Winter 1994

Sharing Accountability for Breast Implants: Strict Products Liability and Medical Professionals Engaged in Hybrid Sales/Service Cosmetic Products Transactions

Richard L. Cupp, Jr.
Pepperdine University School of Law

Follow this and additional works at: http://ir.law.fsu.edu/lr
Part of the Medical Jurisprudence Commons, and the Torts Commons

Recommended Citation
http://ir.law.fsu.edu/lr/vol21/iss3/3

This Article is brought to you for free and open access by Scholarship Repository. It has been accepted for inclusion in Florida State University Law Review by an authorized editor of Scholarship Repository. For more information, please contact bkaplan@law.fsu.edu.
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

* Associate Professor of Law, Pepperdine University School of Law; B.A., 1983, Pepperdine University; J.D., 1987, University of California, Davis. I am happily indebted to Robert Cochran and Gregory Ogden for their insightful comments, to Nancy Dragutsky, Peri Hansen, Edward Hueginin, and David Wright for their excellent research assistance, and to the Pepperdine University School of Law for funding my work on this Article with a research grant.

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.


Critics charge that many of these implants and other cosmetic products 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. Although given less attention, other potentially defective cosmetic medical products also have caused injury and have led to products liability litigation. Most of the litigation to date has centered around strict liability in tort causes of action against the manufacturers of the products.

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, the

15. Blakeslee, supra note 11 (penile implants); Breast Implant Issue, supra note 13 (testicle and chin implants).
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 25, 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 Shelheimer, Sales-Service
“lynch pin” of the doctrine is that strict liability facilitates risk spreading.\textsuperscript{21} Strict liability causes sellers to raise prices to pay for insurance against increased liability.\textsuperscript{22} Consumers thus pay more for products, but are assured that they will receive compensation if injured by a defective product.\textsuperscript{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.”\textsuperscript{24} This broad net of liability facilitates the risk spreading goal of strict products liability,\textsuperscript{25} and increases an injured consumer’s chance of obtaining compensation.\textsuperscript{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.\textsuperscript{27} Because most courts will not apply strict

\begin{itemize}
  
  
  
  
  23. \textit{Escola}, 150 P.2d at 441. Sales, supra note 21; Shelhimer, supra note 20, at 791.
  
  
  25. Sales, supra note 21.
  
  26. \textit{Id.}
  
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 merchantability 33 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.

---


31. Id. at 699.

32. Id. at 701.


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.\textsuperscript{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.\textsuperscript{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.\textsuperscript{37} However, if the service aspect predominates, courts generally do not allow a cause of action for strict liability in tort.\textsuperscript{38}

\section*{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,\textsuperscript{39} engaged in hybrid transactions from strict liability in tort.\textsuperscript{40} In Newmark,\textsuperscript{41} the court was careful to note it would not apply strict products liability to doctors and dentists. In addition to pointing out

\begin{itemize}
  \item \textsuperscript{35} Id. at 703.
  \item \textsuperscript{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).
  \item \textsuperscript{37} See, e.g., Cunningham v. MacNeal Memorial Hosp., 266 N.E.2d 897, 900-02 (Ill. 1970); Newmark, 258 A.2d at 701.
  \item \textsuperscript{38} See, e.g., Carmichael, 95 Cal. Rptr. at 393; see also Crump & Maxwell, supra note 36, at 834-36.
  \item \textsuperscript{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).
  \item \textsuperscript{40} Crump & Maxwell, supra note 36, at 831.
  \item \textsuperscript{41} 258 A.2d 697 (N.J. 1969).  
\end{itemize}
the high utility of medical professionals' services to society.\(^4\) New-
mark stated that the essence of the transaction in medical treatment is
the doctor's services rather than the products involved in rendering
the services.\(^4\) Further, a doctor's use of medical products does not
rise to the level of a "sale" as required under strict products liability.\(^4\)

Another frequently cited case in support of exempting doctors from
strict products liability is \textit{Magrine v. Krasnica}.\(^5\) In \textit{Magrine}, the plain-
tiff sued her dentist under strict liability in tort when the dentist's de-
fective hypodermic needle broke in her jaw.\(^6\) The court noted the
traditional exemption provided to medical professionals, and ex-
plained that the essence of a transaction involving professional serv-
dices is the service rather than the products used in rendering the
service.\(^7\) Further, for purposes of strict products liability, medical
professionals are generally not "merchants" in the business of selling
products.\(^8\) 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 nec-
essary incident in providing his professional services.\(^9\) Finally, the
court agreed with Newmark that policy concerns favoring affordable
health care outweigh concerns favoring strict liability for medical
professionals.\(^0\)

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, in-
volving . . . 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), \textit{aff'd sub nom.} Magrine v. Spector, 250 A.2d

\(^{46}\) Id. at 540. In \textit{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, \textit{supra} note 29.

\(^{49}\) \textit{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.  

(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.  

(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.  

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

(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.  

(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. Keble, 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.  


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).  


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


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


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).


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. 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, statutes of the goddess Diana dating from the Roman Empire depict her with numerous large breasts. Americans have always shared this perception that large breasts enhance a woman's beauty. 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."

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. The injections, although initially achieving the desired results, led to disastrous health problems and were soon discontinued.

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.

---


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 . . . 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.

particular favorite was transformer insulating fluid.\textsuperscript{73} The insulating fluid was made of liquid silicone, a plastic used extensively during the war in synthetic rubber, hydraulic fluid, and other products.\textsuperscript{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.\textsuperscript{75} In 1965 \textit{Newsweek} magazine estimated that seventy-five doctors in Los Angeles alone were performing the procedure.\textsuperscript{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.\textsuperscript{77}

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

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

\textsuperscript{73.} \textit{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 \textit{Hearings}]; \textit{See also} Hilts, supra note 72.

\textsuperscript{74.} \textit{Hearings, supra note 73; Hilts, supra note 72.}

\textsuperscript{75.} \textit{Escalation, Newsweek, Oct. 25, 1965, at 110.}

\textsuperscript{76.} \textit{Id.}


\textsuperscript{78.} \textit{Hearings, supra note 73; Hilts, supra note 72, at 1.}

\textsuperscript{79.} \textit{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).}

\textsuperscript{80.} \textit{Hearings, supra note 73; Foreman, supra note 77, at 1; Berkman, supra note 10, at A1.}

\textsuperscript{81.} Hilts, supra note 72, at A1.

\textsuperscript{82.} \textit{Id.}

\textsuperscript{83.} Glenn Kessler et al., \textit{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, Current file).

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 pur-
chased 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
device 92 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, Current File) [hereinafter All Things Considered].
88. Id. See also Roan, supra note 84, at E1.
89. See Sandra G. Boorman, Four Types of Implants, WASH. POST, June 23, 1992
(Health), at Z13; Hilt, 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?, NEWSWEEK, Dec. 5, 1989, at 9. See also Nicholas E. Leffert, 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; Gor-
cial skin to remove wrinkles. 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. Only a handful of attorneys litigated breast implant cases in late 1991; by early 1992, though, between 250-300 attorneys were litigating such cases. By mid-1993, it was estimated that the number of attorneys was between 500 and 1,000. By late 1993 as many as 15,000 lawsuits were filed alleging defective implants. The FDA received 3,400 complaints of physical problems related to implants by early 1992, 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. Despite


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, Current file). Thus, in little over one year, approximately fifteen 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, Current file).

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

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, and the litigation could potentially continue another twenty years.

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; (2) problems related to hardening of the breasts; and (3) increased difficulty in detecting cancer due to implants. Of these, the most litigated area involves injuries resulting from exposure to liquid silicone or polyurethane. The FDA reports that approximately six percent of all silicone breast implants have ruptured. Furthermore, unruptured silicone implants still expose users to liquid silicone through a process known as “bleeding.” 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.


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. Hilts, 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).


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, Current file).

110. See Frankel, supra note 79, at 82.
The effect of silicone escaping into the body is difficult to prove, but plaintiffs' attorneys assert that it leads to lymphatic disorders, cancer, and autoimmune diseases such as lupus and connective tissue disease. Despite substantial causation problems, plaintiffs' attorneys won large verdicts in several cases litigated in the early 1990s.

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

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. 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, CH. 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, Nexas library, Current 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.


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

rather than the ultimate consumer. 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., 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. 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.

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. 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. Further, strict liability causes of action are seldom pursued against the doctor who provided the implant because of doctors' exemption from strict products liability.

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.
or how the doctor failed to diagnose or remedy problems created by the device. 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. 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.

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. 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. 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).


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).

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.*, courts must treat doctors differently from other sellers because doctors provide essential products rather than an "aesthetic convenience or luxury."  

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." 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." This criticism argues that the impact would be particularly harmful to low-income households, since they are the least able to absorb increased costs.

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. Sellers, in turn, raise prices to fund their additional insurance and liability costs. Thus, consumers pay more for products, but will likely receive compensation if the products prove to be defective. In this manner the risk of

135.  Id. at 702.
137.  Selbert, supra note 63, at 412.
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.\footnote{142}

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

\textbf{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.\footnote{147}

\footnote{143. Id.}
\footnote{144. Id.}
\footnote{145. Id. at 546.}
\footnote{146. Id. at 545-46.}
\footnote{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. 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.

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, where a physician on staff at the defendant hospital, while inserting sutures in the plaintiff's vagina, broke a surgical needle that became imbedded in her vagina. The plaintiff alleged that the needle was a defective product, and pleaded a cause of action for strict liability in tort against the hospital. 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.
151. Id. at 189.
152. Id.
ACCOUNTABILITY FOR BREAST IMPLANTS

ject to the same standard of liability as any other supplier of products.\textsuperscript{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.\textsuperscript{154} Rather, the hospital was merely a user of the needle in the process of providing professional medical services.\textsuperscript{155} Numerous other cases also have declined to find a sale in similar circumstances.\textsuperscript{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."\textsuperscript{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."\textsuperscript{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" test. The California Supreme Court provided a controversial illustration of this scenario in \textit{Murphy v. E.R. Squibb \& Sons, Inc.}\textsuperscript{160} In \textit{Murphy}, the plaintiff asserted a design de-

\begin{enumerate}
\item \textsuperscript{153} \textit{Id.} at 190.
\item \textsuperscript{154} \textit{Id.}
\item \textsuperscript{155} \textit{Id.} at 190-91.
\item \textsuperscript{157} \textit{Restatement (Second) of Torts} § 402A cmt. f (1993).
\item \textsuperscript{158} \textit{U.C.C.} § 2-106 (1977).
\item \textsuperscript{159} See supra notes 36-38 and accompanying text.
\item \textsuperscript{160} 710 P.2d 247 (Cal. 1985). \textit{Murphy} was a 4-to-3 decision in which five out of seven justices felt compelled to write their own opinions. \textit{Id.}; See also Stephen A. Spitz, \textit{From Res Ipsa Loquitur to Diethylstilbestrol: The Unidentifiable Tortfeasor in California}, 65 \textit{Ind. L.J.} 591, 617-19 (1990) (noting that the \textit{Murphy} decision has led some commentators to argue that the substantial share requirement is unnecessary).
fect in the drug stilbestrol. The plaintiff sued both a manufacturer of the drug and the pharmacy where the drug was purchased under strict liability in tort. 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." 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.

While the court ostensibly held the service element to be the essence of the transaction, the court's conclusion appeared to be heavily influenced by concern about keeping prescription drugs inexpensive.

---

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] engage[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 Liab. §§ 9.08[4], 9-120 (1981). These statutes appear
ACCOUNTABILITY FOR BREAST IMPLANTS

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. In cosmetic medical products cases, the parties generally intend for the patient to retain physical possession of the product. Medical professionals often include a specific charge for the cost of the product in their bills. 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.

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, Current 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, Current 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. 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.

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. 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. Many physicians engaged in providing cosmetic medical products specialize in that field. 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 year—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. Regardless of whether cosmetic medical providers can spread risks as effectively as typical retailers, they can unquestionably spread them better than consumers. 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. 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. 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, 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.
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, and approximately thirty percent of the implants have come from a single manufacturer—Dow Corning Corporation. Although implant types differ, it is not unreasonable to expect a physician conducting a breast implant to know which of the eight companies manufactured the product he bought. 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.

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 Mails Dropping Implant Line: Silicone Breast Implants, CHEM. MARKETING RPTR., 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. Boodman, 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


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. 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.


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.


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
ACCOUNTABILITY FOR BREAST IMPLANTS

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.

---

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").


196. Id. at 1545.

197. Frankel, supra note 79, at 82.


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. Although this analysis is in many respects similar to a simple negligence analysis, 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. 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. 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. TWEIRSKY, 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).


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.
ACCOUNTABILITY FOR BREAST IMPLANTS

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.\textsuperscript{204} Courts need not have special societal concerns over higher prices when the products at issue are cosmetic rather than therapeutic.\textsuperscript{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.\textsuperscript{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."\textsuperscript{207} Consumers have filed thousands of lawsuits and the number is increasing steadily.\textsuperscript{208} A large majority of the cases that have proceeded to trial have

\textsuperscript{204.} See supra text accompanying notes 139-142.

\textsuperscript{205.} See supra text accompanying notes 143-147.

\textsuperscript{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.

\textsuperscript{207.} Frankel, supra note 79, at 82.

\textsuperscript{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. Many of these judgments have been for over $1 million, with the highest reaching $25 million. 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. 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. Asbestos manufacturers have paid approximately $12 billion in damages, and future costs could total as much as $100 billion. The legal fees manufacturers have paid are also enormous. Although the industry was large and healthy prior to the onslaught of litigation, these judgments have completely overwhelmed asbestos manufacturers. Every manufacturer of asbestos has either declared bankruptcy or is in danger of doing so. Consequently, injured consumers are now able to recover nothing or only a portion of the damages they suffered and will continue to suffer.

---


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, Current file) [hereinafter Landmark Proposal]. Fifty to sixty additional asbestos lawsuits are filed every day. Id.


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.


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, Current 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, and approximately fifty percent of these women have suffered damages attributable to alleged defects in the implants. One commentator has estimated that the litigation will likely continue for at least another fifteen to twenty years.

All but two of the manufacturers of silicone implants have abandoned the market. 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. Since the corporation's insurance may only cover $250 million in claims, a potential uninsured exposure of $1.75 billion could remain. While at least one analyst believes Dow Corning could weather this financial loss, others believe the corporation will file for Chapter 11 bankruptcy protection in the near future.

Dow Corning and other breast implant manufacturers have proposed settling a large number of the lawsuits for approximately $4.75 billion. 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. 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. Many plaintiffs attorneys whose clients' cases are addressed by the proposed settlement have indicated they

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.
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.\footnote{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.\footnote{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."\footnote{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.\footnote{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.\footnote{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.

\footnote{230}{See Dick Lehr, \$4.75 Billion Accord Eyed on Breast Implants; Plaintiffs, Manufacturers Agree on Compensation Fund, \textit{The Boston Globe}, Sept. 10, 1993, at 1.}
\footnote{231}{See Mary Hull, Ruling Tangles Breast-Implant Talks, \textit{Texas Lawyer}, Dec. 13, 1993, at 8.}
\footnote{232}{Id.}
\footnote{233}{Castaneda & Puente, \textit{supra} note 100.}
\footnote{234}{Id. See also Betsy Pisik, Alternatives to Silicone; Mastectomy Patients Have Safe Choices, \textit{Washington Times}, July 14, 1992, at E3.}
Webster's dictionary defines "cosmetic" as "relating to or making for beauty . . . correcting defects.\textsuperscript{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 \textit{Hufft v. Horowitz},\textsuperscript{236} the plaintiff purchased an allegedly defective penile prosthesis.\textsuperscript{237} The penile implant was an inflatable device designed to alleviate a penile erectile dysfunction.\textsuperscript{238} The court noted that a purchaser could desire the implant "for procreation, alleviation of an impotency problem or cosmetic purposes."\textsuperscript{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

\begin{footnotes}
\item[235] \cite{webster}
\item[236] \cite{hufft}
\item[237] \cite{hufft} at 377.
\item[238] \cite{hufft} at 378.
\item[239] \cite{hufft} at 383 n.9.
\end{footnotes}
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.

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. 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?

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.\textsuperscript{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.\textsuperscript{243} Courts usually apply the comment's exemption to prescription drugs.\textsuperscript{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.\textsuperscript{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.\textsuperscript{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

\textsuperscript{242} See supra notes 89-90 and accompanying text.
\textsuperscript{243} Restatement (Second) of Torts § 402A comment k (1993).
\textsuperscript{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*, 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. 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.” 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. 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. 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. However, the likely 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.*

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, in which the California Supreme Court held that although "there is some appeal in the basic premise of Kearl," 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. 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. 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.

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. Although policy concerns have properly persuaded courts to exempt medical professionals from strict products liability when they are engaged in therapeutic medicine, the

254. Id. at 481.
255. Id. at 481-82. See also Jackson, supra note 244, at 203; 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.