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SHARING ACCOUNTABILITY FOR BREAST IMPLANTS: STRICT PRODUCTS LIABILITY AND MEDICAL PROFESSIONALS ENGAGED IN HYBRID SALES/ SERVICE COSMETIC PRODUCT TRANSACTIONS

RICHARD L. CUPP, JR.*

I. INTRODUCTION

COURTS do not apply strict liability in tort to defective services, but generally allow strict liability causes of action in cases involving defective products.¹ Medical professionals providing cosmetic medical products, such as breast implants, are engaged in hybrid transactions involving both the sale of a product and a service.² In most circumstances, courts addressing sales/service hybrid transactions allow causes of action for strict products liability.³ For several reasons, however, a strong majority of jurisdictions exempt medical professionals engaged in hybrid transactions from strict products liability.⁴

This Article analyzes the policy reasons provided by courts and commentators for exempting medical professionals from strict products liability, and concludes that the arguments for exemption lose their persuasiveness when applied to cosmetic products such as breast implants. Extending strict products liability to medical professionals providing defective cosmetic products would not conflict with the rationales used to exempt medical professionals in other types of cases.⁵ Although courts must struggle with deciding how to define a product as "cosmetic" in this context, existing case law provides models for making such a determination.⁶ Extending strict products liability to medical professionals engaged in hybrid transactions has important

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1. See *infra* notes 24-26 and accompanying text.
2. See *infra* notes 27-29 and accompanying text.
3. See *infra* notes 30-34 and accompanying text.
4. See *infra* notes 39-63 and accompanying text.
5. See *infra* notes 132-191 and accompanying text.
6. See *infra* notes 233-257 and accompanying text.

consequences. In cases involving breast implants, strict liability for plastic surgeons may prove to be an injured woman's best hope of obtaining adequate compensation for the harm caused by a defective product.⁷

A. *The Increasing Use of Cosmetic Medical Products*

Both men and women have used cosmetic products throughout recorded history.⁸ Rapidly developing technology, however, has generated a multitude of new cosmetic products that require the expertise of a surgeon or other medical professional.⁹ For example, since the early 1960s, millions of American women have purchased implants of various types to improve the appearance of their breasts.¹⁰ Consumers also have used surgically implanted devices or substances to improve the appearance of teeth,¹¹ skin,¹² calves,¹³ pectoral mus-

7. See *infra* notes 207-226 and accompanying text.

8. See CONNIE KROCHMAL, *A GUIDE TO NATURAL COSMETICS 1-7* (1973). The use of cosmetics predates written history. *Id.* at 1. The early Egyptians placed great importance on hair decoration, often spending many hours sculpting their hair with oils. *Id.* at 4.

Primitive people used cosmetics to protect against evil, record brave deeds in battle, mark spiritual events or crises, identify tribal units, and attract those of the opposite sex. *Id.* at 1. Many of these customs continue in remote parts of the world. *Id.* at 2.

Ancient writings such as the Hebrew Scriptures and the Babylonian Talmud often speak of cosmetics. *Id.* at 3. The ancient Hebrews regarded their bodies as gifts from God, and thus placed great emphasis on sanitation and body cleanliness. *Id.* The Greeks and Romans also shared the philosophy that the body was a temple. *Id.*

Cosmetic surgery has also existed in various crude forms for thousands of years. *Id.* at 1. Tattooing began with the ancient Egyptians. *Id.* The Flathead Indians of North America flattened the heads of their children because they viewed it as aesthetically desirable. *Id.* In parts of Africa, a broad lower lip was, and to some still is, considered attractive, so the Ubangi tribe would broaden the lower lip by inserting a small wooden disc in it. *Id.*

9. Paula Dranov, *VANITY FAIR*, May 1987, at 65. Today a plastic surgeon can create more voluptuous breasts, erase wrinkles and bags around the eyes, reshape and sculpture the nose, remove fat deposits from many different areas of the body, and lift years off the face. The rapid growth in technology also allows surgeons to perform these procedures with ever increasing speed, quality, cost efficiency, and reduced discomfort to the consumer. *Id.*

10. Approximately two million American women have purchased breast implants since the 1960s. Leslie Berkman, *The Silicone Controversy*, *L.A. TIMES*, Dec. 4, 1990, at E1; *The Breast Implant Debacle*, *CHI. TRIB.*, Jan. 10, 1992, at 22.

11. See Sandra Blakeslee, *Data Suggests That Implants May Pose Risk of Later Harm*, *N.Y. TIMES*, July 25, 1989, at C1; *Permanent Dentures with Bioactive Materials*, *HIGH TECH. L.J.*, Aug. 1986, at 6; *Something to Smile About*, *HEALTH*, Dec. 1985, at 20.

12. See *Skin in the Bank*, *HEALTH*, Nov. 1989, at 18 (lab generated skin); *Synthetic Skin Promotes Healing*, *HIGH TECH. L.J.*, July 1986, at 7.

13. See *Surgically Sculpting Athletic Physiques: Liposuction and Calf and Pectoral Implants*, *THE PHYSICIAN AND SPORTS MED.*, Feb. 1992, at 153 [hereinafter *Surgically Sculpting Athletic Physiques*]; *California Society of Plastic Surgeons Inc. Criticizes FDA's Handling of Breast Implant Issue*, Feb. 10, 1992 (LEXIS, Nexis library, Wires file) [hereinafter *Breast Implant Issue*].

cles,¹⁴ and other body parts.¹⁵

Critics charge that many of these implants and other cosmetic products¹⁶ provided by medical professionals to consumers are defective. As widely heralded in the news media, up to fifty percent of the approximately two million women in the United States with silicone breast implants have suffered complications that many attribute to product defects.¹⁷ Although given less attention, other potentially defective cosmetic medical products also have caused injury and have led to products liability litigation.¹⁸ Most of the litigation to date has centered around strict liability in tort causes of action against the manufacturers of the products.¹⁹

B. *The Use of Strict Liability in Tort in Sales/Service Hybrid Cases*

Although courts and commentators have provided several rationales to support applying strict products liability to defective products,²⁰ the

14. See *Surgically Sculpting Athletic Physiques*, *supra* note 13; *Breast Implant Issue*, *supra* note 13.

15. Blakeslee, *supra* note 11 (penile implants); *Breast Implant Issue*, *supra* note 13 (testicle and chin implants).

16. See Kenneth Posner, *Implantable Medical Devices and Products Liability*, 28 MED. TRIAL TECH. Q. 255, 256 (1982) (defective implantable devices were responsible for 731 deaths and over 10,000 injuries over a six-year period prior to 1975, citing *Medical Device Amendments of 1975: Hearings on H.R. 5545, H.R. 974 and S. 510 Before the Subcomm. on Health and the Environment of the Comm. on Interstate and Foreign Commerce, 94th Cong., 1st Sess. 200* (1975) (statement of Rep. Rooney); Blakeslee, *supra* note 11 ("Up to 15 percent of the shunts used by neurosurgeons each year, 25 percent of the pacemakers, and 40 percent of the breast implants ultimately fail.").

17. Berkman, *supra* note 10, at E1. Other sources have estimated the number at 40 percent. See *Is the FDA Protecting Patients from the Dangers of Silicone Breast Implants?: Hearing Before the Human Resources and Intergovernmental Relations Subcomm. of the House of Representatives Comm. on Government Operations, 101st Cong., 2d Sess. 31* (1990) (statement of Dr. Nir Kossovsky); *\$4 Million Awarded in Breast-Implant Cancer Case*, N.Y. TIMES, March 24, 1991, § 1, at 35.

18. See David W. Christensen & David R. Parker, *Don't Overlook Products in Medical Cases*, TRIAL, Nov. 1989, at 78; Posner, *supra* note 16; Marc L. Carmichael, Annotation, *Liability of Hospital or Medical Practitioner Under Doctrine of Strict Liability in Tort, or Breach of Warranty, for Harm Caused by Drug, Medical Instrument, or Similar Device Used in Treating Patient*, 54 A.L.R.3d 258 (1973).

19. Telephone Interview with Fredric Ellis, plaintiffs' breast implant litigator for Gilman, McLaughlin & Hanahan in Boston, Mass. (May 26, 1993); Telephone Interview with Mario Horowitz, defense breast implant litigator for Dickson, Carlson & Campillo in L.A., Cal. (May 25, 1993); Telephone Interview with Diana McBride, plaintiffs' breast implant litigator for Schneider, Bayless & Chesley in Cincinnati, Ohio (May 25, 1993); Telephone Interview with Joseph Price, defense breast implant litigator for Faegre & Benson in Minneapolis, Minn. (May 27, 1993).

20. Strict liability in tort, embodied in section 402A of the Restatement (Second) of Torts, provides an avenue of recovery for consumers injured by defective products which, at least theoretically, does not require proof that the defendant was at fault. Dana Shelhimer, *Sales-Service*

"lynch pin" of the doctrine is that strict liability facilitates risk spreading.²¹ Strict liability causes sellers to raise prices to pay for insurance against increased liability.²² Consumers thus pay more for products, but are assured that they will receive compensation if injured by a defective product.²³

Under strict products liability, an injured plaintiff may generally recover against manufacturers, wholesalers, distributors, retailers, and all other sellers in the "chain of distribution."²⁴ This broad net of liability facilitates the risk spreading goal of strict products liability,²⁵ and increases an injured consumer's chance of obtaining compensation.²⁶

Numerous courts have addressed the problems that arise when a transaction by a party in the chain of distribution has characteristics of both a sale and a service.²⁷ Because most courts will not apply strict

Hybrid Transactions and the Strict Liability Dilemma, 43 Sw. L.J. 785, 789-90 (1989); John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825 (1973). Although strict liability is theoretically free from considerations of fault, negligence principles still pervade strict products liability to varying extents in different jurisdictions. William C. Powers, Jr., *The Persistence of Fault in Products Liability*, 61 TEX. L. REV. 777, 778 (1983). The problem of proving fault arises most often in three areas. First, courts often use negligence standards to determine if the product is defective. Second, courts will often use negligence principles when it becomes necessary to apportion loss among multiple parties. Third, courts sometimes rely on the negligence concept of foreseeability to determine proximate causation. *Id.* at 780-81.

Most authorities agree on four primary policy considerations supporting strict liability. Michael M. Greenfield, *Consumer Protection in Service Transactions—Implied Warranties and Strict Liability in Tort*, 1974 UTAH L. REV. 661, 688; John Riper, Note, *Strict Liability in Hybrid Cases*, 32 STAN. L. REV. 391, 393 (1980). First, the seller can best absorb the cost and spread the risk. Second, the seller is in the best position to discover and prevent defects. Third, the consumer places reliance on the skill, care and reputation of the seller. Fourth, privity requirements of negligence often cause wasteful litigation in product defects cases. Another 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. *Id.* at 393 n.8. See also Michael Goodman, *Strict Liability and the Professional Transaction*, 50 INS. COUNS. J. 201, 204 (1983); 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).

21. James B. Sales, *The Service-Sales Transaction: A Citadel Under Assault*, 10 ST. MARY'S L.J. 13, 34 (1978).

22. *Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 441 (Cal. 1944) (Traynor, J., concurring); Page Keeton, *Products Liability—Some Observations about Allocation of Risks*, 64 MICH. L. REV. 1329, 1333 (1966); William L. Prosser, *The Assault Upon the Citadel—Strict Liability to the Consumer*, 69 YALE L.J. 1099, 1120 (1960); Sales, *supra* note 21, at 16; Shelhimer, *supra* note 20, at 791; Riper, *supra* note 20, at 394.

23. *Escola*, 150 P.2d at 441. Sales, *supra* note 21; Shelhimer, *supra* note 20, at 791.

24. *Deines v. Vermeer Mfg. Co.*, 755 F. Supp. 350, 353 (D. Kan. 1990). See Greenfield, *supra* note 20, at 678.

25. Sales, *supra* note 21.

26. *Id.*

27. *Vergott v. Deseret Pharmaceutical Co.*, 463 F.2d 12 (5th Cir. 1972); *Mauran v. Mary Fletcher Hosp.*, 318 F. Supp. 297 (D. Vt. 1970); *Carmichael v. Reitz*, 95 Cal. Rptr. 381 (Cal. Ct.

liability in tort to pure service transactions,²⁸ "hybrid" transactions raise an issue as to the appropriate standard of liability—whether courts should allow strict liability in tort, as in cases involving pure product sales, or should require plaintiffs to prove negligence, as in pure service transactions.²⁹

Most courts allow plaintiffs to use strict products liability in hybrid transactions involving nonprofessional sellers/service providers. Perhaps the best known case demonstrating this approach is *Newmark v. Gimbel's, Inc.*,³⁰ where the plaintiff alleged that a permanent wave solution that the defendant hairdressing salon's employee applied was defective and caused damage to the plaintiff's scalp.³¹ The case involved both the sale of a product (the permanent wave solution) and the providing of a service (applying the solution to the plaintiff's hair).³² The New Jersey Supreme Court allowed the plaintiff's implied warranty of merchantability³³ cause of action to stand, reasoning that a seller should not escape strict liability simply because it applies a product in addition to selling it.³⁴ In dicta, the court noted that it would not apply this standard of strict liability to doctors and dentists

App. 1971); *Silverhart v. Mount Zion Hosp.*, 98 Cal. Rptr. 187 (Cal. Ct. App. 1971); *Magrine v. Krasnica*, 227 A.2d 539 (Hudson County Ct. 1967), *aff'd sub. nom. Magrine v. Spector*, 250 A.2d 129 (N.J. 1969). The distinction between pure sales transactions and hybrid sales/service transactions could appear misleading, in that every sale involves at least some element of service. Those transactions treated by courts as "hybrid" have tended to involve significant services in addition to the sale.

28. *Winans v. Rockwell Int'l Corp.*, 705 F.2d 1449 (5th Cir. 1983); *Raritan Trucking Corp. v. Aero Commander, Inc.*, 458 F.2d 1106 (3rd Cir. 1972); *Klein v. Council of Chem. Ass'ns.*, 587 F. Supp. 213 (E.D. Pa. 1984). See *Shelhimer*, *supra* note 20, at 791 n.58 (additional cases refusing to apply strict liability to service transactions).

29. See generally *William C. Powers, Jr., Distinguishing Between Products and Services in Strict Liability*, 62 N.C. L. REV. 415 (1984); *Sales*, *supra* note 21; *Shelhimer*, *supra* note 20; *John C. Wunsch, The Definition of a Product for Purposes of Section 402A*, 50 INS. COUNS. J. 344 (1983); *Riper*, *supra* note 20.

30. 258 A.2d 697 (N.J. 1969).

31. *Id.* at 699.

32. *Id.* at 701.

33. Although it generally is pleaded as a separate and distinct cause of action, in most jurisdictions implied warranty of merchantability requires a substantially similar, if not identical, showing of proof as strict liability under section 402A of Restatement (Second) of Torts. *Farr v. Armstrong Rubber Co.*, 179 N.W.2d 64, 68 (Minn. 1970). In fact, many jurisdictions treat the two as synonymous. See, e.g., *Bowler v. Stewart-Warner Corp.*, 563 A.2d 344, 346 (D.C. 1989); *Cottom v. McGuire Funeral Service Inc.*, 262 A.2d 807, 808 (D.C. 1970); *Goblirsch v. Western Land Roller Co.*, 246 N.W.2d 687, 690 (Minn. 1976); *Spring Motors Distrib., Inc. v. Ford Motor Co.*, 489 A.2d 660, 666 (N.J. 1985); *Realmuto v. Straub Motors, Inc.*, 322 A.2d 440, 443-44 (N.J. 1974). See generally *Donald J. Rapson, Products Liability Under Parallel Doctrines: Contrasts between the Uniform Commercial Code and Strict Liability in Tort*, 19 RUTGERS L. REV. 692 (1965).

34. *Newmark*, 258 A.2d at 702, 704-05.

engaged in sales/service hybrid transactions, because the importance of their services outweighs the policy objectives of strict liability.³⁵

Most courts apply an "essence of the transaction" test in determining whether to apply strict liability to hybrid transactions. This test focuses on the predominating aspect of the transaction.³⁶ If the key aspect of a transaction is the sale of a product, and the attendant service provided is merely ancillary, most courts allow a cause of action for strict liability in tort.³⁷ However, if the service aspect predominates, courts generally do not allow a cause of action for strict liability in tort.³⁸

C. *The Exemption From Strict Liability for Professionals Engaged in Hybrid Transactions*

For several reasons, courts are "virtually unanimous" in exempting medical professionals, and in some cases other professionals,³⁹ engaged in hybrid transactions from strict liability in tort.⁴⁰ In *Newmark*,⁴¹ the court was careful to note it would not apply strict products liability to doctors and dentists. In addition to pointing out

35. *Id.* at 703.

36. See 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, 834-36 (1982)(providing a historical and legal analysis of the sale/service distinction as well as a general discussion of the creation and development of the "essence of the transaction" test). For an example of the "essence" test as it is applied in the strict products liability context, see Carmichael v. Reitz, 95 Cal. Rptr. 381, 383-84 (Cal. Ct. App. 1971) (holding that strict liability would not be imposed on a doctor for prescribing a drug that caused his patient to suffer embolisms and thrombophlebitis).

37. See, e.g., *Cunningham v. MacNeal Memorial Hosp.*, 266 N.E.2d 897, 900-02 (Ill. 1970); *Newmark*, 258 A.2d at 701.

38. See, e.g., *Carmichael*, 95 Cal. Rptr. at 393; see also Crump & Maxwell, *supra* note 36, at 834-36.

39. In addition to doctors, courts also have exempted other professionals engaged in hybrid transactions from strict liability. See, e.g., *La Rossa v. Scientific Design Co.*, 402 F.2d 937 (3d Cir. 1968). *La Rossa* held that a company employed to design, engineer, and supervise the construction of a chemical plant would not be held to the standard of strict liability when the plaintiff's husband died from throat cancer caused by his inhaling chemical dust while working at the plant. *Id.* at 942-43. The court reasoned that because there was "no mass production of goods or a large body of distant consumers whom it would be unfair to require to trace the article . . . to the original manufacturer" and then subsequently prove negligence, the goals and policies of strict liability would not be achieved. *Id.* See also *K-Mart Corp. v. Midcon Realty Group*, 489 F. Supp. 813, 819 (D. Conn. 1980) (architect); *Del Mar Beach Club Owners Ass'n v. Imperial Contracting Co.*, 176 Cal. Rptr. 886, 894 (Cal. Ct. App. 1981) (architects and engineers). See generally *Sales*, *supra* note 21 (examining the policy considerations behind strict liability and their applicability to both pure service transactions and professional and non-professional hybrid transactions); *Shelhimer*, *supra* note 20, at 799 (analyzing the non-medical, professional exemption to strict liability).

40. Crump & Maxwell, *supra* note 36, at 831.

41. 258 A.2d 697 (N.J. 1969).

the high utility of medical professionals' services to society,⁴² *Newmark* stated that the essence of the transaction in medical treatment is the doctor's services rather than the products involved in rendering the services.⁴³ Further, a doctor's use of medical products does not rise to the level of a "sale" as required under strict products liability.⁴⁴

Another frequently cited case in support of exempting doctors from strict products liability is *Magrine v. Krasnica*.⁴⁵ In *Magrine*, the plaintiff sued her dentist under strict liability in tort when the dentist's defective hypodermic needle broke in her jaw.⁴⁶ The court noted the traditional exemption provided to medical professionals, and explained that the essence of a transaction involving professional services is the service rather than the products used in providing the service.⁴⁷ Further, for purposes of strict products liability, medical professionals are generally not "merchants" in the business of selling products.⁴⁸ In this case, the dentist did not intend to "sell" his patient the needle that broke in her jaw; he merely used the product as a necessary incident in providing his professional services.⁴⁹ Finally, the court agreed with *Newmark* that policy concerns favoring affordable health care outweigh concerns favoring strict liability for medical professionals.⁵⁰

Numerous courts and commentators have echoed these and other concerns supporting the exemption of medical professionals from strict products liability. The significant arguments against applying such liability to medical professionals engaged in hybrid transactions may be summarized as follows:

(1) The services and products provided by medical professionals are essential to society, so the risk spreading rationale underlying strict products liability is not persuasive in this context. Risk spreading

42. *Id.* (arguing that "the nature of the services, the utility of and the need for them, involving . . . the health and . . . survival of many people, are so important to the general welfare as to outweigh . . . any need for the imposition on dentists and doctors . . . of strict liability in tort").

43. *Id.* at 702-03.

44. *Id.*

45. 227 A.2d 539 (Hudson County Ct. 1967), *aff'd sub nom.* *Magrine v. Spector*, 250 A.2d 129 (N.J. 1969).

46. *Id.* at 540. In *Magrine*, the plaintiff argued "that 'strict liability' is not confined to 'sales' . . . [and] the basic policy considerations of the doctrine apply to the use of a needle by a dentist . . ." *Id.* at 541.

47. *Id.* at 543, 545.

48. *Id.* at 544-45. For a general discussion concerning the various methods courts have employed in defining "product" for purposes of strict liability, see Wunsch, *supra* note 29.

49. *Magrine*, 227 A.2d at 544-45.

50. *Id.* at 545-46.

through strict liability will raise prices for all consumers, making necessary medical services and products inaccessible to the poor.⁵¹

(2) Strict liability could persuade medical professionals to stop providing some medical products and services. Because the services and products provided by medical professionals are essential to society, courts must limit the liability of medical professionals so that they will continue to provide these services and products.⁵²

(3) No true "sale" as defined by section 402A of the Restatement (Second) of Torts takes place when medical professionals use defective products as part of their services.⁵³

(4) In providing medical services and products, the essence of the transaction is the professional's service, rather than the products used.⁵⁴ The products are merely incidental to the medical professionals' services,⁵⁵ in part because medical professionals' services are complex,⁵⁶ require extensive training,⁵⁷ and are inherently uncertain in terms of results.⁵⁸ Consumers focus on doctors' skills, training, and performance more than on the products they use.⁵⁹ Consumers' expectations are thus different with regard to hybrid medical transactions than they are with other types of sales/service hybrid transactions.⁶⁰

(5) Because medical professionals typically have a relatively small client base, risk spreading through raised prices is less practicable than it is with other product retailers, who typically have larger client bases.⁶¹

(6) Unlike most other retailers, medical professionals may

51. See *infra* notes 135-147 and accompanying text. See also *Magrine*, 227 A.2d at 545-46; *Hoven v. Kelble*, 256 N.W.2d 379, 391 (Wis. 1977) (holding that strict liability should not be extended to the delivery of medical services on the grounds that such would obfuscate the availability of important medical treatment); *Sales*, *supra* note 21, at 25-26.

52. See *Newmark v. Gimbel's, Inc.*, 258 A.2d 697, 702-03 (N.J. 1969).

53. See *infra* notes 148-157 and accompanying text. See also *Magrine*, 227 A.2d at 544; *Crump & Maxwell*, *supra* note 36 at 836-40 (supporting the proposition that a "sale" does not occur when a medical professional uses or furnishes a good in conjunction with a service). *But see* *Cunningham v. MacNeal Memorial Hosp.*, 266 N.E.2d 897, 900-02 (Ill. 1970) (holding that the blood supplied in a hospital-administered blood transfusion constituted a "sale" for purposes of strict liability).

54. See *infra* notes 159-166 and accompanying text. See also *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 392-93 (Cal. Ct. App. 1971); *Silverhart v. Mount Zion Hosp.*, 98 Cal. Rptr. 187, 191 (Cal. Ct. App. 1971); *Magrine*, 227 A.2d at 543.

55. *Carmichael*, 95 Cal. Rptr. at 392-93; *Magrine*, 227 A.2d at 546.

56. *Posner*, *supra* note 16, at 268.

57. See *Carmichael*, 95 Cal. Rptr. at 393; *Newmark*, 258 A.2d at 703.

58. See *Posner*, *supra* note 16, at 268.

59. See *Carmichael*, 95 Cal. Rptr. at 393.

60. See *Greenfield*, *supra* note 20, at 689-90.

61. See *Riper*, *supra* note 20, at 394-96.

be unable to obtain indemnification from manufacturers because medical professionals often do not know who manufactured the products they use.⁶²

(7) Many sellers lull consumers into a false sense of security through advertising. This justification for strict products liability does not apply to medical professionals, however, because typically they do not advertise their products or services.⁶³

Because of these concerns, medical professionals engaged in hybrid transactions, including medical professionals selling cosmetic medical products such as breast implants, have largely avoided strict products liability.

II. INCREASING LITIGATION RELATED TO COSMETIC MEDICAL PRODUCTS

In recent years, the number of lawsuits alleging personal injuries caused by cosmetic products has risen dramatically. The most significant increase involves silicone breast implants. This litigation, however, has focused mostly on the strict liability and negligence of manufacturers,⁶⁴ with few plaintiffs filing suit against the medical professionals who provided the allegedly defective products.⁶⁵ Further, those cases including causes of action against medical professionals have primarily been based on negligence rather than on strict liability

62. See *infra* notes 178-179 and accompanying text. See also, e.g., *Magrine v. Krasnica*, 227 A.2d 539, 546 (Hudson County Ct. 1967).

63. Robert L. Seibert, Note, *Hospital Liability—Seller of a Product or Provider of Services—Is This Distinction Necessary?* 23 S. Tex. L.J. 397, 411 (1982). Commentators have identified at least two other policy concerns with applying strict products liability to medical professionals engaged in hybrid transactions. First, allowing strict products liability against medical professionals would discourage them from using new or experimental medical products. Arthur Leff, *Medical Devices and Paramedical Personnel: A Preliminary Context for Emerging Problems*, 1967 WASH. U. L.Q. 332, 335 (1967); Comment, *Professional Negligence*, 121 U. PA. L. REV. 627, 651 (1973). Second, because doctors' professional reputations are damaged by liability claims, courts should not allow liability where a doctor is not at fault. Posner, *supra* note 16, at 268.

64. See e.g., *Landry v. Dow Corning Corp.*, No. 92-1139-B, 1992 WL 142512 (E.D. La. June 17, 1992); *Steward v. Dow Corning Corp.*, No. 92-1105-K, 1992 WL 75195 (D. Kan. Mar. 13, 1992); *Woolard v. Heyer-Schulte*, 791 F. Supp. 294 (S.D. Fla. 1992); *Livshits v. Natural Y Surgical Specialties, Inc.*, 60 U.S.L.W. 2436 (S.D.N.Y. Nov. 27, 1991); *Rosburg v. Minnesota, Mining & Mfg. Corp.*, 226 Cal. Rptr. 299 (Cal. Ct. App. 1986); *3-M Corp.-McGhan Medical Reports v. Brown*, 475 So. 2d 994 (Fla. 1st DCA 1985).

65. Ellis Interview, *supra* note 19 (most breast implant defect lawsuits do not name doctors as defendants); Horowitz Interview, *supra* note 19 (most breast implant defect lawsuits do not name doctors as defendants, and those that do are often trying to avoid diversity jurisdiction and prevent removal to federal court); McBride Interview, *supra* note 19 (because of the diversity jurisdiction issue, most lawsuits filed in both federal and state courts do not name doctors as defendants); Price Interview, *supra* note 19.

in tort.⁶⁶ This section surveys the rise in prominence of cosmetic medical products and the litigation that has accompanied this rise.

A. *The Development of the Cosmetic Medical Products Industry*

1. *Breast Implants*

Attraction to large breasts predates modern times. For example, statues of the goddess Diana dating from the Roman Empire depict her with numerous large breasts.⁶⁷ Americans have always shared this perception that large breasts enhance a woman's beauty.⁶⁸ Early efforts to enhance the appearance of breasts focused on external padding. A popular saying among American women in the nineteenth century was "[w]hat God has forgotten can be replaced with cotton."⁶⁹

Other modern cultures also favor large breasts. In the early twentieth century, doctors in Germany began experimenting with breast enlargement by injecting a mixture of paraffin, petroleum jelly and olive oil in women's chests.⁷⁰ The injections, although initially achieving the desired results, led to disastrous health problems and were soon discontinued.⁷¹

Injections into women's breasts began again, this time in Japan, shortly after World War II. Japanese cosmeticians used numerous substances, including goat's milk, motor oil, bees' wax, shellac, vegetable oils, and spun glass to make their customers' breasts larger.⁷² A

66. In fact, most cases place very little emphasis on the defective nature of the product. See, e.g., *Leggett v. Kumar*, 570 N.E.2d 1249, 1252 (Ill. App. Ct. 1991); *McGuire v. Sifers*, 681 P.2d 1025, 1028 (Kan. 1984); *Sansone v. Londe*, 753 S.W.2d 339, 340 (Mo. Ct. App. 1988); *Skripek v. Bergamo*, 491 A.2d 1336, 1338 (N.J. Super. App. Div. 1985).

67. See, e.g., Oliver Bernier, *A Tale of Two Ducal Cities*, N.Y. TIMES, Dec. 5, 1982, at 19 (eight breasts); Tom Lubbock, *The Dilemma Between Stone and Flesh*, THE INDEPENDENT, May 13, 1990, at 26 ("multiple" breasts).

68. Linda Grant, *Real Life: A Distortion of Physical Reality: We Know How It's Done, But Why They Ever Do It?*, THE INDEPENDENT, Jan. 12, 1992, at 18. Grant also notes that some women seeking larger breasts have even turned to a hypnotist who chants to his entranced patients: "And now, blood is pumping into your breasts from your heart, pumping . . . pumping . . . pumping . . . and your breasts are swelling larger . . . and larger . . . and larger . . . to the perfect size." *Id.*

69. Statement of Norman D. Anderson, Associate Professor of Medicine and Surgery, The Johns Hopkins School of Medicine, and former chairman of the Food and Drug Administration's Breast Implant Advisory Panel, when addressing attorneys attending Symposium of Breast Implant Litigation: Current Medical and Legal Theories (June 1, 1992).

70. *Id.*

71. *Id.*

72. Philip J. Hilt, *Strange History of Silicone Held Many Warning Signs*, N.Y. TIMES, Jan. 18, 1992, at A1.

particular favorite was transformer insulating fluid.⁷³ The insulating fluid was made of liquid silicone, a plastic used extensively during the war in synthetic rubber, hydraulic fluid, and other products.⁷⁴

By the early 1960s, liquid silicone injections were gaining popularity in the United States. Las Vegas and Los Angeles were recognized as the centers of the industry.⁷⁵ In 1965 *Newsweek* magazine estimated that seventy-five doctors in Los Angeles alone were performing the procedure.⁷⁶ The most widely publicized recipient of these injections was a San Francisco striptease artist named Carol Doda, whose bust was transformed from a 34B to a 44DD.⁷⁷

Eventually the medical community discovered that the injections led to serious medical problems, and the Food and Drug Administration (FDA) prohibited their use.⁷⁸ Although injections continued in Tijuana, Mexico, their popularity among American women abated.⁷⁹ Nevertheless, a total of approximately 50,000 American women received silicone breast injections before their popularity waned.⁸⁰

The development of a silicone breast implant in 1962 significantly contributed to the decline of silicone injections.⁸¹ Dr. Thomas Cronin, a respected plastic surgeon, created an implant consisting of a rubbery silicone sack enclosing a softer mass of silicone gel.⁸² He obtained the silicone from Dow Corning Corporation, the major manufacturer of industrial silicone in the United States.⁸³ Eventually, Dow Corning expanded from merely supplying the silicone to manufacturing the implants.⁸⁴ Doctors viewed the silicone implant as safer than silicone

73. *Is the FDA Protecting Patients from the Dangers of Silicone Breast Implants?: Hearings Before the Human Resources and Intergovernmental Relations Subcomm. of the House of Representatives Comm. on Government Operations*, 101st Cong., 2d Sess. 30 (1990) (statement of Norman D. Anderson) [hereinafter *Hearings*]; See also Hilts, *supra* note 72.

74. *Hearings*, *supra* note 73; Hilts, *supra* note 72.

75. *Escalation*, *NEWSWEEK*, Oct. 25, 1965, at 110.

76. *Id.*

77. Judy Foreman, *Women and Silicone: A History of Risk*, *BOSTON GLOBE*, Jan. 19, 1992, at 1.

78. *Hearings*, *supra* note 73; Hilts, *supra* note 72, at 1.

79. See Alison Frankel, *From Pioneers to Profits*, *AM. LAW.*, June 1992, at 82 (popularity of silicone injections declined in the early 1960s with the introduction of silicone implants in the United States).

80. *Hearings*, *supra* note 73; Foreman, *supra* note 77, at 1; Berkman, *supra* note 10, at A1.

81. Hilts, *supra* note 72, at A1.

82. *Id.*

83. Glenn Kessler et al., *The Implant Business: Controversy Threatens to Be a Legal, Ethical Nightmare*, *NEWSDAY*, Jan. 19, 1992, at 7; Dow Corning Corporation News Conference Regarding Breast Implants, Feb. 10, 1992 (LEXIS, Nexis library, Currnt file).

84. See Marlene Cimonis, *Dow Corning Expected to Stop Making Gel Implants*, *L.A. TIMES*, Mar. 19, 1992, at A1; Shari Roan, *Time Not on Their Side, Say Women With Implants*, *L.A. TIMES*, May 18, 1993, at E1.

injections because less liquid silicone was released into the body.⁸⁵ Further, because silicone implants do not require an injection, FDA approval was not initially required.⁸⁶

Seven other major manufacturers later entered the breast implant market,⁸⁷ although Dow Corning remained the largest.⁸⁸ There are four types of breast implants: silicone gel implants, polyurethane-coated silicone gel implants, saline-filled implants, and double lumen, or combination, implants.⁸⁹ Approximately eighty percent of the two million women who have purchased breast implants have done so for purely cosmetic reasons;⁹⁰ the remaining fifteen percent have purchased implants to alleviate disfigurement following mastectomies.⁹¹

2. Other Cosmetic Medical Products

Although consumers are most familiar with claims of defectiveness related to breast implants, medical professionals sell numerous other cosmetic products. Dental professionals sell orthodontic cosmetic devices⁹² to several million Americans each year.⁹³ In addition to breasts, silicone implants improve the appearance of calves, men's pectoral muscles, biceps, and other body parts.⁹⁴ In an increasingly controversial procedure, cosmetic surgeons inject collagen under fa-

85. See Frankel, *supra* note 79, at 82 (switch from injections to implants "changed the consistency of the silicone and encapsulated it in bags that were supposed to prevent the silicone from migrating to other parts of the body").

86. Boyce Rensberger, *Top Scientist for Implant Firm Covered Up Findings on Silicone*, HOUST. CHRON., Jan. 18, 1992, at A9. See Frankel, *supra* note 79, at 82.

87. *All Things Considered* (National Public Radio broadcast, Mar. 27, 1992) (LEXIS, Nexis library, Currnt File) [hereinafter *All Things Considered*].

88. *Id.* See also Roan, *supra* note 84, at E1.

89. See Sandra G. Boodman, *Four Types of Implants*, WASH. POST, June 23, 1992 (Health), at Z13; Hiltz, *supra* note 72, at A1.

90. Warren E. Leary, *Breast Implants: A Look at the Record*, N.Y. TIMES, Nov. 13, 1988, at D9.

91. *Id.*

92. For a listing and explanation of the latest cosmetic dental products and technology, see Mary Garner Ganske, *Designer Smiles: New Dental Wizardry Can Make Every Mouth a Star*, HEALTH, Nov. 1989, at 82; Steven Morris, *Brushing Up on Cosmetic Dentistry*, CHI. TRIB., Feb. 19, 1992 (Business), at 1.

93. Approximately 4.5 million Americans currently wear braces. Judith E. Randal, *Dental Braces, at Your Age?*, NEWSDAY, Dec. 5, 1989, at 9. See also Nicholas E. Lefferts, *What's New in Dentistry*, N.Y. TIMES, Sept. 8, 1985, § 3, at 15 (4.4 million current wearers of braces).

94. See Jill Y. Miller, *Men Turn to Pec Implants*, CALGARY HERALD, Feb. 11, 1992, at C4; Harry Shearer, *Man Bites Town: Silicone Peaks and Valleys; Now That the Breast-Implant Craze Has Sprung a Leak, a Moment of Reflection*, L.A. TIMES MAG., Feb. 2, 1992, at 6; Gordon Slovut, *Allergic to Exercise? It Happens*, STAR TRIB., Mar. 8, 1992, at C18.

cial skin to remove wrinkles.⁹⁵ Any of these products may be defective in design, manufacture, or in failure to provide an adequate warning of danger, raising the issue of the appropriate standard of liability in a hybrid sales/service transaction involving medical professionals.

B. *The Increase in Cosmetic Medical Product Litigation*

1. *Litigation Against Breast Implant Manufacturers*

Silicone breast implant litigation gained prominent media coverage beginning in 1991, and may well be the most significant area of mass products liability litigation in the United States this decade.⁹⁶ Only a handful of attorneys litigated breast implant cases in late 1991; by early 1992, though, between 250-300 attorneys were litigating such cases.⁹⁷ By mid-1993, it was estimated that the number of attorneys was between 500 and 1,000.⁹⁸ By late 1993 as many as 15,000 lawsuits were filed alleging defective implants.⁹⁹ The FDA received 3,400 complaints of physical problems related to implants by early 1992,¹⁰⁰ and approximately 9,000 women had undergone operations to remove them. Of the two million women with breast implants, estimates of potential defectiveness range as high as fifty percent—approximately one million potential plaintiffs in products liability actions.¹⁰¹ Despite

95. *Collagen Corp. Receives Notice of Allowance on Collagen-Polymer Conjugates Patent Application*, BUS. WIRE, July 7, 1992; Bernard Idson, *Dry Skin Moisturizing and Emolliency, COSMETICS AND TOILETRIES*, July 1992, at 69; Jeremiah O'Leary, *Father Time Ravages Old Leatherneck Body*, WASH. TIMES, June 15, 1992, at B1.

96. See *infra* notes 97-103 and accompanying text. See also Frankel, *supra* note 79, at 82.

97. Frankel, *supra* note 79, at 82. Between late 1990 and May 1992, Public Citizen's breast implant clearinghouse membership grew from four to 179 members. *Id.*

98. Ellis Interview, *supra* note 19 (rough estimate of 1,000); Price Interview, *supra* note 19 (rough estimate of "in excess of 500").

99. David R. Olmos, *Settlement Talks Falter in Breast Implant Case*, L.A. TIMES, Nov. 15, 1993, at D2. See also Ellis Interview, *supra* note 19 (rough estimate of 10,000 cases nationwide); Price Interview, *supra* note 19 (rough estimate of 7,500 to 10,000 cases). By mid-1992, plaintiffs had filed only an estimated 1,000 lawsuits alleging defective breast implants. See *Dow Corning Sees \$45 Million Charge*, REUTER BUS. REP., June 18, 1992 (LEXIS, Nexis library, Currnt file). Thus, in little over one year, approximately fifteen as many lawsuits were filed. One group of attorneys estimates that as many as two million women may eventually seek relief from manufacturers in court. *Justice Department Asked to Probe Dow-Corning*, REUTER BUS. REP., Feb. 16, 1992 (LEXIS, Nexis library, Currnt file).

100. Carol J. Castaneda & Maria Puente, *Breast Implants: Fear, Suits—Terrified Women Turn to the Courts*, USA TODAY, Jan. 22, 1992, at 3A.

101. Berkman, *supra* note 10, at E1. Some sources estimate the number of potential plaintiffs at 40%. See *Is the FDA Protecting Patients from the Dangers of Silicone Breast Implants?: Hearings Before the Human Resources and Intergovernmental Relations Subcomm. of the House of Representatives Comm. on Government Operations*, 101st Cong., 2d Sess. 31 (1990) (statement of Dr. Nir Kossovsky); *\$4 Million Awarded in Breast-Implant Cancer Case*, N.Y. TIMES, Mar. 24, 1991, § 1, at 35.

the efforts of Dow Corning Corporation, the largest manufacturer of silicone implants, to settle its lawsuits, the corporation may face liability of up to two billion dollars,¹⁰² and the litigation could potentially continue another twenty years.¹⁰³

The medical problems creating this avalanche of breast implant litigation are varied, but they may be categorized as follows: (1) problems related to exposure to liquid silicone or polyurethane;¹⁰⁴ (2) problems related to hardening of the breasts;¹⁰⁵ and (3) increased difficulty in detecting cancer due to implants.¹⁰⁶ Of these, the most litigated area involves injuries resulting from exposure to liquid silicone or polyurethane.¹⁰⁷ The FDA reports that approximately six percent of all silicone breast implants have ruptured.¹⁰⁸ Furthermore, unruptured silicone implants still expose users to liquid silicone through a process known as "bleeding."¹⁰⁹ At least a small amount of the liquid silicone in the center of a breast implant "bleeds" through the rubbery external shell into the body.¹¹⁰

102. Susan Moffat, *Girding for Battle: Dow Corning Prepares for Flood of Lawsuits Over Breast Implants*, L.A. TIMES, Mar. 13, 1992, at D1. A proposal by Dow Corning and other defendants to settle about half of the lawsuits for \$4.75 billion would involve payment of approximately \$1.24 billion by Dow Corning. David R. Olmos, *Dow Corning Expecting \$1.24 Billion Implant Tab*, L.A. TIMES, Jan. 15, 1994, at D1.

103. Mike McKee, *Bar Split Over Implant Ruling's Impact; Plaintiffs Counsel Say Restrictions Won't Affect Current Suits*, THE RECORDER, Feb. 21, 1992, at 1.

104. See *infra* notes 107-115 and accompanying text.

105. Lawsuits asserting injuries associated with hardening of the breasts focus on the body's propensity to respond to the insertion of an implant by creating a hard capsule around it. All breast implant patients experience some degree of encapsulation around the implants, and in 30% to 50% percent of all patients the hardening creates a significant problem. Berkman, *supra* note 10, at E1. The hardening itself often causes severe pain and disfigurement, and steps taken by physicians to remedy the hardening may lead to further injuries. Judy Foreman, *Before You Opt for a Breast Implant . . . Host of Problems Often Follows Simple Surgery*, BOSTON GLOBE, July 22, 1991 (Science and Technology), at 37.

106. Even if something other than the implants causes breast cancer, the implants may block or distort mammograms, causing a lump to go undetected at an early stage of cancer when it is still small. Hiltz, *supra* note 72, at A1. Only a small number of lawsuits against breast implant manufacturers center on this claim. In one of the few cases asserting this claim, the plaintiff underwent a surgical procedure during which one of her silicone breast implants ruptured. She alleged that the silicone and other foreign materials that remained in her body after the procedure made it impossible to use mammography to monitor the breast for future cancer. *Livshits v. Natural Y Surgical Specialties Inc.*, 60 U.S.L.W. 2436 (S.D.N.Y. Nov. 27, 1991).

107. See, e.g., *Knapp v. Dow Corning Corp.*, 941 F.2d 1336 (5th Cir. 1991); *Morreale v. Surgitek, Inc.*, No. 92-1391, 1992 WL 193489 (E.D. La. July 30, 1992); *Woolard v. Heyer-Schulte*, 791 F. Supp. 294 (S.D. Fla. 1992); *Livshits*, 60 U.S.L.W. at 2436.

108. *Panel Rules on Breast Implants*, FACTS ON FILE WORLD NEWS DIG., Apr. 2, 1992, at 233 G2.

109. The term "bleeding" is a widely accepted term of art in the context of breast implants. See, e.g., *Saline Breast Implants—Call for Data*, PR NEWSWIRE, Jan. 5, 1993 (LEXIS, Nexis library, Currnt file).

110. See Frankel, *supra* note 79, at 82.

The effect of silicone escaping into the body is difficult to prove,¹¹¹ but plaintiffs' attorneys assert that it leads to lymphatic disorders,¹¹² cancer,¹¹³ and autoimmune diseases such as lupus and connective tissue disease.¹¹⁴ Despite substantial causation problems, plaintiffs' attorneys won large verdicts in several cases litigated in the early 1990s.¹¹⁵

Most breast implant lawsuits include causes of action based on strict liability in tort for defective product design and/or failure to warn.¹¹⁶ Many include defect claims based on the implied warranty of merchantability,¹¹⁷ which in a majority of jurisdictions is nearly equivalent to strict liability in tort when applied to design defect and warning defect claims.¹¹⁸ As in *Hopkins v. Dow Corning Corp.*, many lawsuits also plead causes of action for fraud and misrepresentation.¹¹⁹

Although plaintiffs generally succeed in lawsuits against breast implant manufacturers, at least one manufacturer avoided liability against a defective warning claim by use of the learned intermediary defense. The learned intermediary doctrine is applied in failure to warn cases, usually involving drugs.¹²⁰ If the manufacturer is selling a product to a sophisticated intermediary, such as a physician, the manufacturer may be able to avoid liability by warning the intermediary

111. See *Six Major Areas of Litigation Predicted For the 1990s*, INSIDE LITIG., Mar. 1992, at 32 (discussing generally the causation problems associated with proving the harmful effects of breast implant leakage) [hereinafter *Litigation*]. See also *Toole v. McClintock*, 778 F. Supp. 1543, 1549 (M.D. Ala. 1991), *vacated and remanded on other grounds*, 999 F.2d 1430 (11th Cir. 1993) (medical experts presented conflicting testimony regarding the potential harmful effects of ruptured silicone implants); Frankel, *supra* note 79, at 84.

112. See Frankel, *supra* note 79, at 84. See also *Toole*, 778 F. Supp. at 1549.

113. The National Cancer Institute has undertaken a study of the risks of cancer, while the University of Michigan and New York University are researching a possible connection between implants and autoimmune disease. Dr. Allan Bruckheim, *Health Line—Letters*, CHI. TRIB., Mar. 22, 1993, at C7.

114. See Frankel, *supra* note 79, at 82.

115. See Frankel, *supra* note 79, at 82. See also *Dow Corning Sees \$45 Million Charge*, REUTER BUS. REP., June 18, 1992 (LEXIS, Nexis library, Currrnt file); Mike McKee, *Plaintiff: Dow Corning Fraud Enough to Sustain Verdict*, THE RECORDER, Feb. 4, 1993, at 5.

116. Ellis Interview, *supra* note 19; Horowitz Interview, *supra* note 19; McBride Interview, *supra* note 19; Price Interview, *supra* note 19.

117. Ellis Interview, *supra* note 19; Horowitz Interview, *supra* note 19; McBride Interview, *supra* note 19; Price Interview, *supra* note 19. See also *supra* note 33.

118. See, e.g., *Desmarais v. Dow Corning Corp.*, 712 F. Supp. 13, 14 (D. Conn. 1989) (plaintiff sought \$350,000 in damages for defendant's alleged misrepresentation, negligence, strict tort liability, and failure to warn).

119. McBride Interview, *supra* note 19; Price Interview, *supra* note 19; See also, e.g., *Desmarais*, 712 F. Supp. at 14.

120. See *Lee v. Baxter Health Care Corp.*, 721 F. Supp. 89, 94-95 (D. Md. 1989), *aff'd*, 898 F.2d 146 (4th Cir. 1990).

rather than the ultimate consumer.¹²¹ In such cases, the injured consumer will have only a cause of action against the doctor who failed to pass on the warning. In *Lee v. Baxter Healthcare Corp.*,¹²² the court analogized breast implants to prescription drugs and granted the defendant manufacturer's summary judgment motion on a failure to warn claim. The court based its holding on the manufacturer's written provision to doctors warning of the possibility that the implants might leak.¹²³ However, the learned intermediary defense is likely to work only in cases where the plaintiff obtained her implants fairly recently; until the late 1980s, many manufacturers did not provide doctors with detailed warnings.¹²⁴

2. *Litigation Against Doctors Providing Breast Implants*

Lawsuits related to breast implants have largely ignored the physicians who provided the defective products. Those lawsuits that do name doctors as defendants usually do so to destroy diversity jurisdiction and prevent manufacturers from removing the cases to federal court.¹²⁵ Because most cosmetic surgeons were not fully aware of the risks now believed to accompany breast implants, plaintiffs' attorneys have, for the most part, decided that the doctors could not have been negligent in providing the product or in failing to warn of its dangers.¹²⁶ Further, strict liability causes of action are seldom pursued against the doctor who provided the implant because of doctors' exemption from strict products liability.¹²⁷

When plaintiffs target doctors in lawsuits related to breast implants or other cosmetic products, the cause of action is often based on negligence related to the way in which the doctor implanted the device,¹²⁸

121. *Id.* at 95.

122. 721 F. Supp. at 89.

123. *Id.* at 95.

124. *See, e.g.*, *Toole v. McClintock*, 778 F. Supp. 1543, 1547 (M.D. Ala. 1991), *vacated and remanded on other grounds*, 999 F.2d 1430 (11th Cir. 1993) (learned intermediary defense fails because "[t]he jury could reasonably conclude that the warning provided to physicians by [the manufacturer] did not properly convey the risks . . .").

125. Ellis Interview, *supra* note 19; Horowitz Interview, *supra* note 19; McBride Interview, *supra* note 19; Price Interview, *supra* note 19.

126. *See, e.g.*, Frankel, *supra* note 79, at 82 (discussing a breast implant case in which the plaintiff's attorney believed that the jury exonerated the doctor because "[t]hey felt the manufacturer had not told him enough.").

127. Ellis Interview, *supra* note 19; Horowitz Interview, *supra* note 19; McBride Interview, *supra* note 19; Price Interview, *supra* note 19. *See also supra* notes 39-63 and accompanying text.

128. *See, e.g.*, *Fitz v. Dolyak*, 712 F.2d 330, 331 (8th Cir. 1983) (alleging that physician performed silicone injections negligently); *McGuire v. Sifers*, 681 P.2d 1025 (Kan. 1984) (alleging physician negligence in removing breast tissue and adding implants); *Davis v. Caldwell*, 79 A.D.2d 1088 (N.Y. App. Div. 1981) (same); *Henderson v. Heyer-Schulte Corp.*, 600 S.W.2d 844, 846 (Tex. Ct. App. 1980) (alleging physician negligence in inserting implants).

or how the doctor failed to diagnose or remedy problems created by the device.¹²⁹ Nevertheless, in the large majority of injuries related to breast implants, the product itself is the cause of harm, rather than the way in which the doctor applied his professional skills to the implanting and treatment of the product.¹³⁰ Thus, in most lawsuits plaintiffs presently may not successfully sue the doctor who sold and inserted the implant. Indeed, doctors have refused to participate in the proposed \$4.75 billion settlement of many of the breast implant lawsuits, based on their confidence that doctors face minimal liability.¹³¹

III. POLICY CONSIDERATIONS IN APPLYING STRICT PRODUCTS LIABILITY TO MEDICAL PROFESSIONALS PROVIDING COSMETIC PRODUCTS

This section considers whether the medical professional exemption from strict products liability should apply in the context of cosmetic medical products. As discussed above, courts and commentators have made numerous policy arguments to justify exempting medical professionals from strict products liability. Support for the exemption, however, is not unanimous.¹³² At least one court has held that a case-by-case determination—as opposed to a blanket exemption—is required when deciding whether medical professionals and hospitals should be subject to strict liability.¹³³ However, regardless of whether one supports an exemption from strict liability for medical professionals in other circumstances, such an exemption is not defensible in the context of cosmetic products. As detailed below, none of the major policy arguments provided for exempting medical professionals from strict liability retains its persuasiveness when applied to defective cosmetic medical products.

129. See, e.g., *Toole*, 778 F. Supp. at 1546 (alleging that doctor acted negligently when treating problems related to pain and hardening of silicone implant).

130. The surgical procedure for both silicone and saline implants is relatively simple. Claudia Feldman, *Concerns Over Breast Implants*, HOUST. CHRON., Jan. 8, 1992, at 1. Complications that may arise after the surgery are generally attributed to the effects of materials contained in the implant. *Id.* See also Judy Siegel, *Ministry Panel to Study Silicone Breast Implants*, JERUSALEM POST, Jan. 9, 1992 (LEXIS, Nexis library, Omni file) (approximately 150,000 U.S. women undergo this relatively simple surgical procedure each year at a cost of about \$5,000).

131. See Mike McKee, *Plastic Surgeons Pass on Implant Settlement; They Say \$5 Billion Accord is Manufacturer's Responsibility*, THE RECORDER, Nov. 5, 1993, at 1.

132. See *Cunningham v. MacNeal Memorial Hosp.*, 266 N.E.2d 897, 904 (Ill. 1970) (holding hospital strictly liable as supplier of blood infected with hepatitis virus despite the fact that supplying products was merely an incidental function of the hospital); Posner, *supra* note 16, at 269 (finding theoretical justifications for holding doctors and hospitals liable for defective products); William R. Russell, Note, *Products and the Professional: Strict Liability in the Sale-Service Hybrid Transaction*, 24 HASTINGS L.J. 111, 132-33 (1980) (policy considerations demand that strict liability be applied regardless of the professional or commercial nature of a transaction).

133. *Johnson v. Sears, Roebuck & Co.*, 355 F. Supp. 1065, 1067 (E.D. Wis. 1973).

A. Concern Over Higher Prices

Perhaps the most cited justification for exempting medical professionals from strict products liability is that the higher prices associated with strict products liability are unacceptable when applied to necessities. As stated in *Newmark v. Gimbel's, Inc.*,¹³⁴ courts must treat doctors differently from other sellers because doctors provide essential products rather than an "aesthetic convenience or luxury."¹³⁵

Several commentators share the *Newmark* court's concern. One writer argues that strict liability for doctors is unacceptable because "unlike products, the availability of which may not be critical to the public welfare, the availability of affordable medical services under any criteria is of the utmost public concern."¹³⁶ Another writer, attacking the application of strict products liability to hospitals, asserts that the resulting increase in hospitalization costs "could be devastating to the national economy."¹³⁷ This criticism argues that the impact would be particularly harmful to low-income households, since they are the least able to absorb increased costs.¹³⁸

Few proponents of strict products liability would deny that it often leads to increased prices. However, proponents justify the price increase under a risk spreading rationale. Strict products liability increases sellers' tort exposure, resulting in sellers purchasing additional insurance to compensate for the added risk.¹³⁹ Sellers, in turn, raise prices to fund their additional insurance and liability costs.¹⁴⁰ Thus, consumers pay more for products, but will likely receive compensation if the products prove to be defective.¹⁴¹ In this manner the risk of

134. 258 A.2d 697 (N.J. 1969).

135. *Id.* at 702.

136. Sales, *supra* note 21, at 25-26.

137. Seibert, *supra* note 63, at 412.

138. See Frank J. Vandall, *Applying Strict Liability to Professionals: Economic and Legal Analysis*, 59 IND. L.J. 25, 27-28 (1983) (rise in insurance rates caused by application of strict liability will raise the costs of medical treatment beyond the reach of low-income households).

139. See Robert G. Berger, *The Impact of Tort Law Development on Insurance: The Availability/Affordability Crisis and Its Potential Solutions*, 37 AM. U. L. REV. 285, 308 (1988); Richard A. Posner, *Symposium, Alternative Compensation Schemes and Tort Theory: Can Lawyers Solve the Problems of the Tort System?*, 73 CALIF. L. REV. 747, 753 (1985); Gary T. Schwartz, *The Ethics and Economics of Tort Liability Insurance*, 75 CORNELL L. REV. 313, 330 (1990); W. Kip Viscusi, *Wading Through the Muddle of Risk-Utility Analysis*, 39 AM. U. L. REV. 573, 584 (1990).

140. See John B. Attanasio, *The Principle of Aggregate Autonomy and the Calabresian Approach to Products Liability*, 74 VA. L. REV. 677, 710 (1988); Mark M. Hager, *The Emperor's Clothes Are Not Efficient: Posner's Jurisprudence of Class*, 41 AM. U. L. REV. 7, 46 (1991); Viscusi, *supra* note 139, at 584.

141. See Attanasio, *supra* note 140, at 710; Berger, *supra* note 139, at 308; Schwartz, *supra* note 139, at 330.

injuries occurring due to defective products is spread over a large number of consumers, avoiding too harsh a burden on any individual consumer. All sellers in the chain of distribution—including retailers—are liable, but retailers and others lower in the chain may obtain indemnification from those higher in the chain.¹⁴²

Even courts exempting medical professionals from strict products liability have acknowledged the societal benefits of strict liability risk spreading. In *Magrine v. Krasnica*,¹⁴³ the court stated that while the objective of spreading risks is a “relevant consideration,”¹⁴⁴ it is “not nearly enough when laid beside other more basic considerations.”¹⁴⁵ Prominent among these “more basic considerations” was concern over the adverse impact strict liability would have on the price of medical care.¹⁴⁶

Courts and commentators concerned with raising prices on necessities have painted with too broad a brush for the realities of modern medical practice. Increasing the costs of breast implants and other cosmetic products would not deprive poorer consumers of essential medical care. Indeed, in light of the dangers associated with breast implants and other cosmetic medical products, increased prices may benefit society. If the products are more expensive, fewer consumers will purchase them and fewer consumers will suffer if the products prove to be defective. Further, if one accepts the view that society’s current allocation of resources on beauty (and the pressure women feel to focus on their external appearance) is unhealthy, then allowing higher prices to discourage consumers from purchasing expensive cosmetic products such as breast implants might be beneficial. Consumer autonomy would not be impaired; if consumers desire to purchase the products they may do so, but perhaps at a higher price.

B. The Risk That Physicians May Stop Selling Cosmetic Medical Products If Strict Liability Applies

A second rationale supporting the medical professional exemption from strict products liability also relates to the “necessary” nature of medical products. The argument is that society must limit the liability of medical professionals so that they will continue to provide the medical products necessary to society.¹⁴⁷

142. *Magrine v. Krasnica*, 227 A.2d 539, 545 (Hudson County Ct. 1967), *aff’d sub nom. Magrine v. Spector*, 250 A.2d 129 (N.J. 1969).

143. *Id.*

144. *Id.*

145. *Id.* at 546.

146. *Id.* at 545-46.

147. *See supra* text accompanying note 52.

No evidence exists that significant numbers of medical professionals would stop providing cosmetic products if they were suddenly saddled with strict products liability.¹⁴⁸ Even if they did stop selling cosmetics, the result would not necessarily detriment society. If the product defects lead to a high rate of injuries, as breast implants do, and the product provides purely superficial benefits such as enhanced physical attractiveness, then society may benefit from the deterrent effect of strict liability.

Further, the cost of therapeutic medicine may decrease if imposing strict products liability discourages medical specialists from practicing cosmetic medicine. In the event some medical professionals leave the practice of cosmetic medicine because of high liability costs, they will not likely turn to selling shoes. Rather, most will focus their practices on therapeutic medicine, where strict liability in tort is not—and should not—be applicable. If more medical professionals are practicing therapeutic medicine, competitive economic pressures would tend to force the price of such services down. Although the lowered prices may be only marginal, they provide another basis for removing cosmetic medical professionals' exemption from strict products liability.

C. *Is There a Sale, and What is the Essence of the Transaction?*

Two of the rationales for exempting medical professionals from strict products liability are closely related. They are (1) a medical professional may not be deemed a seller or merchant involved in a "sale" as defined by the Restatement (Second) of Torts section 402A, or the Uniform Commercial Code (UCC), and (2) even in those cases involving a "sale," the essence of the transaction is usually the service provided rather than the product sold.¹⁴⁹

Numerous courts have addressed cases in which plaintiffs pleaded a strict products liability cause of action against a medical professional who was not engaged in a true sale of a product. One example is *Silverhart v. Mount Zion Hospital*,¹⁵⁰ where a physician on staff at the defendant hospital, while inserting sutures in the plaintiff's vagina, broke a surgical needle that become imbedded in her vagina.¹⁵¹ The plaintiff alleged that the needle was a defective product, and pleaded a cause of action for strict liability in tort against the hospital.¹⁵² She argued that as a "supplier" of the needle, the hospital should be sub-

148. See Greenfield, *supra* note 20, at 687.

149. See *supra* text accompanying notes 36-38.

150. 98 Cal. Rptr. 187 (Cal. Ct. App. 1971).

151. *Id.* at 189.

152. *Id.*

ject to the same standard of liability as any other supplier of products.¹⁵³

The court rejected the plaintiff's strict liability cause of action, primarily on the ground that the hospital was not a "seller" of needles as defined in section 402A of the Restatement (Second) of Torts.¹⁵⁴ Rather, the hospital was merely a user of the needle in the process of providing professional medical services.¹⁵⁵ Numerous other cases also have declined to find a sale in similar circumstances.¹⁵⁶

Silverhart and cases like it are properly adjudicated. Section 402A of the Restatement (Second) of Torts defines a "seller" as "any person engaged in the business of selling products for use or consumption."¹⁵⁷ The UCC, which sets forth the strict liability standard for violating an implied warranty of merchantability in the sale of a product, defines a sale as "the passing of title from the seller to the buyer for a price."¹⁵⁸ The use of a surgical needle in *Silverhart* did not involve either a sale or a seller under these definitions. The doctor using the needle did not intend for the plaintiff to take title to the needle. The hospital did not set a price for the purchase of the needle, nor did it expect the plaintiff to retain possession of the needle. Rather, the needle was merely a tool the doctor used in performing a medical service. Although the hospital and its doctor may be liable if the doctor was negligent in the way he used this tool, neither party should be subject to strict products liability under these circumstances.

In other cases involving medical professionals and assertions of strict products liability, a sale may take place along with the provision of a service, but the service predominates over the sale under the "essence of the transaction"¹⁵⁹ test. The California Supreme Court provided a controversial illustration of this scenario in *Murphy v. E.R. Squibb & Sons, Inc.*¹⁶⁰ In *Murphy*, the plaintiff asserted a design de-

153. *Id.* at 190.

154. *Id.*

155. *Id.* at 190-91.

156. See, e.g., *Carmichael v. Reitz*, 95 Cal. Rptr. 381, 393 (Cal. Ct. App. 1971); *Magrine v. Spector*, 241 A.2d 637, 638 (N.J. Super. Ct. App. Div. 1968), *aff'd*, 250 A.2d 129 (N.J. 1969) (doctor not strictly liable when he "merely purchased and used" a defective product); *Perlmutter v. Beth David Hosp.*, 123 N.E.2d 792, 796 (N.Y. 1954) (holding that providing blood for transfusions is a service rather than a sale); *Foster v. Memorial Hosp. Ass'n*, 219 S.E.2d 916, 920 (W. Va. 1975).

157. RESTATEMENT (SECOND) OF TORTS § 402A cmt. f (1993).

158. U.C.C. § 2-106 (1977).

159. See *supra* notes 36-38 and accompanying text.

160. 710 P.2d 247 (Cal. 1985). *Murphy* was a 4-to-3 decision in which five out of seven justices felt compelled to write their own opinions. *Id.*; See also Stephen A. Spitz, *From Res Ipsa Loquitur to Diethylstilbestrol: The Unidentifiable Tortfeasor in California*, 65 IND. L.J. 591, 617-19 (1990) (noting that the *Murphy* decision has led some commentators to argue that the substantial share requirement is unnecessary).

fect in the drug stilbestrol.¹⁶¹ The plaintiff sued both a manufacturer of the drug and the pharmacy where the drug was purchased under strict liability in tort.¹⁶² Over a vigorous dissent, a four to three majority of the court ruled that a pharmacist is not subject to strict liability in claims related to prescription drugs.

Murphy's facts are markedly different from those in *Silverhart*. In *Murphy*, the court conceded that "it cannot be disputed that a sale in fact occurs."¹⁶³ Unlike the hospital in *Silverhart* that merely used a defective needle, the defendant pharmacy in *Murphy* was unquestionably engaged in the business of selling the product at issue.

The majority purported to apply an essence of the transaction test as part of its justification for relieving the pharmacy of strict liability. The court noted that pharmacists are highly educated, that they often consult with customers about the use of prescription drugs, and that these considerations characterize the selling of drugs as a service.¹⁶⁴ While the court ostensibly held the service element to be the essence of the transaction,¹⁶⁵ the court's conclusion appeared to be heavily influenced by concern about keeping prescription drugs inexpensive.¹⁶⁶

161. 710 P.2d at 249.

162. *Id.*

163. *Id.* at 251.

164. *Id.*

165. *Id.* (dismissing plaintiff's comparison between a pharmacist and an ordinary sales clerk).

166. In arriving at this dubious holding, the court failed meaningfully to analyze why the service should be considered the essence of the transaction. Rather, the court focused on the importance to society of the prescription drugs that pharmacists provide. *Id.* The court's only discussion of the importance of the service element of the transaction was to note that a California statute defined the practice of pharmacy as a "health service." *Id.* at 251-52. In a logic-stretching exercise, the court analogized this law to another California statute that designated sales of blood products as services in order to protect blood suppliers from strict products liability. *Id.* at 252.

The *Murphy* court stated that, because the legislature used the word "service" in describing the practice of pharmacy, and because in another statute it had designated a medical product a service in order to avoid strict products liability, the legislature must also have intended that the practice of pharmacy be exempted from strict products liability. *Id.* The dissenters vigorously disputed that the service element of a pharmacist's sale of drugs outweighs the sale element of the transaction. *Id.* at 263-64 (Bird, C.J., dissenting). Leading the dissenters, Chief Justice Bird criticized the majority's interpretation of the state Health and Safety Code. *Id.* at 264-65. She believed that the state legislature never intended to exempt pharmacists from strict liability: "[The majority] engag[e]s in the purest form of speculation, attempting to divine the motivation which underlay this supposed intent." *Id.* at 265. The dissent, however, recognized that the majority's opinion actually bypassed the essence of the transaction test due to the importance of prescription drugs to society and the perceived harm to society that strict liability would cause in this context. *Id.* at 261-62.

Following a "bombarding" of lobbying efforts nationwide, most states have enacted statutes similar to the one discussed in *Murphy*, characterizing blood transfusions as a service rather than a sale. See Marden Dixon, DRUG PRODUCT LIABILITY, §§ 9.08[4], 9-120 (1981). These statutes appear

In most cases involving sales of cosmetic products by medical professionals, the essence of the transaction is the sale of the products, and, unlike in *Murphy*, no policy concerns require overriding the essence of the transaction test to avoid applying strict products liability.¹⁶⁷ In cosmetic medical products cases, the parties generally intend for the patient to retain physical possession of the product.¹⁶⁸ Medical professionals often include a specific charge for the cost of the product in their bills.¹⁶⁹ Both parties intend for the consumer to take title to the product. No doctor would argue, for example, that the silicone breast implants inserted in a patient continue to belong to the doctor after the patient leaves the operating room. This alone significantly distinguishes cases involving cosmetic medical products from cases such as *Silverhart*, where the defective needle at issue was not "for sale" and was truly incidental to providing a service.

Further, a consumer's expectations and approach to the transaction are likely different in cases involving medical cosmetics than in cases involving therapeutic medical products and services. The essence of the transaction, at least from the consumer's perspective, is much more focused on the product in transactions involving cosmetics than in transactions involving therapeutic treatment. Again, transactions involving breast implants are illustrative. In such transactions, consumers may place more emphasis on choosing the size, type, and appearance of the implant than on choosing the doctor to perform the relatively simple procedure of inserting the implant.¹⁷⁰

to be motivated by a policy concern of protecting the vital supply of blood rather than by a belief that such transactions do not entail the usual characteristics of a sale. They were enacted in response to a decision by the Illinois Supreme Court, *Cunningham v. MacNeal Memorial Hospital*, 266 N.E.2d 897 (Ill. 1970), which recognized that in cases involving the sale of defective blood products, the essence of the transaction is the sale of blood rather than the service of injecting it into the body.

167. See *infra* notes 171-172 and accompanying text.

168. The use of most cosmetic medical products necessitates the direct implantation of a device into the patient's body. Common examples are breast, pectoral, penile, and chin implants. Therefore, the patient leaves the hospital or doctor's office in possession of the medical product.

169. According to Dr. Uwe Reinhardt, a health economist at Princeton University, "[t]he American hospital bill is a source of great humor in the world health economics community; people just laugh." Elisabeth Rosenthal, *Confusion and Error are Rife in Hospital Billing Practices*, N.Y. TIMES, Jan. 27, 1993, at C16. Struggling to increase revenues, hospitals are itemizing each service rendered, such as aspirin after surgery and even extra pillows. *Id.*

170. Breast implants are available in a range of sizes and shapes to suit the personal needs of an individual. Saline implants are made with a silicone rubber shell inflated to the desired size with sterile saline solution. *Saline Breast Implants — Call for Data*, PR NEWSWIRE, Jan. 5, 1993, (LEXIS, Nexis library, Currnt file). The great majority of women seek implants purely for cosmetic reasons, and most seem to have an ideal breast size in mind. See, e.g., *Healthworks: The Controversy of Breast Implants is Reviewed* (CNN television broadcast, Nov. 23, 1992) (Andrew Holtz & Dan Rutz) (transcript #145) (LEXIS, Nexis library, Currnt file).

When a person is ill, his or her objective in visiting a doctor is to get well. The patient's focus is on whatever service the doctor might perform to obtain that result. Even when the doctor uses a product in obtaining the result, such as in prescribing a drug, the patient's focus is on the doctor's skill and expertise in diagnosing the problem and choosing the appropriate drug. In contrast, when a consumer visits a doctor to purchase a cosmetic product such as a breast implant, the doctor's services in implanting the product may be, in the consumer's mind, ancillary to obtaining the product. The consumer focuses more on the product's characteristics than she would if the product were merely a tool used by the doctor to help her "get well."

Finally, cosmetic medical transactions are not as fraught with uncertainty as are many therapeutic medical transactions. This uncertainty is one of the rationales for finding a doctor's services to be the essence of a typical medical sales transaction.¹⁷¹ A patient seeking breast implants may know precisely the product she wants and the cosmetic appearance she desires, and there is little uncertainty regarding whether the product will produce the desired cosmetic result. Breast prostheses surgery is a simple and relatively inexpensive procedure. It is not the essence of the transaction.¹⁷²

D. The Size of Cosmetic Medical Professionals' Client Bases

Courts and commentators have argued that because medical professionals generally have smaller client bases than do other retailers, the risk spreading function of strict products liability is less effective with them than with other retailers.¹⁷³ This argument, however, should not be an issue when dealing with cosmetic medicine, as the client base of a medical professional engaged in the sales of cosmetic products may be substantially larger than that of a medical professional providing therapeutic services and products.¹⁷⁴ Many physicians engaged in providing cosmetic medical products specialize in that field.¹⁷⁵ Also, since other areas of medical practice typically do not even involve sales of

171. See Greenfield, *supra* note 20, at 698; Posner, *supra* note 16, at 268.

172. Greenfield, *supra* note 20, at 698.

173. See *supra* note 63 and accompanying text.

174. See, e.g., L. Erik Bratt, *Implant Moratorium Reduces Time in OR for Plastic Surgeons*, SAN DIEGO UNION-TRIB., Mar. 21, 1992, at C1 (discussing one plastic surgeon who continues to perform about 200 silicone and saline breast implant surgeries a year even after the Food and Drug Administration enacted regulations severely limiting the availability of implants).

175. The growing number of cosmetic medical specialists may be attributed to several factors: "[T]here is seldom review by insurance companies, . . . the practice can be highly lucrative, and . . . any doctor with a medical school degree can hang a shingle as a cosmetic surgeon." Elizabeth Fernandez, *Holding Off the Years*, CHI. TRIB., Mar. 27, 1992, at C7.

products, cosmetic medical specialists are likely to sell more products than other medical professionals. Additionally, providing cosmetic medical products may be faster and simpler than providing therapeutic medical services. Surgeons specializing in breast implants have performed hundreds of such operations in a year¹⁷⁶—arguably as many transactions as engaged in by many automobile dealerships or other “big ticket” product retailers who are subject to strict products liability.

By purchasing insurance, medical professionals should still be able to spread the risks inherent in their products.¹⁷⁷ Regardless of whether cosmetic medical providers can spread risks as effectively as typical retailers, they can unquestionably spread them better than consumers.¹⁷⁸ Thus, concern over the number of sales transactions engaged in by cosmetic medical professionals should not prevent courts from holding them to strict products liability.

E. Knowledge of the Manufacturer's Identity for Purposes of Obtaining Indemnification

At least one court has argued that medical professionals should not be subjected to strict liability in hybrid transactions since they often do not know who manufactured the defective products at issue and thus are in no better position than the consumer to ensure the quality of the product.¹⁷⁹ Because medical professionals often do not know the identities of the manufacturers of products they use, indemnification may be unattainable and medical professionals may be unfairly burdened.¹⁸⁰ This concern is in most respects irrelevant in the context of cosmetic medical transactions. Unlike a dentist, who understandably would not know who manufactured a generic needle she uses,¹⁸¹ a medical professional selling cosmetic products should generally know the manufacturer's identity. When the product itself is the focus, or a major focus, of the transaction, as in the sale of cosmetic medical products, greater attention is likely placed on differentiating between

176. Bratt, *supra* note 174, at C1.

177. See *Magrine*, 241 A.2d at 643 (Botter, J.S.C., dissenting) (possible increase in costs to professionals due to application of strict liability would be offset by insurance); Marc A. Franklin, *Tort Liability for Hepatitis: An Analysis and a Proposal*, 24 STAN. L. REV. 439, 474 (1972); Russell, *supra* note 132, at 130.

178. Greenfield, *supra* note 20, at 691-92.

179. *Magrine v. Krasnica*, 227 A.2d 539 (Hudson County Ct. 1967), *aff'd sub nom. Magrine v. Spector*, 250 A.2d 129 (N.J. 1969).

180. *Id.* at 546.

181. See, e.g., *Magrine*, 241 A.2d at 638 (holding that a dentist is not strictly liable for a needle broken during treatment because he merely purchased and used the defective needle).

manufacturers' products in selecting items the seller or consumer perceives to be superior.

The market for breast implants illustrates this point. Only eight companies have manufactured breast implants,¹⁸² and approximately thirty percent of the implants have come from a single manufacturer—Dow Corning Corporation.¹⁸³ Although implant types differ,¹⁸⁴ it is not unreasonable to expect a physician conducting a breast implant to know which of the eight companies manufactured the product he bought.¹⁸⁵ Between the medical professional and the consumer, the medical professional should bear the burden of identifying the responsible manufacturer, since the doctor is in a better position to know who manufactured the product.¹⁸⁶

F. *Cosmetic Medical Professionals and Advertisements*

A traditional policy rationale supporting strict liability in tort involves the consideration that manufacturers and retailers often advertise heavily for products, and that this advertising lowers a consumer's guard. According to this theory, advertising creates familiarity with

182. *All Things Considered*, *supra* note 87.

183. Approximately two million women have purchased breast implants, and about 600,000 of these were manufactured by Dow Corning Corp. Castaneda & Puente, *supra* note 100. While Dow Corning Corp. is the largest supplier of silicone implants, the company claims that the business accounts for only one percent of its revenues. *Dow Corning Mulls Dropping Implant Line: Silicone Breast Implants*, CHEM. MARKETING RPT., Jan. 27, 1992, at 5.

184. Over the past two decades, four common varieties of implants have been used for breast augmentation. The first are silicone gel implants, which most closely resemble and feel like normal breasts but which are now banned by the FDA. The second are saline implants, which have silicone shells filled with sterile salt water that may be absorbed by the body in case of a leak. The third type are double lumen (combination) implants, which are two bags suspended in one another. One is filled with saline, the other with silicone gel. The fourth type are polyurethane implants, which are silicone implants coated with polyurethane foam. The foam poses a risk of infection and release of chemicals that can cause cancer in laboratory animals. Sandra G. Goodman, *Four Types of Implants*, WASH. POST, June 23, 1992, at Z13.

185. The case of *Lee v. Baxter Healthcare Corp.*, 721 F. Supp. 89 (D. Md. 1989), *aff'd*, 898 F.2d 146 (4th Cir. 1990), illustrates the potential harm to a consumer when a doctor does not keep records of which manufacturer's products are implanted in his patients. The plaintiff in *Lee* asserted injury when her breast implants ruptured. The doctor who conducted the implant procedure testified that he was not sure which manufacturer's implants he used on the plaintiff. *Id.* at 91. Because the plaintiff was not able to prove the manufacturer's identity, defendant Baxter Healthcare Corp. was able to prevail on a motion for summary judgment. *Id.* at 92. This case also provides another argument for extending strict liability to medical professionals providing cosmetic products. Had strict liability been available against the doctor, the plaintiff might not have had cause for concern regarding the doctor's failure to record the identity of the manufacturer.

186. *Magrine*, 241 A.2d at 642 (Botter, J.S.C., dissenting).

and acceptance of products, and diminishes the caution with which a consumer might approach a new and unfamiliar product.¹⁸⁷

At least one commentator has argued that most medical professionals' aversion to advertising provides another basis for exempting them from strict products liability.¹⁸⁸ However, even if most medical professionals shun advertising, this is often not the case for those engaged in transactions involving cosmetic medical products. While advertisements for heart surgery and anesthesiology services remain rare, promotions by breast implant specialists and other cosmetic medical specialists have blossomed. In many magazines and newspapers, "there are pages and pages of glossy ads for cosmetic surgery."¹⁸⁹

After the United States Supreme Court ruled in 1979 that states could not ban doctors from advertising, plastic surgeons were among the first to publicly market their products and services.¹⁹⁰ In this regard, many medical professionals specializing in cosmetic products and procedures appear to be more entrepreneurial than their colleagues in therapeutic medicine. Consequently, the argument that doctors should be treated differently from other retailers because they do not advertise loses its punch when directed toward those engaged in cosmetic product transactions.¹⁹¹

187. Leon Green, *Strict Liability Under Sections 402A and 402B: A Decade of Litigation*, 54 TEX. L. REV. 1185, 1190 (1976); Marshall S. Shapo, *A Representational Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment*, 60 VA. L. REV. 1109, 1371-88 (1974).

188. Seibert, *supra* note 63, at 411.

189. Laura Fraser, *Scar Wars*, SAN FRANCISCO CHRON., May 20, 1990, at 72.

190. Paula Dranov, VANITY FAIR, May 1987, at 68.

191. Commentators have noted at least two additional concerns with subjecting doctors engaged in hybrid transactions to strict liability. First, imposing strict products liability on medical professionals might deter them from developing new medical devices and medicines. Arthur A. Leff, *Medical Devices and Paramedical Personnel: A Preliminary Context for Emerging Problems*, 1967 WASH. U. L.Q. 332, 359 (1967); Comment, *Professional Negligence*, 121 U. PA. L. REV. 627, 651 (1973). This proposition, however, may be doubtful. See Greenfield, *supra* note 20, at 687. In any case, it is not persuasive in the context of cosmetic medical products. An argument can be made that discouraging the further development of cosmetic medical products would further rather than harm societal interests. See *supra* notes 143-146 and accompanying text. Nevertheless, since cosmetic medical products have no greater utility to society than most other types of products, there is no basis for singling them out with the concern that allowing strict products liability might impair future development.

The second concern is that imposing strict products liability on medical professionals might unduly injure the reputations of those found liable, even though there may be no finding of fault. As stated by one commentator, "Any suit in a court of law against a doctor has a damaging effect on his reputation. . . . Since the nature of the doctor-patient relationship requires that a patient have confidence in his doctor, any damage to a doctor's reputation may cause irreparable harm to his practice." William R. Hadley, *Strict Liability—The Medical Malpractice Citadel Still Stands—Hoven v. Kelble*, 79 WIS. 2d 444, 256 N.W. 2d 379 (1977), 11 CREIGHTON L. REV.

IV. SOME LIKELY CONSEQUENCES OF EXTENDING STRICT PRODUCTS LIABILITY TO MEDICAL PROFESSIONALS ENGAGED IN SALES OF COSMETIC PRODUCTS

Presently negligence is the only cause of action an injured consumer normally may bring against medical professionals selling defective cosmetic products. This section analyzes utilizing a negligence theory against medical professionals providing defective cosmetic products, and concludes that in many cases this theory fails to provide an adequate remedy. This section also considers the likelihood that many manufacturers of cosmetic products—the traditional deep pockets in defective cosmetic medical product cases—may become judgment-proof (at least in breast implant cases). Thus, this Article's position that courts should apply strict products liability to medical professionals selling defective cosmetic products likely will be of practical significance in cosmetic product litigation.

A. *Utilizing Negligence Causes of Action Against Medical Professionals Providing Defective Cosmetic Products*

Injured consumers face significant challenges in establishing that medical professionals were negligent in providing cosmetic medical products. For example, in order to prove negligent failure to warn of a dangerous product, the injured plaintiff must prove that the medical professional knew or should have known of the risk she failed adequately to warn against.¹⁹² Providing such proof against a retailer is more difficult than against a manufacturer since, among other things, the manufacturer has control over the development and production of the product. Often retailers are not negligent in failing to warn of dangers for which the manufacturer should have provided a warning. Even if a medical professional does know or should know of a product's danger, an injured consumer may be hard pressed to prove *when* the professional obtained or should have obtained that knowledge.¹⁹³

1357, 1379 (1978). See also Posner, *supra* note 16, at 268.

This argument, made in 1970s, is of less concern today, when malpractice lawsuits are widespread and the public arguably understands that nearly every doctor will be named in a malpractice lawsuit at least once in her career. Also, concerns about the damage to reputation caused to other sellers have not prevented courts from subjecting them to strict liability; sellers of cosmetic services and products are not sufficiently unique to merit special protection for their reputations.

192. See *Warrington v. Pfizer & Co.*, 80 Cal. Rptr. 130, 133-34 (Cal. Ct. App. 1969) (finding manufacturer, not doctor, liable where doctor reasonably relied on manufacturer's assurance of product safety).

193. The difficult burden upon plaintiffs to prove a manufacturer's knowledge in products liability cases led to the development of the imputed knowledge theory. By imputing knowledge to the manufacturer, the plaintiff is "under no obligation to show that the defendant negligently

Unless the plaintiff can prove that the doctor learned or should have learned of the danger prior to the doctor's sale to the plaintiff, the plaintiff likely cannot prevail. Further, even in cases in which the medical professional was negligent, obtaining proof of his level of knowledge about risks may involve substantial difficulty and expense.¹⁹⁴

These concerns have already manifested themselves in the relatively few breast implant cases in which plaintiffs have pursued medical professionals as defendants. In *Toole v. McClintock*,¹⁹⁵ the jury awarded an Alabama woman \$5.4 million against the manufacturer of her defective breast implants but declined to find any liability on the part of the doctor.¹⁹⁶ The plaintiff's attorney believed that the jury exonerated the doctor because "they felt the manufacturer had not told him enough."¹⁹⁷

One way to solve these proof problems is by imputing knowledge of risk to sellers and thus distinguishing strict liability from negligence.¹⁹⁸ In contrast to a negligence action, a court applying the imputed knowledge approach to warnings claims would not require the plaintiff in a breast implant lawsuit to prove that the doctor knew about the dangers of breast implants at the time the doctor sold them to the plaintiff in order for the jury to consider these risks in determining whether the product is defective. The plaintiff would only have to prove that the defendant learned or should have learned of the risks by the time of trial.¹⁹⁹ Using this approach, plaintiffs would recover in many cases in which the doctor under a negligence analysis would be exonerated.

caused the product to be in the dangerous condition or that he was negligent in failing to discover it and do something about it." John W. Wade, *On Product "Design Defects" and Their Actionability*, 33 VAND. L. REV. 551, 556 (1980) [hereinafter *Design Defects*]. Both Wade and Keeton have advocated this approach in order to alleviate the burden of proving a defendant's knowledge at the time a product enters a consumer's hands, or at the time of trial. See John W. Wade, *On the Effect in Product Liability of Knowledge Unavailable Prior to Marketing*, 58 N.Y.U. L. REV. 734 (1983) [hereinafter *Effect in Product Liability*]; Page Keeton, *Product Liability and the Meaning of Defect*, 5 ST. MARY'S L.J. 30, 33 (1973).

194. See Wade, *Effect in Product Liability*, *supra* note 192, at 751-52 (detailing problems in determining defendant's knowledge when "the available knowledge about a product is not so great at the time the product is marketed as at the time of trial").

195. 778 F. Supp. 1543 (M.D. Ala. 1991), *vacated and remanded on other grounds*, 999 F.2d 1430 (11th Cir. 1993).

196. *Id.* at 1545.

197. Frankel, *supra* note 79, at 82.

198. See *Design Defects*, *supra* note 193, at 556; Keeton, *supra* note 193, at 33; Wade, *supra* note 20, at 834-35. Some jurisdictions have adopted the Wade-Keeton approach in specific cases. See, e.g., *Freund v. Cellofilm Properties, Inc.*, 432 A.2d 925 (N.J. 1981); *Phillips v. Kimwood Mach. Co.*, 525 P.2d 1033 (Or. 1974).

199. See, e.g., *Beshada v. Johns-Manville Products Corp.*, 447 A.2d 539 (N.J. 1982).

The imputed knowledge approach is subject to the criticism that it too closely approaches absolute liability—especially in cases involving defective warning claims, where the seller can usually provide a warning easily and cheaply if the seller knows of the danger. If courts applied this approach, however, injured cosmetic product consumers would find recovering against doctors/sellers easier than in a simple negligence action. While many jurisdictions pay lip service to the imputed knowledge approach, few have applied it to cases in which truly unknowable risks existed. Instead, most courts have applied a risk/utility analysis without imputing knowledge of later-discovered risks to the defendant.²⁰⁰ Although this analysis is in many respects similar to a simple negligence analysis,²⁰¹ liability is easier to establish under a strict products liability version of risk/utility balancing.

Courts applying the risk/utility test in a strict products liability cause of action assert that it differs from negligence because the strict liability test focuses on the reasonable safety of the product rather than the reasonableness of the seller's actions.²⁰² Although one may question the significance of this distinction, other more substantial differences also exist: Jury verdicts in favor of plaintiffs have increased dramatically, both in terms of numbers and damage amounts, since courts introduced strict products liability.²⁰³ This marked increase indicates that strict liability has made a difference despite similarities to a negligence risk/utility analysis.

This difference may in part be attributable to jury perceptions that strict liability should allow recovery more readily than negligence, regardless of the analytical tests jurors are instructed to use in determining whether liability exists. Thus, even if the risk/utility test used in negligence claims does not balance substantially different factors than

200. JAMES A. HENDERSON, JR. & AARON D. TWERSKI, PRODUCTS LIABILITY PROBLEMS AND PROCESS 612 (2d ed. 1992) (trend of both courts and commentators to reject imputing knowledge of risks). Interestingly, the commentators now opposed to imputing knowledge of risks include those credited with suggesting the approach—Deans Wade and Keeton. Both have repudiated the approach that they initiated. See *Effect in Product Liability*, *supra* note 193, at 761; W. PAGE KEETON ET AL., PROSSER AND KEETON ON THE LAW OF TORTS 967-98 (8th ed. 1988).

201. See William Powers, Jr., *A Modest Proposal to Abandon Strict Products Liability*, 3 U. ILL. L. REV. 639, 640 (1991).

202. See *Caterpillar Tractor Co. v. Beck*, 593 P.2d 871, 889 (Alaska 1979); Page Keeton, *The Meaning of Defect in Products Liability Law—A Review of Basic Principles*, 45 MO. L. REV. 579, 592 (1980).

203. See Berger, *supra* note 139, at 292. Berger points out that “[w]hereas the first million dollar verdict in a products liability case occurred in 1962 (a year after the adoption of Section 402A), ninety-four such verdicts were rendered in 1980.” *Id.* Further, “[i]n 1984, there were 86 million dollar awards, up 1200% from 1975.” *Id.* at 292 n.32. “In that same time period, the average size of a products liability jury verdict increased from \$393,580 to \$1,850,452, a 370% increase.” *Id.*

the risk/utility test used in strict liability claims, the very fact that the jury is instructed that liability is "strict" under the latter analysis may make it more likely to find that a design's risks outweigh its utility.

No persuasive rationale exists for excluding sellers of cosmetic products from the harsher consequences that strict liability often allows over negligence for other sellers. As discussed above, sellers—including sellers of cosmetics—may spread risks with insurance funded by higher prices to consumers.²⁰⁴ Courts need not have special societal concerns over higher prices when the products at issue are cosmetic rather than therapeutic.²⁰⁵ Even those skeptical of the arguments favoring strict products liability would likely agree that if it is to be applied it should be applied consistently.²⁰⁶ Consistency requires removing any exemptions that might be applied to sellers of cosmetic medical products solely because they are medical professionals.

B. Medical Professionals May Become the Only Parties Against Whom Recovery is Available

Although presently most cosmetic product litigation focuses on the liability of manufacturers, in many cases manufacturers are or may become shielded from liability. Perhaps the area of greatest concern is breast implant litigation. As noted above, breast implant lawsuits against manufacturers have "mushroomed wildly."²⁰⁷ Consumers have filed thousands of lawsuits and the number is increasing steadily.²⁰⁸ A large majority of the cases that have proceeded to trial have

204. See *supra* text accompanying notes 139-142.

205. See *supra* text accompanying notes 143-147.

206. An increasing number of scholars have expressed reservations about the desirability of strict products liability in some or all contexts. See, e.g., Malcolm Wheeler, *The Need for Narrow Tort Reform: Abolishing Strict Products Liability*, in *PRODUCT LIABILITY REFORM: DEBATING THE ISSUES* (Kenneth Chilton ed., 1990); Richard A. Posner, *A Theory of Negligence*, 1 J. LEGAL STUD. 29 (1972); Powers, *supra* note 201, at 639-51.

I am in a bit of an ironic position arguing for an extension of strict products liability, in that I share concerns expressed by some writers critical of applying the doctrine in its present form to warning and, perhaps, design defect cases. However, although I am uncomfortable with the approach courts have taken to strict products liability in some contexts, I believe that employing the doctrine unevenly compounds the problems inherent in the doctrine. In other words, if courts choose to call liability "strict" in warning and/or design cases, they should minimize the confusion and uncertainty that has characterized strict products liability by applying the law as consistently as possible.

207. Frankel, *supra* note 79, at 82.

208. See Moffat, *supra* note 102, at D1. Facing hundreds of lawsuits and threats of thousands more, one breast implant manufacturer "has stopped borrowing in the short-term commercial paper market because lenders are concerned about the firm's situation." *Id.* In Harris County, Texas, where a plaintiff recently won a \$25 million lawsuit, at least 1,000 breast implant cases have been filed, "with hundreds more coming in each week." Richard Connelly, *From Flood to Deluge in Breast-Implant Cases: Houston's Hot in Latest Mass Tort Craze*, TEX. LAW, Jan. 11, 1993, at 1.

resulted in verdicts for the plaintiff.²⁰⁹ Many of these judgments have been for over \$1 million, with the highest reaching \$25 million.²¹⁰ Despite manufacturers' efforts to settle many of these claims, a real possibility exists that this flood of litigation will eventually force breast implant manufacturers into bankruptcy, making them judgment-proof to future claims.

The asbestos litigation which dominated the 1980s and early 1990s provides a powerful analogy.²¹¹ Experts estimate that over 200,000 claimants have brought lawsuits against asbestos manufacturers, with claims based mainly on the failure to warn that the product may cause lung disease.²¹² Asbestos manufacturers have paid approximately \$12 billion in damages,²¹³ and future costs could total as much as \$100 billion.²¹⁴ The legal fees manufacturers have paid are also enormous.²¹⁵ Although the industry was large and healthy prior to the onslaught of litigation, these judgments have completely overwhelmed asbestos manufacturers.²¹⁶ Every manufacturer of asbestos has either declared bankruptcy or is in danger of doing so.²¹⁷ Consequently, injured consumers are now able to recover nothing or only a portion of the damages they suffered and will continue to suffer.²¹⁸

209. Frankel, *supra* note 79, at 82. The most significant judgment resulted in a record \$25 million damage award. Gary Taylor, *Breast Implant Suits Pouring In After \$25 Million Verdict*, NAT'L. L.J., Jan. 18, 1993, at 3.

210. See Tracey Schroth, *Breast Implants: Latest Toxic Tort; Plaintiffs' Bar Launches Aggressive Drive for Clients*, N.J. L.J., Apr. 13, 1992, at 1. Pamela Jean Johnson, the most successful plaintiff, originally sought \$64.3 million, but was satisfied with her \$25 million award. Taylor, *supra* note 209, at 3.

211. The asbestos analogy was indeed played upon by attorneys seeking certification of a federal class action for breast implant cases in Cincinnati. See Frankel, *supra* note 79, at 82.

212. *Landmark Proposal Could Signal the Beginning of the End of Asbestos Litigation in the United States*, PR NEWSWIRE, Jan. 15, 1993 (LEXIS, Nexis library, Currnt file) [hereinafter *Landmark Proposal*]. Fifty to sixty additional asbestos lawsuits are filed every day. *Id.*

213. *Keene Calls For Claims Relief Fund to Resolve Asbestos Crisis; Dept. of Labor Should Manage Funds Contributed by Asbestos Defendants*, PR NEWSWIRE, Oct. 14, 1992, (LEXIS, Nexis library, Currnt file) [hereinafter *Claims Relief Fund*].

214. Glenn Bailey, *Drastic Changes Needed in Managing Asbestos Litigation*, MICH. LAWYERS WEEKLY, June 15, 1992, at 12.

215. Legal fees account for nearly \$9 billion of the \$12 billion manufacturers have expended in asbestos litigation thus far. *Claims Relief Fund*, *supra* note 212. See also *The Asbestos Quagmire*, N.J. L.J., Dec. 28, 1992, at 16; *Landmark Proposal*, *supra* note 212.

216. Seventeen asbestos manufacturers have filed for bankruptcy protection. *Asbestos Maker Foresees Relief in Congress*, LIABILITY WEEK, Jan. 11, 1993.

217. See *The Asbestos Quagmire*, *supra* note 214; *Drastic Changes Needed in Managing Asbestos Litigation*, *supra* note 214; *Claims Relief Fund*, *supra* note 213.

218. Gail Appleson, *Asbestos Victims Suffer Setback With Court Ruling*, REUTER BUS. REP., Dec. 7, 1992 (LEXIS, Nexis library, Currnt file). Plagued by bankruptcy, Mansville Corp. and other asbestos manufacturers established victims' trust funds in order to compensate the most seriously ill victims. *Id.* However, the Second Circuit recently revised its approval of the Manville Corp. trust plan, sending the matter back to district court, which could result in even further delays for victims. *Id.* See also *Landmark Proposal*, *supra* note 212.

Similarly, the number of potential lawsuits from breast implants is staggering. More than two million women have purchased breast implants,²¹⁹ and approximately fifty percent of these women have suffered damages attributable to alleged defects in the implants.²²⁰ One commentator has estimated that the litigation will likely continue for at least another fifteen to twenty years.²²¹

All but two of the manufacturers of silicone implants have abandoned the market.²²² Experts estimate that Dow Corning Corporation, the manufacturer which had the largest market share of breast implant sales, may face tort liability of up to \$2 billion.²²³ Since the corporation's insurance may only cover \$250 million in claims, a potential uninsured exposure of \$1.75 billion could remain.²²⁴ While at least one analyst believes Dow Corning could weather this financial loss,²²⁵ others believe the corporation will file for Chapter 11 bankruptcy protection in the near future.²²⁶

Dow Corning and other breast implant manufacturers have proposed settling a large number of the lawsuits for approximately \$4.75 billion.²²⁷ Under the terms of the proposed agreement Dow Corning would pay a minimum of \$1.24 billion, with its insurers covering part of the payment.²²⁸ However, as of the date this Article went to press, the proposed settlement terms would address less than half (about 6,800) of the approximately 15,000 breast implant lawsuits filed against manufacturers.²²⁹ Many plaintiffs attorneys whose clients' cases are addressed by the proposed settlement have indicated they

219. Andrew Leigh, *Breast Implants: Next Gold Mine for Trial Lawyers*, INVESTOR'S BUS. DAILY, Jan. 10, 1992, at 8.

220. Berkman, *supra* note 10, at E1.

221. Mike McKee, *Bar Split Over Implant Ruling's Impact; Plaintiffs Counsel Say Restrictions Won't Affect Current Suits*, THE RECORDER, Feb. 21, 1992, at 1. At least one attorney believes that the threat of future litigation will not drive breast implant manufacturers out of business. *Id.* Rather, "they will be forced to make totally safe implants to satisfy the market of women who want implants solely for larger breasts." *Id.*

222. In the spring of 1992, Dow Corning Corp. pulled out of the business after having about 30% market share. In the wake of Dow Corning Corp.'s departure, only Mentor Corp. and McGhan Medical Corp. remained. Both are smaller manufacturers based in Santa Barbara, Cal. Rebecca Perl, *Dow Corning's Departure Leaves Only Two Smaller Implant Makers*, ATLANTA J. & CONST., Mar. 20, 1992, at A4.

223. Moffat, *supra* note 102, at D1.

224. *Id.*

225. An analyst with Prudential Securities Research has stated that Dow Corning may be able to absorb up to a \$3.6 billion pre-tax charge. *Id.*

226. *Id.*

227. See David R. Olmos, *Dow Corning Expecting \$1.24 Billion Implant Tab*, L.A. TIMES, Jan. 15, 1994, at D1.

228. *Id.*

229. See Olmos, *supra* note 99, at D2; Levin, *supra* note 102, at 39.

will advise their clients to opt out of the settlement to obtain more money in individual lawsuits.²³⁰ Thus, even if the settlement is approved, it will not necessarily prevent Dow Corning from collapsing.

Additionally, problems may arise in bringing the proposed settlement to fruition. Three months after the proposed settlement was announced, United States District Court Judge Sam C. Pointer held that Dow Chemical Co. and Corning Inc., the parent corporations of Dow Corning, could not be held liable for any damages assessed against their subsidiary.²³¹ This decision removed two of the major parties expected to contribute to the settlement, and led one prominent attorney to declare the settlement proposal "effectively dead."²³²

If Dow Corning and/or other manufacturers of breast implants declare bankruptcy, injured consumers may not be able to fully recover their damages unless they are permitted to recover from the doctors who sold these defective products. The strict products liability policy objective of spreading risks throughout the consuming public rather than subjecting an injured consumer to catastrophic loss would be frustrated. If strict products liability is to be applied consistently, professionals engaged in the sale of cosmetic silicone breast implants should not be exempt simply because they are medical doctors.

V. WHAT IS "COSMETIC"?

Defective breast implants illustrate the problem of distinguishing between cosmetic and noncosmetic medical products. Approximately eighty percent of all breast implants are used solely to increase the size of the purchaser's breasts.²³³ Such an application is likely to be considered cosmetic under any definition. However, approximately twenty percent of all implants are sold to women who have lost one or both breasts following mastectomies.²³⁴ 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.

230. See Dick Lehr, *\$4.75 Billion Accord Eyed on Breast Implants; Plaintiffs, Manufacturers Agree on Compensation Fund*, THE BOSTON GLOBE, Sept. 10, 1993, at 1.

231. See Mary Hull, *Ruling Tangles Breast-Implant Talks*, TEXAS LAWYER, Dec. 13, 1993, at 8.

232. *Id.*

233. Castaneda & Puente, *supra* note 100.

234. *Id.* See also Betsy Pisik, *Alternatives to Silicone; Mastectomy Patients Have Safe Choices*, Wash. Times, July 14, 1992, at E3.

Webster's dictionary defines "cosmetic" as "relating to or making for beauty . . . correcting defects."²³⁵ Under this definition all breast implants are arguably cosmetic, regardless of whether they were purchased in response to a mastectomy or merely to make breasts larger. However, the use of breast implants following mastectomies restores the body to its original appearance. This is distinguishable from adding size to the breasts solely to improve the purchaser's original appearance. Arguing that greater societal utility is derived from the use of implants following mastectomies than from their use merely to enlarge breasts would not likely engender much controversy.

Critics may assert that dividing medical products into those that are necessary and those that are cosmetic is overly simplistic. Relatively few medical products are so necessary that life could not be sustained without them. For example, a patient might require a metal pin in her hip to enable her to walk. She would survive without the product, but the quality of her life would be significantly diminished. Medical products lie on a spectrum of societal utility, ranging from those that are absolutely necessary to sustain life, to those that serve no other purpose than to enhance physical beauty.

Indeed, many products may provide both cosmetic and medical benefits to the same user. In *Hufft v. Horowitz*,²³⁶ the plaintiff purchased an allegedly defective penile prosthesis.²³⁷ The penile implant was an inflatable device designed to alleviate a penile erectile dysfunction.²³⁸ The court noted that a purchaser could desire the implant "for procreation, alleviation of an impotency problem or cosmetic purposes."²³⁹ Thus, although a penile implant may provide cosmetic benefits, it also has noncosmetic utility.

Courts could determine where a medical product lies on the continuum between life-sustaining and cosmetic purposes by utilizing either a bright line approach or an ad hoc balancing test. One bright line approach would be to ask whether the product is primarily cosmetic under a dictionary sense of the word. Using this approach, if a product's primary purpose or utility is to make consumers more physically attractive, strict liability would apply regardless of tangential medical benefits or the consumer's motivation for wishing to appear more attractive. Thus, even in cases in which a consumer purchased a breast implant following a mastectomy, strict liability would apply to the

235. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 514 (1986).

236. 5 Cal. Rptr. 2d 377 (Cal. Ct. App. 1992).

237. *Id.* at 378.

238. *Id.*

239. *Id.* at 383 n.9.

medical professional who sold the product if it is defective. This bright line approach would favor physical needs over psychological needs. It would provide certainty and consistency, but could raise the prices of implants even for women purchasing them after mastectomies.

Another, perhaps more palatable, bright line test differentiates by considering whether the product merely restored the recipient's physical condition (such as obtaining breast implants following mastectomies), or whether the product enhanced the recipient's physical condition (such as obtaining breast implants solely to enlarge the purchaser's natural breasts). Courts may conclude that sales of products purchased primarily to "restore" physical appearance should not subject doctors to strict liability, whereas sales of products intended simply to "improve" physical appearance should be considered cosmetic and not exempt from strict liability.²⁴⁰

Alternatively, under an ad hoc approach, courts could ascertain the benefits—either physical or psychological—of the medical products at issue before deciding whether the importance of making this product cheaply available outweighs the goal of risk spreading and the other policy concerns which normally call for strict products liability. Under this approach a court might apply strict liability in the eighty percent of cases in which consumers purchase breast implants to increase the size of their breasts, and a negligence standard in the other twenty percent. In a case similar to *Hufft*, a court might analyze the particular plaintiff's motivation for purchasing the product prior to deciding whether to apply strict liability to the medical professional/seller. If the perceived cosmetic benefit is not a factor, or is merely an ancillary factor in the plaintiff's decision to purchase the product, then a court may decide that the therapeutic aspects of the product prevail and that the medical professional should be exempt from strict products liability.

Although this ad hoc approach offers the advantage of flexibility, it would also create confusion and uncertainty between both plaintiffs and defendants as to what standard would apply in each case.²⁴¹ How-

240. Utilizing this approach would raise questions over what constitutes "restoring" the body as opposed to "improving" it. Although in the case of breast implants the issue is fairly clear, with other products the issue is more difficult. Collagen implants provide an example. Surgeons implant collagen into patients' faces to remove wrinkles. Is this procedure restoring the body to its original condition, or is it improving the body's appearance?

241. See *Brown v. Superior Ct.*, 751 P.2d 470 (Cal. 1988) (adopting the comment k rule for prescription drugs and expressly disapproving the case-by-case approach of *Kearle v. Lederle Laboratories*, 218 Cal. Rptr. 453 (Cal. Ct. App. 1985)); *Hufft v. Horowitz*, 5 Cal. Rptr. 2d at 383 n.9 (declining to consider whether patient's motivation for penile implant was cosmetic).

ever, of the cosmetic product lawsuits currently pending, a large majority relate to breast implants used by the eighty percent of purchasers motivated solely by the desire to make their breasts larger.²⁴² Regardless of whether a bright line approach or an ad hoc approach is applied, courts would consider product sales made for this purpose to be cosmetic. Thus, in the majority of cases currently pending, the issue of determining what is cosmetic may be of more academic than practical concern.

Nevertheless, a number of courts have established precedents for deciding whether to use a bright line rule or an ad hoc approach in applying strict liability to special classes of products. For example, comment k to section 402A of the Restatement (Second) of Torts exempts "unavoidably unsafe" products from strict liability.²⁴³ Courts usually apply the comment's exemption to prescription drugs.²⁴⁴ However, after years of debate, courts remain divided over whether to apply comment k's exemption to all prescription drugs, or only to those prescription drugs which are determined on a case-by-case basis to be essential to society's welfare.²⁴⁵

The analogy between classifying essential prescription drugs under comment k and difficulties in defining "cosmetic" medical products is striking. Exploring the analogy may offer clues as to how courts might ultimately determine when to apply strict liability to medical professionals/sellers.

Courts justify exempting prescription drugs from strict liability under comment k because prescription drugs provide great utility to society.²⁴⁶ Not all prescription drugs, however, are of equal utility. Indeed, consumers may use some prescription drugs primarily for cosmetic purposes, while others may be necessary to sustain life. For example, penicillin's societal utility greatly outweighs the utility of a prescription acne medication. Thus, the issue arises whether comment k's protection from strict liability should apply to all prescription

242. See *supra* notes 89-90 and accompanying text.

243. Restatement (Second) of Torts § 402A comment k (1993).

244. See, e.g., *Hill v. Searle Lab.*, 884 F.2d 1064, 1068-69 (8th Cir. 1989) (drafters of comment k considered and rejected extension of strict liability exemption to all prescription drugs); *Brown v. Superior Court*, 751 P.2d 470, 480 (Cal. 1988) (extending protection of comment k to all prescription drugs); *Toner v. Lederle Lab.*, 732 P.2d 297, 306-08 (Idaho 1987) (declaring that comment k applies only to drugs whose benefits clearly outweigh their risks). See generally Gregory C. Jackson, *Pharmaceutical Product Liability May Be Hazardous to Your Health: A No-Fault Alternative to Concurrent Regulation*, 42 AM. U. L. REV. 199 (1992).

245. George H. King, *A Prescription for Applying Strict Liability: Not All Drugs Deserve Comment k Immunization*, *Brown v. Superior Court*, 44 Cal. 3d 1049, 751 P.2d 470, 245 Cal. Rptr. 412 (1988), 21 Az. St. L.J. 809 (1989).

246. See, e.g., *Brown*, 751 P.2d at 480.

drugs—even those which offer primarily cosmetic utility—or only to those which have a strong medical utility.

Some courts addressing the comment k issue have opted to engage in ad hoc balancing of the utility of the drug at issue to society in determining whether to apply strict products liability. An often cited example is *Kearl v. Lederle Laboratories*,²⁴⁷ where the plaintiff contracted polio as a result of taking an oral polio vaccine manufactured by the defendant. Although the vaccine prevented polio for the vast majority of users, it caused crippling or death in about one in four million users.²⁴⁸ The plaintiff's assertions of warning and design defects in the vaccine focused on the failure to make the vaccine in a form capable of being administered through an injection, which would not carry the risk of causing polio as do oral doses.

While agreeing that comment k should protect prescription drug manufacturers in some cases, the *Kearl* court expressed discomfort with "the rather routine and mechanical fashion by which many appellate courts have concluded that certain products, particularly drugs, are entitled to such special treatment."²⁴⁹ The court thus concluded that applying comment k's protection from strict liability to prescription drugs and other products should be determined on a case-by-case basis. The court created a three-factor test to determine whether to apply comment k.²⁵⁰ The test focused on the importance of the product's benefit, the seriousness of the risk presented by the product, and the societal interest in making the product available versus enhanced accountability imposed through strict liability.²⁵¹ Applying this test, the court held that comment k's negligence standard would likely apply to an extremely important, relatively low-risk drug such as the defendant's polio vaccine.²⁵² However, the court would have applied strict liability to a drug with a cosmetic application, such as acne medication.

Other courts have disagreed with *Kearl* and held that all prescription drugs should merit comment k's negligence standard, regardless of their relative utility and danger. A leading example is *Brown v.*

247. 218 Cal. Rptr. 453 (Cal. Ct. App. 1985).

248. *Id.* at 456.

249. *Id.* at 463.

250. The factors include: "(1) whether, when distributed, the product was intended to confer an exceptionally important benefit that made its availability highly desirable; (2) whether the then-existing risk posed by the product both was 'substantial' and 'unavoidable'; and (3) whether the interest in availability (again measured as of the time of distribution) outweighs the interest in promoting enhanced accountability through strict liability design defect review." *Id.* at 464.

251. *Id.*

252. *Id.*

Superior Court,²⁵³ in which the California Supreme Court held that although "there is some appeal in the basic premise of *Kearl*,"²⁵⁴ limiting comment k's applicability to prescription drugs to a case-by-case analysis would create too much uncertainty for drug manufacturers, and thus would limit the availability and affordability of drugs.²⁵⁵ Further, the same drug might be held to a negligence standard by one court and to a strict liability standard by another, since the balancing advocated by *Kearl* depends on the facts of each case and on the particular judge's subjective view of the drug's importance.²⁵⁶ Finally, even in the same case, the judge and the jury might come to conflicting conclusions on whether *Kearl*'s balancing test calls for strict liability or negligence.²⁵⁷

Courts adopting this Article's call to apply strict liability to medical professionals engaged in sales of cosmetic medical products might differ, based on their preference for *Kearl* or *Brown*, on how they define which products are cosmetic. Courts favoring the *Kearl* approach might analyze the significance of a product's medical utility on a case-by-case basis in determining whether it should be labelled cosmetic and its seller subjected to strict liability. Courts favoring *Brown* might shy away from labelling any medical products as cosmetic due to the difficulties in balancing discussed above. Alternatively, courts might adopt a bright line definition of cosmetic, such as the dictionary definition of any product relating to or making for beauty or correcting defects.

VI. CONCLUSION

As breast implant and other cosmetic product litigation matures, medical professionals who sell these cosmetics are likely to become an increasingly attractive target for liability. Applying the strict products liability approach that courts have applied to other sellers of products would make recovery against medical professionals cheaper and easier than reliance on negligence actions.²⁵⁸ Although policy concerns have properly persuaded courts to exempt medical professionals from strict products liability when they are engaged in therapeutic medicine, the

253. 751 P.2d 470 (Cal. 1988).

254. *Id.* at 481.

255. *Id.* at 481-82. See also Jackson, *supra* note 244, at 203; *Vaccine Injury Compensation: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Energy and Commerce*, 99th Cong., 2d Sess. 115 (1986); *American Med. Ass'n Proceedings of the House of Delegates*, 137th Annual Meeting 79 (1988).

256. Jackson, *supra* note 244, at 203.

257. Jackson, *supra* note 244, at 203.

258. See *supra* notes 192-206 and accompanying text.

time has come to hold them accountable on an equal footing with other sellers when their sales relate to beauty rather than to health.