UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division

In re:	)	Master File No.
	)	CV 92-P-10000-S
SILICONE GEL BREAST IMPLANTS	)	
PRODUCTS LIABILITY LITIGATION	)	This document relates
(MDL 926)	)	to all cases

ORDER and JUDGMENT
Scotfoam Summary Judgment

For the reasons stated in the accompanying opinion, the Motion for Summary Judgment filed by defendants Scotfoam Corporation, '21' International Holdings, Inc, '21' Foam Company, Inc., Knoll International Holdings, Inc., General Felt Industries, Inc., Foamex Products, Inc., Recticel Foam Corporation, and Scott Paper Company is GRANTED. All claims against these companies are hereby SEVERED under Fed. R. Civ. P. 42 from other issues and claims remaining in this litigation and are DISMISSED WITH PREJUDICE.

Under Fed. R. Civ. P. 54(b), the court expressly determines that there is no just reason for delay and expressly directs entry of final judgment dismissing all claims against these companies in all cases pending in this court under the master file number CV 92-P-10000-S.

This the 25th day of April, 1995.

/s/ Sam C. Pointer, Jr.
United States District Judge

Service:
Plaintiffs' Liaison Counsel
Defendants' Liaison Counsel

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OPINION
(Scotfoam Summary Judgment)

Under submission after appropriate discovery, extensive briefing, and oral argument is the motion for summary judgment filed by defendant Scotfoam Corporation and its related entities.[1] Scotfoam makes polyurethane foam, some of which was attached to breast implants by several implant manufacturers, including Medical Engineering Corporation, Heyer-Schulte Co., Cox-Uphoff, Inc., and Aesthetech.[2] Scotfoam asserts that it is not liable for alleged injuries to breast implant recipients on the ground, *inter alia*, that, as a bulk supplier, it had no duty to provide warnings regarding polyurethane foam to breast-implant recipients or their physicians. The parties agree that, with discovery substantially complete, this motion is ripe for decision. For the reasons stated below, the court concludes that Scotfoam's motion should be granted.

I. STANDARD OF REVIEW

The basic principles governing summary judgment under Fed. R. Civ. P. 56 were clarified in the trilogy of cases decided by the Supreme Court in 1986: *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242 (1986); *Matsushita Elec. Industrial Co.*

1These companies include '21' International Holdings, Inc.; '21' Foam Company, Inc.; Knoll International Holdings, Inc.; General Felt Industries, Inc.; Foamex L.P.; Foamex Products, Inc.; Recticel Foam Corporation; and Scott Paper Company. For convenience, Scotfoam Corporation and these entities are referred to collectively in this opinion as "Scotfoam."

2Each of these companies manufactured the Natural Y implant for some time period between 1970 and 1991.

v. Zenith Radio Corp., 475 U.S. 574 (1986). Summary judgment is proper if, because of facts shown not to be in genuine dispute, a party is entitled to judgment as a matter of law. Material facts in genuine dispute are assumed to be favorable to the party against whom summary judgment would be entered. In deciding whether a party is entitled to a judgment as a matter of law, the court uses the same standards and burdens of production and persuasion that would apply at a jury trial.

II. CHOICE OF LAW

In federal multidistrict proceedings, the transferee court applies the substantive law of the transferor courts. *See, e.g., In re San Juan Dupont Plaza Hotel Fire Litigation*, 745 F.Supp. 79, 81 (D.P.R. 1990) (quoting *Ferens v. John Deere Co.*, 494 U.S. 516 (1990)) and MANUAL FOR COMPLEX LITIGATION, SECOND § 31.122 n. 25 (1985). The transferor courts in diversity cases would be bound to apply the law of the forum state, including its choice of law rules. *Klaxon Co. v. Stentor Electric Mfg. Co.*, 313 U.S. 487 (1941). *See also* MANUAL FOR COMPLEX LITIGATION, SECOND § 33.23 n. 36 (1985).

This MDL proceeding involves diversity-jurisdiction cases filed in, or removed to, federal courts in 90 of the 94 districts, located in virtually every state, the District of Columbia, Puerto Rico, and the Virgin Islands. Scotfoam is currently involved in cases transferred from 39 jurisdictions.[3] This court must therefore look to the laws of the several states to determine whether Scotfoam's motion should be granted. Because of variations in state law or in the factual context — such as when the foam used in a particular implant was sold by Scotfoam — summary judgment could be proper in some cases while not warranted in others.

III. FACTS

Scotfoam manufactures bulk foam for sale in large buns or rolls. This foam is used in many applications, such as in mattresses, furniture padding, carpet underlay, audio speaker

3As of March 7, 1994, these jurisdictions included Alabama, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Idaho, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maryland, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Mexico, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia, and Wisconsin.

surrounds, cosmetic applicators, and blood filters. Scotfoam sells it in bulk to various distributors and fabricators, which in turn may cut and further process the foam for a particular application. All foam sold by Scotfoam was accompanied by a statement that it did not recommend foam for any particular use and that the buyer was responsible for determining the appropriateness of the application.

One of Scotfoam's customers was Wilshire Foam Company. Wilshire would cut buns of foam into thin sheets and have them specially washed by clean-room processors. Wilshire then sold these treated "clean wipes" to a variety of companies in the computer, electronics, aerospace, and medical industries. Implant manufacturers purchasing clean wipes from Wilshire would then attach them to an implant and heat-seal it. After being sterilized, the final products were distributed by manufacturers to physicians for implantations.

At least by 1984 Scotfoam had become aware that some of its foam sold to Wilshire was being processed and resold for use in breast implants. Whether it earlier knew of that use is a matter in factual dispute. The evidence is without dispute that Scotfoam never recommended its foam *for* use in breast implants, and recommended *against* such usage when, because of pending litigation, Cooper-Aesthetech's Vice President of Manufacturing inquired in 1987 about the composition of foam.

Some studies have shown that degraded foam may release toluene diisoycanote (TDI) and toluene diamine (TDA), chemicals linked to cancer in lab animals. Plaintiffs allege that Scotfoam had knowledge of this potential hazard which it did not share with Wilshire, implant manufacturers, physicians, or implant recipients. Scotfoam states that its knowledge was derived from information publicly available or from implant manufacturers and, in any event, that these manufacturers had vastly more knowledge than it ever had. It notes that implant manufacturers represented that they had conducted research on the use of polyurethane foam as an implant cover and had determined that foam was safe for that use.

IV. ANALYSIS

Plaintiffs do not dispute that foam has hundreds of safe uses, nor do they contend that there

was any manufacturing defect in foam made by Scotfoam. They assert, however, that Scotfoam had a duty to warn of particular dangers that might be associated with using foam coatings on a product to be implanted in the human body. They argue that Scotfoam is liable under Restatement (Second) of Torts § 388 for failing to provide appropriate warnings, under § 402A for selling a product unsafe for its intended use and failing to warn of TDA dangers, and under § 389 for selling a chattel unlikely to be made safe for use, as well as under more traditional common law theories of negligence and fraudulent misrepresentation.

Scotfoam denies that it has any liability to the plaintiffs, the ultimate recipients of implants having a foam-coated covering. It was merely a bulk supplier of a product that was not unreasonably dangerous for its intended uses; moreover, the implant manufacturers had greater knowledge than it of any dangers created by incorporating the product into implants.

Many cases have analyzed tort claims against a company like Scotfoam by focussing on the nature of the duty owed by such a seller, often describing this as the"bulk seller" or "raw material supplier" defense. Other cases have analyzed such claims under the "sophisticated user" or "learned intermediary" defenses, which also implicate the element of proximate causation. As indicated in the A.L.I.'s Tentative Draft No. 2 of a new Restatement on Products Liability, it may be a misnomer to describe these as defenses, since they are aspects of concepts of defect and causation.

A. Duty to Warn

Although not specifically adopted as substantive law by all states, § 388 of the Restatement (Second) of Torts provides a convenient starting point for analysis. This section states:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
>
> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
>
> (b) has no reason to believe that those for whose use the chattel is supplied

will realize its dangerous condition, and

> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Under this section — and the court has not discovered any state law that would dispense with such a requirement — Scotfoam would not be liable for failure to warn implant recipients or their physicians of potential hazards before it had reason to know its foam was being used in breast implants. The issue, rather, is whether it had a duty to warn after it acquired that knowledge in 1984 (or, according to plaintiffs, in the mid-1970s).

Cases imposing liability under this section, § 389, § 402A, and their state-law analogues have usually involved suppliers of a product or a component part that was in substantially the same condition when used by the consumer as when sold by the supplier. Indeed, a showing that the product has not been substantially altered is a prerequisite to liability in many states. Here it is undisputed that bulk foam as sold by Scotfoam was not directly implanted into any of the plaintiffs. Rather, as noted, Scotfoam's bulk foam was cut by Wilshire into thin sheets and specially washed before being sold to implant manufacturers, which then heat-sealed these "clean wipes" to the covering of implants and subjected them to a sterilization process. Whether this foam can be considered as being in substantially the same condition when implanted as when sold by Scotfoam is highly doubtful, though not critical to the court's granting summary judgment in favor of Scotfoam.

Some states have imposed liability on a supplier of a raw material used as an ingredient in the final product when that material was inherently dangerous, such as a toxic chemical or a contaminated food. Notwithstanding plaintiffs' evidence that degraded foam may release a chemical that has been associated with cancer in animals,[4] bulk foam, with its broad array of apparently safe uses, should not be viewed as an inherently dangerous product.

Plaintiffs have cited only one case in which a court imposed a duty to warn on the supplier

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4Scotfoam vigorously challenges the sufficiency of any evidence showing that foam used in implants may have caused injury to any plaintiff. The court does not reach this issue.

of a raw material not inherently dangerous. *Suchomajcz v. Hummel Chem. Co.*, 524 F.2d 19 (3d Cir. 1975) (applying Pennsylvania law), held that a manufacturer whose chemicals, though not inherently dangerous, were used to create illegal fireworks kits was liable for injuries caused by them. A critical factor in the decision was that the manufacturer knew that its chemicals would be incorporated into a final product that was illegal. The court stated, "[T]he social utility of knowingly selling chemicals for illegal use is minimal; the social consequences of such sales may be devastating." *Id.* at 25. Later cases in the same jurisdiction have not extended the limited holding in *Suchomajcz. See Fleck v. KDI Sylvan Pools, Inc.*, 981 F.2d 107 (3d Cir. 1992) (duty to warn exists only when component has a specific purpose and use), *cert. denied,* ___ U.S. ___ (1993); *and Kalinowski v. E.I. dupont de Nemours & Co.*, 851 F.Supp. 149 (E.D. Pa. 1994), *motion to vacate denied,* 1994 WL 230832 (E.D. Pa. May 23, 1994) (no duty on raw material supplier to warn ultimate user of medical device).

The evidence reflects that less than .00001% of Scotfoam's total foam production found its way into breast implants. To require Scotfoam to warn of a danger — indeed, one that is subject to genuine dispute — from such a special application of its product would be even more extreme than the example used by the A.L.I. to suggest limits on the doctrine of products liability; namely, whether a company would have a duty to warn that its pigiron is unsuitable for use in a tricycle. See Restatement (Second) of Torts § 402A, Comment p. (1965). The A.L.I. recognized that the proper scope of the duty to warn would have to be developed through subsequent cases. In the thirty years since publication of the Restatement, plaintiffs have, in a variety of circumstances, asserted claims against suppliers of materials incorporated into products made by other manufacturers. As anticipated, courts have concluded that there are limits to the potential liability of one selling a product used in the manufacture or fabrication of other products.[5]

As explained in *TMJ Implants Product Liability Litigation,* No. 94-MD-1001 (D. Minn.

5The Institute, in its Tentative Draft No. 2 of a new Restatement on the law of Product Liability, appears to adhere to the view that some limits on the liability of suppliers of raw materials are appropriate, primarily through considering the effect of product modification or alteration on either the reasonableness or feasibility of warnings or on proximate causation.

Jan. 17, 1995), many courts have expressly adopted the so-called raw material supplier defense. The court identified decisions from California, Connecticut, Hawaii, Minnesota, New Jersey, North Carolina, Oklahoma, and Pennsylvania. *Id*. at 14-17. Several additional jurisdictions have recognized this defense: Missouri, in *Crossfield v. Quality Control Equip. Co., Inc.*, 1 F.3d 701 (8th Cir. 1993) (manufacturers of component parts cannot be held liable for dangers of final product they did not design or build); Utah, in *House v. Armour of America, Inc.*, No. 930552-CA, 1994 WL 614153 (App. Utah Oct. 31, 1994) (bulk supplier of raw material not inherently dangerous has no duty to warn ultimate user); Michigan, in *Nowak v. E.I. dupont de Nemours & Co., Inc.*, 827 F.Supp. 1334 (W.D. Mich. 1993) (supplier of raw material not inherently defective did not owe duty to remote user); and North Dakota, in *Veil v. Vitek, Inc.*, 803 F.Supp. 229 (D. N.D. 1992) (supplier of raw materials not inherently dangerous has no duty to warn ultimate user).

Judge O'Neill recently recognized the limitations on a component parts supplier in the breast implant context. *In re Coordinated Breast Implant Litigation*, No. JCCP-2754 (Cal. Ct. App. Apr. 13, 1995). Although he determined that Dow Corning's motion for summary judgment should not be granted because of existing factual questions, he recognized that a manufacturer of a non-defective component part has no duty to evaluate all possible end uses of its product. *Id.* at 7 citing *Walker v. Stauffer Chemical Corp.*, 19 Cal. App.3d 669, 674 (1971) and *Kealoha v. E.I. dupont de Nemours & Co., Inc.*, 884 F.Supp. 590, 594 (D. Haw. 1994).

A major problem with imposing on Scotfoam a duty to warn is that there was no feasible method for it to have warned potential implant recipients or their physicians of possible dangers in using foam-covered implants. To require a general advertising campaign or perhaps mailings to plastic surgeons who might be engaged in breast implantations can hardly be viewed as reasonable, would be of doubtful effectiveness in light of marketing strategies by implant manufacturers selling such implants, and, indeed, might even become the basis for still further claims premised upon Restatement § 324A (negligent undertaking). The law, as it has developed, recognizes that such a burden on sellers of products having widespread safe uses would be too onerous, particularly in light of the more direct responsibility of those selecting the product for their specific

application, such as, in this litigation, the implant manufacturers.

After reviewing the decisions in the various states, as well as the Restatement and public policy considerations, this court concludes that no state would impose liability in a raw material supplier situation like this, not involving an inherently dangerous or a defectively manufactured product. Scotfoam did not, under §§ 388, 389, 402A, or state-law analogues, have a duty to warn about possible hazards from using foam in the human body. It is also significant that decisions in the only state that has addressed Scotfoam's liability in the breast implant cases have granted summary judgment in its favor. *See Goldrich v. Natural Y Surgical Specialties Inc.*, No. WEC 104664 (Sup. Ct. Los Angeles County, Cal. Mar. 14, 1991) *and In re Coordinated Breast Implant Litigation*, No. JCCP-2754 (Sup. Ct. San Diego County, Cal. Oct. 7, 1994).

B. Proximate Cause

One may argue that Scotfoam had a duty to warn its purchasers, such as Wilshire, of any dangers of which it was aware relating to implanting foam in the human body. Even so, there was no proximate cause between its failure to give such a warning and the plaintiffs' alleged injuries. Factual disputes may exist concerning what knowledge Wilshire had or should have been expected to have. The evidence, however, is without genuine dispute that (1) Scotfoam did not represent foam as suitable for human implantation and, when asked, advised against such a usage; (2) Scotfoam had no information concerning the potential consequences of implanting foam in the human body that was unknown to the implant manufacturers purchasing clean wipes from Wilshire; and (3) these implant manufacturers in fact had greater knowledge than Scotfoam about any such problems.

Implant manufacturers in 1984 represented to Scotfoam that foam had been used on implants for years without any problems, and in 1987 provided Scotfoam with additional information regarding the use of foam for breast implants. It appears that, though not at the time known to Scotfoam, Aesthetech, in opposing a proposal to classify breast implants as Class III medical devices, had submitted studies to the Food and Drug Administration in 1982 about the use of polyurethane in implants and, in particular, any carcinogenic effects.

Because Scotfoam had no information it could have given the manufacturers that they did not already possess, its failure to provide to the manufacturers the information it did possess was not a proximate cause of any of the plaintiffs' injuries.

C. Other Claims

Plaintiffs claim that, under traditional common law tort principles, Scotfoam was negligent in selling foam after knowing it was being used in breast implants. To be liable for negligence, there must be a duty, breach of that duty, proximate cause, and damages. For the reasons indicated in IV.A and B above, the court concludes that Scotfoam had no duty to warn physicians or potential implant-recipients of possible dangers relating to use of foam-covered implants and that any failure to warn Wilshire or implant manufacturers of such dangers was not a proximate cause of any of the plaintiffs' injuries.

Plaintiffs' final argument — that Scotfoam is liable for fraudulent misrepresentation — likewise has no merit. There is no evidence that any plaintiff, or any plaintiff's physician, relied upon any statement made by Scotfoam or would have made any different decision regarding a breast implant if Scotfoam had disclosed the limited information it had concerning possible dangers of using foam in implantations. *See, e.g., General Motors Acceptance Corp v. Central Nat'l Bank*, 773 F.2d 771, 778 (7th Cir. 1985).

V. CONCLUSION.

By separate order, summary judgment will be entered in favor of Scotfoam Corporation and its related entities. The claims against these companies will be severed under Fed. R. Civ. P. 42 from other issues and claims remaining in this litigation, and the order, dismissing these claims, will be made final under Fed. R. Civ. P. 54(b).

This the 25th day of April, 1995.

/s/ Sam C. Pointer, Jr.
United States District Judge