 1009 (Ill. 1996). In *Advincula*, the court stated: “By enacting [the blood shield statute], the legislature was responding to [*Cunningham*], which held a hospital strictly liable for the sale of tainted blood to a patient.” *Id.* at 650. Interestingly, *Advincula* also failed to mention *Garcia*, which has no negative history.

184. *See* Brief of Respondents at ii-iv; *see also* Amicus Curiae Brief Submitted on Behalf of the South Carolina Trial Lawyers Association at ii.

Garcia holding regarding *Cunningham*, the court would likely still have rejected *Cunningham* as flatly as it rejected *Bell*.

2. *The Defective Products Act Does Not Apply to Services*

In *In re Breast Implant* the South Carolina Supreme Court explained that section 15-73-10, which codifies section 402A nearly verbatim, does not apply to services.¹⁸⁵ *DeLoach v. Whitney*¹⁸⁶ provided the court's "analytic starting point."¹⁸⁷ In *DeLoach*, the defendant, after installing new tires, left a deteriorated valve stem on the wheel of the plaintiff's car. The valve stem, which was not a part of any tire, later ruptured while the plaintiff was driving, injuring him.¹⁸⁸ "The sole issue submitted to the jury was whether the appellant was liable under strict liability for failing to install a new valve stem or not warning respondent of the deteriorated condition of the one on the wheel."¹⁸⁹ The court declined to extend strict tort liability to the "negligent installation of a non-defective product."¹⁹⁰

The *In re Breast Implant* court explained that although *DeLoach* is unclear as to whether services generally are outside the scope of section 15-73-10, its holding in *Samson v. Greenville Hospital System*¹⁹¹ clarifies *DeLoach*.¹⁹² The *Samson* court held that section 15-73-10 "imposes strict liability in tort upon the suppliers of defective products. This section applies only to products and not to services."¹⁹³ Though *Samson* is a post-blood-shield-statute case involving blood, it shows that pure services generally are not subject to strict liability in South Carolina. The court properly declined to equate blood with implants or other medical products, referring to *Samson* only for its interpretation of *DeLoach* and for its broad holding regarding the service exemption of section 15-73-10.¹⁹⁴

Importantly, *Samson* construes *DeLoach* as holding only that service providers are not strictly liable *for their services*. The cases focus on whether services qualify as products under section 15-73-10, not on whether *service providers* are *sellers* under section 15-73-10. Thus, the cases do not directly address the issue at hand, namely, whether a service provider that transfers a defective product while providing services is liable as a seller of that product. Rather, *Samson* and *DeLoach* merely establish that the term "products" in the statute does not encompass services. Neither case addresses the scope of the

185. *In re Breast Implant*, 331 S.C. at 545-46, 503 S.E.2d at 448.

186. 275 S.C. 543, 273 S.E.2d 768 (1981).

187. *See In re Breast Implant*, 331 S.C. at 546, 503 S.E.2d at 448.

188. *DeLoach*, 275 S.C. at 543-44, 273 S.E.2d at 768-69.

189. *Id.* at 544, 273 S.E.2d at 769.

190. *Id.* at 545, 273 S.E.2d at 769.

191. 297 S.C. 409, 377 S.E.2d 311 (1989) (per curiam).

192. *See In re Breast Implant*, 331 S.C. at 546, 503 S.E.2d at 448.

193. *Samson*, 297 S.C. at 410, 377 S.E.2d at 311.

194. *In re Breast Implant*, 331 S.C. at 546, 503 S.E.2d at 448.

term “seller.” As noted earlier,¹⁹⁵ breast implants are products; this fact has long been established and is not the dispositive issue.

Despite accurately portraying the holdings of *Samson* and *DeLoach*, the court concluded: “[W]hen analyzed together, *DeLoach* and *Samson* teach that providers of services may not be held liable under section 15-73-10.”¹⁹⁶ Though this overly broad statement stretches the combined effect of the two holdings, the court apparently wished to convey that it was merely restating an established rule that service providers are not liable under section 15-73-10 *for their services*. However, by going on to apply the Essence Test, the court implicitly acknowledged South Carolina’s remaining need to settle the question of service-provider liability under section 15-73-10 *for selling*.¹⁹⁷

3. *Services Are the Essence of the Transaction*

Having established that section 15-73-10 does not apply to services, the court turned to the “pivotal” question of “whether health care providers, including those who perform breast implant procedures, offer services or products.”¹⁹⁸ The court declared: “In analyzing this question, we must consider whether the essence of the transaction is the provision of a service or a product.”¹⁹⁹ Though the court cited no authority to support its application, South Carolina courts have used the predominant factor test for many years.²⁰⁰ The court determined that health care providers who perform breast augmentation procedures are “fundamentally and predominantly offering a service” because of the medical expertise required.²⁰¹ The court noted that an implant “may not be purchased independently of the service”²⁰² but failed to acknowledge that the converse is also true—one may not obtain the service without the implant. The interdependence of the implant and the procedure contradicts the court’s holding that the service predominates; rather, both the

195. See *supra* note 47 and accompanying text.

196. *In re Breast Implant*, 331 S.C. at 547, 503 S.E.2d at 448.

197. See *id.*

198. *Id.*

199. *Id.*

200. See, e.g., *United States v. Southern Contracting of Charleston, Inc.*, 862 F. Supp. 107, 109 (D.S.C. 1994) (applying the predominant factor test to a contract for the provision and installation of an incinerator); *Kline Iron & Steel Co. v. Gray Communications Consultants, Inc.*, 715 F. Supp. 135, 139 (D.S.C. 1989) (applying the predominant factor test to a contract for the construction of a television tower); *Ranger Constr. Co. v. Dixie Floor Co.*, 433 F. Supp. 442, 445 (D.S.C. 1977) (applying the predominant factor test to a flooring installation contract); *Plantation Shutter Co. v. Ezell*, 328 S.C. 475, 478-79, 492 S.E.2d 404, 406 (Ct. App. 1997) (applying the predominant factor test to a contract for the special manufacture and installation of shutters). Though the author found no South Carolina cases applying the essence or predominant factor test to a strict tort liability claim, the similarities between implied warranty actions and strict tort liability actions and the equivalent nature of the predominant factor test and the Essence Test render the court’s ready adoption of the two tests for section 15-73-10 a logical step.

201. *In re Breast Implant*, 331 S.C. at 547, 503 S.E.2d at 448.

202. *Id.* at 547, 503 S.E.2d at 449.

service and the implant are equally necessary for breast augmentation surgery.

After finding the procedure to be primarily a service, the court explained that strict liability in tort is generally inapplicable to service providers, not only for a defective service as indicated by *Samson* and *DeLoach*, but also for a defective product “‘used’” while rendering the service.²⁰³ Unlike the courts in *Newmark v. Gimbel’s Inc.*²⁰⁴ and *Magrine v. Krasnica*,²⁰⁵ the court failed to justify its decision by expressly distinguishing professional and nonprofessional services.²⁰⁶ Even though *DeLoach* is irrelevant to the scope of the term “seller” in section 15-73-10, the court’s reliance on this commercial service-provider case emphasizes its failure to assert explicitly that a different standard applies to health care providers and other professionals than to commercial service providers.

By failing to draw a distinction between commercial and professional services, the court obviated the need to discuss extensive public policy justifications for its decision based on the noncommercial nature of hospitals. Implying that service-provider immunity to strict liability in tort applies equally to commercial and professional service providers, the court escaped having to explain why doctors and hospitals receive a special exemption despite their growing client bases, huge profits, and increased marketing. The court avoided this explanation by refusing to acknowledge that a special “professional” exemption exists.

Importantly, however, the professional/commercial distinction controls the results of the Essence Test, and, therefore, the distinction need not be made after a court applies the test. The determination of whether the sale or the service predominates a transaction often depends primarily on whether the provider is a professional or commercial entity. Courts are far more likely to consider professional services the essence of a transaction that also involves a product transfer.²⁰⁷ Thus, although the *In re Breast Implant* court failed to

203. *Id.* (quoting 1 AMERICAN LAW OF PRODUCTS LIABILITY 3D § 1:77, at 84 (Timothy E. Travers et al. eds., 1987)).

204. 258 A.2d 697 (N.J. 1969).

205. 227 A.2d 539 (Hudson County Ct., N.J. 1967), *aff’d sub nom. Magrine v. Spector*, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968) (per curiam), *aff’d*, 250 A.2d 129 (N.J. 1969) (per curiam).

206. *In re Breast Implant*, 331 S.C. at 547, 503 S.E.2d at 449 (“In general, the courts have refused to apply the concept of strict liability in tort to a person rendering professional or nonprofessional services, where injury occurs through a defective product used by the person rendering such services, or as a result of allegedly defective services themselves.”) (quoting 1 AMERICAN LAW OF PRODUCTS LIABILITY 3D, *supra* note 203, § 1:77, at 84).

207. See KEETON ET AL., *supra* note 2, § 104, at 720, in which the authors explained:

[D]rawing the line between professional and nonprofessional services is not always easy and perhaps in the final analysis the real question is whether or not the service provider is the kind of enterpriser who ought in the public interest to be strictly accountable for harm resulting from the defects in things transmitted in the course of

acknowledge a distinction between the treatment of professionals and nonprofessionals in the hybrid transaction context, a distinction nevertheless exists. Perhaps often unknowingly, courts tend to weigh the service side of the Essence Test balance more heavily when the case involves a professional.

The court listed cases following the majority rule and briefly summarized their holdings.²⁰⁸ Other than quoting the cases on which it relied, the court addressed none of the policy arguments against applying strict products liability to health care providers. The four cases that received the most attention from the court are *Hector v. Cedars-Sinai Medical Center*,²⁰⁹ *Cafazzo v. Central Medical Health Services, Inc.*,²¹⁰ *Ayyash v. Henry Ford Health Systems*,²¹¹ and *Porter v. Rosenberg*.²¹² The court cited these cases primarily to show how these courts applied the Essence Test to medical treatment involving the use or transfer of a defective product,²¹³ although the court also cited *Cafazzo* to refute the plaintiffs' claims that health care providers are sellers because they charge separately for the implants, often at a significant mark-up.²¹⁴ The court also cited *Ayyash*, but for more than its Essence Test results. The South Carolina Supreme Court made one of its few references to policy considerations by paraphrasing the *Ayyash* court's reasoning as follows:

[B]ecause the primary function of physicians and hospitals is to provide care, not to manufacture or distribute products, those economic theories that underlie the imposition of strict liability upon makers and sellers of products (e.g. spreading the risk, redistribution of wealth, and problems of proof and deterrence) do not justify the extension of strict liability to medical service providers.²¹⁵

The court implicitly rejected the reasoning in the South Carolina Trial Lawyers Association's amicus brief on behalf of the plaintiffs, which consisted primarily of arguments against this contention.²¹⁶ Understandably, the court focused more on the weight of relevant authority from other jurisdictions, the vast majority of which supports its decision.

rendering services.

208. See *In re Breast Implant*, 331 S.C. at 547-50, 503 S.E.2d at 449-50.

209. 225 Cal. Rptr. 595 (Ct. App. 1986).

210. 668 A.2d 521 (Pa. 1995).

211. 533 N.W.2d 353 (Mich. Ct. App. 1995).

212. 650 So. 2d 79 (Fla. Dist. Ct. App. 1995).

213. *In re Breast Implant*, 331 S.C. at 548, 503 S.E.2d at 449-50.

214. See *id.* at 548, 503 S.E.2d at 449. The *Cafazzo* court held that "separate consideration" is simply irrelevant to the outcome of the Essence Test. *Cafazzo*, 668 A.2d at 524.

215. *In re Breast Implant*, 331 S.C. at 548, 503 S.E.2d at 449.

216. See Amicus Curiae Brief Submitted on Behalf of the South Carolina Trial Lawyers Association at 13-20.

4. *No Distinction Between Implants and Instruments*

Citing *Magrine v. Krasnica*²¹⁷ and several other cases involving instruments used during treatment alongside transferred device and implant cases, the court never acknowledged a distinction between used and transferred defective products. In fact, the court went to lengths to stretch the concept of “used” products to include devices that actually leave the hospital in the patient’s physical possession. This Procrustean endeavor even appears in the court’s phrasing of the issue: “May a health care provider be held strictly liable under S.C. Code Ann. § 15-73-10 for a medical device or instrument *used in the course of treating a patient*?”²¹⁸ The court likewise carefully equated medical devices and instruments throughout.

The idea that a court should hold a health care provider strictly liable for a defective product merely used during treatment—a product for which the patient did not bargain and which did not leave the hospital in the patient’s possession—is inherently suspect. By implicitly equating incidental use with implantation, the court suggests that the idea that implants are sold during breast augmentation surgery is just as ridiculous as the concept that a scalpel merely used during surgery is sold to the patient.²¹⁹ In sharp contrast, comment d to section 20 of the proposed final draft of the Restatement (Third) of Torts: Products Liability provides a clear explanation of the distinction between implanted and incidentally used devices:

“[S]ale-service hybrid transactions” . . . tend to fall into two categories. In the first, the product component is consumed in the course of providing the service, as when a hair dye is used in treating a customer’s hair in a salon. Even when the service provider does not charge the customer separately for the dye, the transaction ordinarily is treated as a sale of the material that is consumed in providing the service. When the product component in the sale-service transaction is not consumed or permanently transferred to the customer—as when defective scissors are used in the hair salon—the transaction ordinarily is treated as one not involving a sale of the product to the

217. 227 A.2d 539 (Hudson County Ct., N.J. 1967), *aff’d sub nom. Magrine v. Spector*, 241 A.2d 637 (N.J. Super. Ct. App. Div. 1968) (per curiam), *aff’d*, 250 A.2d 129 (1969) (per curiam).

218. *In re Breast Implant*, 331 S.C. at 544, 503 S.E.2d at 447 (emphasis added).

219. Though a few courts have held service providers strictly liable for used, non-transferred products, such decisions are both anomalous and insupportable. *See, e.g., Skelton v. Druid City Hosp. Bd.*, 459 So. 2d 818, 823 (Ala. 1984) (reversing summary judgment for the hospital on an implied warranty claim involving a defective suturing needle because a hospital is a “merchant” under the Uniform Commercial Code).

customer.²²⁰

The comment goes on to explain, with a tone that belies the drafters' recognition of a double standard, that "[i]t should be noted that, in a strong majority of jurisdictions, hospitals are held not to be sellers of products they supply in connection with the provision of medical care, *regardless of the circumstances*."²²¹ This testament to the preferential treatment that hospitals, and possibly doctors, receive shows that while the undeniable distinction between used and transferred products is significant in determining liability relating to most hybrid transactions, courts simply ignore the distinction when hospitals are involved. Liability will be denied regardless of the circumstances.

5. *No Distinction Between Cosmetic and Medically Necessary Products*

The *In re Breast Implant* court used *Weissman v. Dow Corning Corp.*,²²² also a breast implant case, to assert that no difference between medically necessary treatment and elective cosmetic procedures exists.²²³ No doubt wary of the difficulty of distinguishing between the two types of procedures in some instances, the court summarily refused to impute any significance to the patient's reason for undergoing treatment.²²⁴ But because the court never relied on the policy argument that health care providers should not be held strictly liable due to the necessity of the services they provide, its refusal to recognize the cosmetic/medically-necessary distinction fails to stand out as a weak point in its rationale.

6. *Holding as to Strict Liability in Tort Determines Warranty Holding*

As noted above, when a plaintiff asserts both strict liability in tort and breach of warranty, courts almost always decide both claims the same way because the two theories share the same governing principles.²²⁵ The *In re Breast Implant* court followed suit, finding that its conclusion that "health care providers offer services, not products" determined its holding as to the warranty claims under Article II of the U.C.C.²²⁶ To hold Healthcare Defendants liable under breach of warranty while finding them exempt from strict tort liability would go against the overwhelming weight of authority that essentially equates

220. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 20 cmt. d (Proposed Final Draft 1997).

221. *Id.* (emphasis added).

222. 892 F. Supp. 510 (S.D.N.Y. 1995).

223. *See In re Breast Implant*, 331 S.C. at 549, 503 S.E.2d at 450.

224. *See id.*

225. *See supra* notes 39-43 and accompanying text.

226. *In re Breast Implant*, 331 S.C. at 553, 503 S.E.2d at 452.

strict liability in tort to U.C.C. warranty claims.²²⁷

C. Implications of and Justifications for the South Carolina Decision

With *In re Breast Implant*, South Carolina joins the majority in refusing to impose strict products liability on health care providers for defective products used or transferred during treatment. Quite understandably, the court relied on the weight of relevant precedent from other jurisdictions.²²⁸ Because those jurisdictions also adopted section 402A nearly verbatim, their interpretations of their own strict tort liability statutes are relevant to South Carolina's interpretation of section 15-73-10.²²⁹ Further, majority rule proponents have provided persuasive responses to minority-rule policy arguments, which, although largely unmentioned in *In re Breast Implant*, nevertheless charge the opinion. So why does a reader of the opinion feel as though the court pulled one over on the plaintiffs? The answer is simple: the court relied on the Essence Test, the outcome of which can only be a legal fiction in the context of surgically implanted devices.

The court's Essence Test results stem from the court's failure to make several key distinctions. The court simplified the problem in order to provide a simple answer. For example, even before any questions came to the court, the court merged hospitals and doctors into one group, Healthcare Defendants, though hospitals and physicians have differing roles in breast implant selection and provision and different interests to protect. The court also blurred two other boundary lines, the line separating instruments from transferred devices and the line differentiating cosmetic procedures from medically necessary surgery.

The court's failure to acknowledge key distinctions weakened the foundation of the decision by rendering it overwhelmingly broad. This obfuscation expedited the court's adoption of the majority rule, a rule that makes sense regarding instruments and perhaps even medically necessary transferred devices, but that lacks justification regarding implanted cosmetic products. Despite such distinctions, the court implicitly equated marketed, cosmetic breast implants, which are transferred to a patient at a significant markup, with a defective hypodermic needle merely used and discarded in the course of medically necessary treatment.

Despite the court's blurring of several key dichotomies, one distinction remains clear—the professional/commercial distinction. Though the court neither overtly distinguished nor equated professional and commercial services, the court implicitly condoned their segregation by applying the Essence Test,

227. The court concluded this section of the opinion by dismissing the plaintiffs' claim for breach of a common law warranty of soundness and quality because the plaintiffs cited no South Carolina cases recognizing such a warranty in the context of medicine, and the court was aware of no such authority. *Id.*

228. *See id.* at 547-50, 503 S.E.2d at 449-50.

229. *See supra* note 34 and accompanying text.

the outcome of which so often rests on the professional/commercial distinction. As mentioned above, courts are simply more likely to hold services that are professional, rather than commercial, as predominate in hybrid transactions.²³⁰

If the court had made some of the distinctions mentioned above, it would have also had to decide how to distinguish between products that health care providers “sell” and those they do not, no doubt a formidable task.²³¹ But by limiting its opinion to a string citation of majority rule cases and a quick application of the Essence Test, the court avoided some of the stickier questions underlying the outdated predominant-factor formula. This Note has analyzed the policy arguments on both sides of the issue and has shown that both minority rule and majority rule proponents make compelling claims. However, despite all the persuasive minority rule arguments, the majority rule position that public policy demands the preservation of accessible medical treatment remains valid. A large majority of courts has decided that satisfying some plaintiffs is simply not worth the perceived risk of jeopardizing the availability of medical services. Although no one can reliably predict how widespread adoption of the minority rule would affect the availability of medical services, the “preserving availability” argument cannot be dismissed—it must be weighed against minority rule arguments. However, by focusing on the essence of the transaction, courts have avoided this impossible balancing test. At any rate, regardless of whether the majority position is the “best” approach, courts unfortunately feel compelled to resort to legal fiction either to promote or to renounce it.²³²

VI. CONCLUSION

One commentator believes the majority rule pervades simply because “the law has not caught up with th[e] transformation in the health care field” through which the implantation of medical devices has become increasingly common.²³³ This statement could be based on the hope that once courts realize the proliferation of these devices and the implications of denying an increasing number of plaintiffs this avenue of recovery, they will “modernize” their view of health care providers and treat them as the commercial entities they have become. However, courts do not apply the Essence Test in favor of health care providers because they do not understand the transferred nature of some medical devices; they apply it in order to justify, however illogically, doing

230. See *supra* note 207 and accompanying text.

231. See *supra* notes 150-51 and accompanying text.

232. Even the court in the leading *minority* rule case, *Bell v. Poplar Bluff Physicians Group, Inc.*, 879 S.W.2d 618 (Mo. Ct. App. 1994), relied on the Essence Test for its ruling. See *supra* note 107 and accompanying text.

233. Adler, *supra* note 12, at 96.

what they think will help preserve the availability of medical services.²³⁴ This justification apparently rests on the notion that the needs of a relatively small class of plaintiffs that cannot recover from bankrupt manufacturers are subordinate to the universal need for accessible health care.²³⁵ While this argument is entirely defensible, courts should be able to further the argument's goal without relying on a logical fallacy.

Perhaps the above commentator's statement about the law's lag behind technology should be directed not at our courts, but at our legislatures. As the court in *Hoven v. Kelble*²³⁶ recognized, "[b]ecause of the unknown costs and the inability to assess the results" of imposing strict liability on the medical profession, the issue could be better addressed by the state legislature or private groups.²³⁷ If legislatures adopted laws either expressly exempting health care

234. See Poppell, *supra* note 98, at 300. Poppell states:

[T]he basic arguments for an exemption from strict liability for medical professionals boil down to two considerations: (1) there are situations in which medical professionals are using tools in rendering their services and it is felt that Section 402A should not apply since there is no clear transfer, and thus the medical professional cannot be clearly said to be a supplier of such products; (2) there may be other situations in which there is a clear transfer of a product from the medical professional to the patient, but Section 402A should not apply because of fears related to the costs, availability, and quality of medical care. *In order to avoid arguing these conclusions strictly on policy grounds, the courts often resort to deciding that there is no "sale" involved between patient and doctor because the essence of the transaction is services-oriented.*

Id. (emphasis added) (footnote omitted).

235. See Ayyash v. Henry Ford Health Sys., 533 N.W.2d 353, 355 (Mich. Ct. App. 1995). In *Ayyash* the court stated:

It is reasonable to conclude that the vast majority of patients would bear the increased costs associated with such an impractical imposition of liability upon the medical profession for the benefit of a few who for some reason (here bankruptcy) may not be able to obtain recovery from the manufacturer of the defective product. . . . [T]his Court should not and will not let its compassion in this case persuade it to adopt a rule of law that would likely cause greater long-term harm to more patients and the medical profession by an ill-advised adoption of strict liability against health care providers."

Id. at 355-56.

236. 256 N.W.2d 379 (Wis. 1977).

237. *Id.* at 392; see Christopher L. Thompson, Note, *Imposing Strict Products Liability on Medical Care Providers*, 60 MO. L. REV. 711, 716 (1995) (citing *Hoven*, 256 N.W.2d at 393).

providers from or including them within the scope of strict products liability in the context of sales-service transactions, courts would no longer need to resort to strained applications of the Essence Test.

The case of strict products liability for medical instruments and devices mirrors the “bad blood” cases that inspired almost every jurisdiction to enact blood shield statutes.²³⁸ As technology advances and the use of transferred medical devices increases, the instances of defective devices will no doubt soon approach the number of incidents involving defective blood. Courts need an updated method of resolving future strict liability claims against health care providers—something concrete rather than a test that so often results in legal fiction. If our legislatures share the underlying theory of majority rule courts—that we must exempt health care providers from strict liability to preserve the availability of medical services—they should give courts a reliable tool with which to implement that theory.²³⁹ Until our legislatures decide, courts will persist in clinging to fallacious applications of the Essence Test to find some non-policy justification for immunizing health care providers from strict liability for medical devices.

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238. See discussion *supra* Part V.B.1.

239. But see Adler, *supra* note 12, at 123-24. Adler critically notes that because of blood shield statutes, “[c]ourts no longer have to awkwardly debate whether a sale of blood is occurring or if a hospital is a seller of blood . . . the legislatures have done the work for them.” *Id.* While this author sees legislative action as a potentially positive solution for medical devices as well as for blood, Adler “offers the blood case history as a *contrast* to possible future treatment of surgical implants” and “as a warning as well.” *Id.* at 124.

