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 to all
(MDL 926)	)	cases

OPINION and ORDER
(Denying General Electric's Motion for Summary Judgment)

Under submission after appropriate discovery and briefing is a motion filed by General Electric Company ("GE") seeking summary judgment in all breast-implant cases that are currently, or may hereafter be, pending in this court. GE supplied silicone materials to several breast implant manufacturers during the 1970s. GE asserts that it is not liable to breast implant recipients for alleged injuries because it was merely a bulk supplier and had no duty to warn breast implant recipients or their physicians of potential harm resulting from the human implantation of silicone gel breast implants. For the reasons stated below, General Electric's motion should be denied.

I. STANDARD OF REVIEW

Summary judgment is appropriate if there is no genuine issue of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). 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. Indus. Co. v. Zenith Radio Corp*., 475 U.S. 574 (1986). Summary judgment is proper if, based on the admissible evidence that would be available and the applicable burdens of production and persuasion, a party would be entitled at trial to judgment as a matter of law because of material facts that either are not in substantial controversy or lack sufficient evidentiary support. Facts in genuine dispute are assumed to be favorable to the party against whom summary judgment would be entered.

II. CHOICE OF LAW

In federal multidistrict litigation ("MDL") proceedings under 28 U.S.C. § 1407, the transferee court is obliged to apply the substantive law of the transferor court, as it would be in transfers under 28 U.S.C. § 1404(a). *Ferens v. John Deere Co.*, 494 U.S. 516 (1990)*; Van Dusen v. Barrack,* 376 U.S. 612, 639 (1964); *see also Manual for Complex Litigation, Third* § 31.132 n.803 (1995). The transferor courts in diversity cases are bound to apply the substantive law of the forum state, including its choice of law rules. *Klaxon Co. v. Stentor Elec. Mfg. Co*., 313 U.S. 487, 496 (1941).

This MDL proceeding involves diversity-jurisdiction cases filed in, or removed to, federal courts in 92 of the 94 districts, located in every state, the District of Columbia, Puerto Rico, and the Virgin Islands. General Electric is currently involved in cases transferred from many of these jurisdictions. As the transferee court, bound to apply the laws of numerous transferor courts, this court cannot grant summary judgment applicable in all cases unless there would be no genuine dispute as to a material fact under any relevant state law.

III. FACTS

In evaluating whether summary judgment should be granted in favor of General Electric, the court treats the following facts as established, either because they are not in genuine dispute or because they are supported by evidence viewed in the light most favorable to the plaintiffs.

From 1971 to 1976, GE supplied silicone materials to three breast implant manufacturers: Medical Engineering Corporation ("MEC"), Heyer-Schulte Corporation ("Heyer-Schulte"), and McGhan Medical Corporation ("McGhan"). Prior to 1970, GE had manufactured two types of general purpose silicone compounds, RTV-617 and RTV-619, for use in industrial applications, including electrical components and orthopedic bed pads. In 1970, one of the breast implant manufacturers, MEC, specifically requested that GE make a softer silicone compound for use in external mammary prostheses. GE complied with MEC's request by developing RTV-6191. The following year, 1971, also at MEC's request, GE developed CRTV-6193, the first silicone compound GE manufactured for internal body use. CRTV-6193 was the precursor to GE's CRTV-6195, the silicone compound commonly supplied to breast implant manufacturers during the 1970s to fill the implants.

In 1972, MEC requested that GE develop a silicone compound for use as a breast implant shell.

GE complied with MEC's request and developed RTV-7100, a strong sack-like material to be used to encase the silicone gel in breast implants. RTV-7100 differed from previous shell materials in that it was a phenyl copolymer, which was clearer and allowed imperfections in the implant to be visible. RTV-7100 was also a more stable compound than previously used shell materials and would better contain the gel material because the phenyl copolymer in the shell material would not interact with the methyl in the gel material.

GE sold these two silicone compounds, CRTV-6195, used to fill the interior of mammary implants, and RTV-7100, used to make the silicone outer shells of mammary implants, to implant manufacturers during the 1970s. GE knew that the silicone compounds were being sold to implant manufacturers for resale for implantation use in the human body.

Both compounds were shipped in fifty-five gallon drums and five gallon pails. Both materials were shipped in two parts, "A" and "B," to prevent the curing of the materials. The implant manufacturers then mixed and cured the materials, creating the final product—breast implant devices. The characterizations by plaintiffs and GE of the breast implant manufacturers' processes of combining the silicone gels and shells to form finished breast implants differ markedly. GE asserts that variations existed among each of the three implant manufacturer's processes and that each of the manufacturing processes substantially altered the materials sold by GE. For example, GE claims that McGhan's lengthy manufacturing process involved the addition of a solvent, xylene, to the shell materials, the dipping and baking of the breast-shaped molds, the addition of accessories such as suture tabs to the shells, the mixing of the interior gel in a ratio determined by the manufacturers, and the curing of the interior gel material by baking. The plaintiffs, on the other hand, assert that GE sold the gel and shell materials in two parts, A and B, and instructed the manufacturers to mix the two parts together in a ratio prescribed by GE.

Although the silicone compounds were developed at the request of breast implant manufacturers, the exact same compounds sold to breast implant manufacturers were also sold by GE to other companies, including Aerospace Corporation, Goodyear, International Paper, IBM, and Martin Marietta, for other purposes. The product data sheets which accompanied the materials stated that it was the responsibility of the user of the industrial product to determine the safety, compatibility, and approval necessary for use

in a medical application.

GE employees provided technical assistance to breast implant manufacturers in solving manufacturing and design problems. GE employed "Tech Marketing Specialists" who gave technical assistance to GE salesmen and responded to manufacturing problems in the customers' plants. Richard Striker, one of the GE employees who invented CRTV-7100, went to Heyer-Schulte to investigate and solve a problem Heyer-Schulte experienced of the uneven distribution of CRTV-7100 over the breast implant molds, resulting in ripples on the implant shell. Medical Engineering Corporation submitted a finished breast implant to GE for testing and for assistance in solving specific design problems. Wilfred Lynch, the founder of Medical Engineering Corporation, conferred with Ed Jeram, a principal chemist at GE and one of the inventors of CRTV-7100, on issues such as why silicone shells tended to leak gel, filtering silica from the shell material, and the clarity of the implant shells.

As of 1970, GE was aware of the potential dangers to human health posed by silicone breast implants. GE had commissioned a study in 1958 entitled "Metabolic Study of a C-14 Labeled Silicone Oil in the Rat," which analyzed whether polydimethylsiloxane, the basic building block for the silicone compounds CRTV-6193, 6195, and 7100, was absorbed into the body. The study indicated that small amounts of the silicone were absorbed. In 1965, a GE salesperson reported that a biochemist and customer of GE had reported serious complaints about Dow Corning's 360 fluid, the equivalent of GE's SF-96 fluid—polydimethylsiloxane—such as granulomas, silicone drifts in the body, and dissolution of silicone. Dr. Richard Mansfield, the manager of GE Silicones' Analytical Services Operation, indicated in a 1968 letter that silicone was not an inert substance. Ed Jeram had found that injectable silicones tended to migrate through the body, and he did not believe it was a good idea to inject silicone fluid into the breast. Jeram was also aware that some components of the silicone gel used to fill implants could migrate through the shell. Dr. Richard Mansfield testified that GE had decided it would not be a good idea to market silicones for medical applications because of the testing which would be required and the potential for liability.

IV. ANALYSIS

Plaintiffs argue that GE is strictly liable under the Restatement (Second) of Torts § 402A for selling a product unsafe for its intended use and under § 388 for failing to provide appropriate warnings. GE, on the other hand, claims that it was merely a bulk supplier of a product that was not unreasonably dangerous for its intended uses, and that the learned intermediary doctrine should apply to preclude it from liability.

A. Strict Liability Under §402A of the Restatement of Torts Plaintiffs argue that GE is subject to strict liability under § 402A of the Restatement (Second) of Torts for selling a product unsafe for its intended use. The Restatement (Second) of

Torts states:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
> (a) the seller is engaged in the business of selling such a product, and
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts § 402(A).

GE asserts that the reasoning from this Court's April 25, 1995, decision granting summary judgment to Scotfoam Corporation should control the outcome of GE's motion. *In re Silicone Gel Breast Implants Products Liability Litigation (MDL 926)*, 887 F. Supp. 1463 (N.D. Ala. 1995) [hereinafter *Scotfoam*]. In the *Scotfoam* summary judgment decision, this court applied the bulk supplier and learned intermediary defenses.[1]

The bulk supplier defense is generally applied to preclude strict liability against a manufacturer of a component part that is combined with other parts to make a device or machine, when the component part itself is not inherently defective. *In re TMJ Implants Products Liability Litigation*, 872 F. Supp. 1019, 1025 (D. Minn. 1995). Many courts have expressly adopted the bulk supplier defense, as noted in the *Scotfoam* decision: California, Connecticut, Hawaii, Minnesota, New Jersey, North Carolina, Oklahoma, Pennsylvania, Missouri, Utah, Michigan, and North Dakota. *Scotfoam*, 887 F. Supp. at 1467. The rationale supporting application of the bulk supplier defense is that manufacturers of bulk materials should not be required to hire experts to evaluate the safety of each of their client's products. *Crossfield v. Quality Control Equip. Co*., 1 F.3d 701, 704 (8th Cir. 1993) (applying Missouri law); *Childress v. Gresen Mfg. Co*., 888 F.2d 45 (6th Cir. 1989) (applying Michigan law). The frequently cited example of the bulk supplier defense, provided by the American Law Institute, states that the manufacturer of pigiron would not be likely to be held strictly liable when the pigiron is found unsuitable for use in a child's tricycle. *Restatement (Second) of Torts* § 402A Comment p (1965).

Applying the bulk supplier defense in the *Scotfoam* summary judgment opinion, this Court found

that Scotfoam merely supplied foam as a raw material, did not recommend the foam for any particular use, and had much less knowledge than the breast implant manufacturers about the risks associated with breast implant devices. The present facts are distinguishable from those in Scotfoam in several ways.

Unlike Scotfoam, GE knew the silicone it manufactured and sold would be used in breast implants. GE had formulated the silicone compounds specifically for use in breast implant devices. GE sold directly to breast implant manufacturers, unlike Scotfoam. Scotfoam's product was not in substantially the same condition when used by the consumer as when sold by the supplier. Scotfoam sold its product in large buns or rolls to Wilshire Foam Company, which then cut the foam into thin strips, washed them, and sold these processed "clean wipes" to companies in the computer, electronics, aerospace, and medical industries. It is a disputed fact, on the other hand, whether the compounds GE sold were in substantially the same condition when sold to the ultimate consumer as when purchased by the intermediary implant manufacturers. The silicone compounds were shipped in two parts, A and B, and were then mixed and cured by the manufacturers. The characterizations by plaintiffs and GE of the breast implant manufacturers' processes of making finished breast implant devices from the two parts differ markedly.

The facts of the present case, distinguished from those in *Scotfoam*, do not warrant granting summary judgment to GE on the basis of the bulk supplier defense. One court, explaining the rationale of the bulk supplier defense, emphasized that the defense should apply to preclude liability on the part of a manufacturer of a component part when the manufacturer had no role in developing the finished product. *Crossfield v. Quality Control Equip Co*., 1 F.3d 701, 704 (8th Cir. 1993) (applying Missouri law). That is not the case with GE, which had an important role in developing silicone compounds specifically for use in breast implant devices. At least one court declined to apply the bulk supplier defense where the manufacturer had not warned the distributor next in line about the risks of the product. *Donahue v. Phillips Petroleum Co.*, 866 F.2d 1008 (8th Cir. 1988). In *Donahue*, the Eighth Circuit, applying Missouri law, declined to extend the bulk supplier defense to a manufacturer of an odorizing agent made for use with propane gas, because of the lack of evidence that the manufacturer of the odorizing agent had provided adequate instructions to the distributor next in line or to ascertain that the distributor was

informed and in a position to convey the information to the ultimate consumer. The evidence does not show that GE warned the breast implant manufacturers about potential dangers posed by silicone breast implants, even though GE had such information during the 1970s. Thus, this court cannot state that the bulk supplier defense would be applied in every state to the facts of this case. Under the substantive law of at least some states—though not necessarily all states—a reasonable trier of fact could determine that GE is strictly liable for selling a product in a defective condition unreasonably dangerous to the user or consumer that reached the consumer without substantial change in the condition in which it was sold. *Restatement (Second) of Torts* § 402A.

B. Duty to Warn Under § 388 of the Restatement (Second) of Torts

§ 388 of the Restatement (Second) of Torts 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.

Some jurisdictions have adopted exceptions to the rule for liability set forth in § 388, known as the "sophisticated user" exception to § 388(b) and the "learned intermediary" exception to § 388(c). The sophisticated user exception applies when a party is or should be independently aware of a danger, so that a failure to warn the party could not be the proximate cause of injury resulting from that danger. *Lindsay v. Ortho Pharmaceutical Corp.*, 637 F.2d 87, 92 (2d Cir. 1980). When the sophisticated user exception applies, the supplier is excused from giving any warning at all. *Koonce v. Quaker Safety Products & Manufacturing Co.*, 798 F.2d 700, 716 (5th Cir. 1986). A supplier has no duty to warn of danger in using the product when the ultimate user possesses special knowledge, sophistication, or expertise. *Id.* The sophisticated user exception usually applies when the user of the product is a member of a particular trade or profession with regard to a danger that is generally known to that trade or profession. *Strong v. E.I. DuPont de Nemours Co.*, 667 F.2d 682, 687 (8th Cir. 1981). In the present MDL cases, the plaintiffs

were consumers, not professionals with particular expertise or specialized knowledge of the characteristics of the products they purchased, so the sophisticated user defense does not apply.

The other exception to the duty to warn—the learned intermediary doctrine—exempts a manufacturer from being required to give warnings to the ultimate consumer if the manufacturer adequately informs an intermediary.[2] The doctrine has been applied in areas outside of the prescription drug context, such as the industrial workplace context, when the purchaser of materials is an employer who is in a better position to warn the user/employee of the dangers posed by the product. *See, e.g.*, *Adams v. Union Carbide Corp*., 737 F.2d 1453 (6th Cir. 1984), *cert. denied*, 469 U.S. 1062, 105 S.Ct. 545, 83 L.Ed.2d 432 (1984) (manufacturer of chemical toluene diisocyanate discharged duty to warn user of product by relying on plaintiff's employer to convey information). The learned intermediary doctrine has been applied in the product liability context. *See, e.g., Jacobs v. E.I. DuPont de Nemours & Co.*, 67 F.3d 1219 (6th Cir. 1995); *In re TMJ Products Liability Litigation*, 872 F. Supp. 1019, 1029, 1033 (D. Minn. 1995); *Harwell v. American Medical Systems, Inc.*, 803 F. Supp. 1287, 1299 (M.D. Tenn. 1992). GE claims that the breast implant manufacturers—Heyer-Schulte, MEC, and McGhan—were learned intermediaries, knowledgeable of the dangers posed by breast implant devices, so that GE had no duty to warn the ultimate consumer and could instead rely on the implant manufacturers to communicate the warning to the consumer.

The determination of whether the learned intermediary defense should apply depends on the facts of a particular case and a balancing of considerations. Comment n to § 388 lists six factors to be balanced in determining whether a manufacturer has satisfied the standard of reasonable care stated in § 388(c):

(1) the dangerous condition of the product;
(2) the purpose for which the product is used;
(3) the form of any warnings given;
(4) the reliability of the third party as a conduit of necessary information about the product;
(5) the magnitude of the risk involved; and
(6) the burdens imposed upon the supplier by requiring that he directly warn all users.

Comment (n) provides in part:

> [I]t is obviously impossible to state in advance any set of rules which will automatically determine in all cases whether one supplying a chattel for the use of others through a third person has satisfied his duty to those who are to use the chattel by informing the third person of the dangerous character of the chattel, or of the precautions which must be exercised in using it in order to make its use safe.

The trier of fact determines whether the supplier's duty has been reasonably discharged pursuant to these factors. *Jones v. Meat Packers Equipment Co.*, 723 F.2d 370, 374 (4th Cir. 1983)*; Bryant v. Technical Research Co.*, 654 F.2d 1337, 1345 (9th Cir. 1981). Based upon a balancing of the six factors under Comment n to § 388, a reasonable trier of fact could find that the defendant failed to meet the standard of

"reasonable care" set forth in § 388 in neglecting to take some steps to warn the ultimate user about the potential dangers involved from the use of its products.

As to the first factor, the dangerous condition of the product, GE was aware of potential dangers posed by breast implant devices. While the danger to health posed by breast implants is contested by defendants in breast implant cases, and several recent scientific studies do not establish a link between implants and diseases such as lupus and scleroderma, the evidence presented on the present motion for summary judgment indicates GE had concerns about the dangerous condition of breast implants as early as 1958, concerns that were still present when it developed the silicone compounds in the early 1970s. As to the second factor, the purpose for which the product was used, it is clear that the purpose for which the silicone compounds were developed by GE—implantation in the human body—could pose grave risks of harm were the devices not safe for such purpose.

As to the third factor, the form of the warnings given, the evidence shows that GE did not make any warnings to the breast implant manufacturers, plastic surgeons, or directly to consumers regarding the potential hazards of the silicone compounds, even though GE employees were concerned about the dangers posed. Fourth, as to the reliability of the third party as a conduit of necessary information about the product, GE could have easily ascertained whether the manufacturers were warning consumers of potential risks. GE had a close relationship with the implant manufacturers since it developed the silicone compounds specifically for the manufacturers and later engaged in evaluating and testing the finished implants. The evidence presented does not unequivocally establish that the manufacturers were sufficiently warning physicians or consumers about the potential risks of implants, that GE believed such warnings were being made, or that GE relied on the manufacturers to make such warnings.

Fifth, the magnitude of the risk involved was very great, since the devices posed potentially grave harm to human health. As to the final factor, the burdens imposed on the supplier by requiring that it directly warn all users, a reasonable trier of fact could determine it would not be unduly burdensome to require GE to either ensure that the implant manufacturers were warning consumers or itself attempt to provide some warnings to physicians, if not potential implant recipients. In *Scotfoam*, this Court held that, since less than .00001 % of Scotfoam's total foam production found its way into breast implants and Scotfoam had never recommended its foam for usage in breast implants, requiring Scotfoam to warn of dangers in the use of foam-covered implants would be too onerous a burden. Unlike Scotfoam, however, GE specifically manufactured silicone compounds for use in breast implant devices, and a fact-finder might conclude it would have been feasible for GE to provide warnings to plastic surgeons, or ensure that the implant manufacturers themselves were directly warning such surgeons.

Even if the learned intermediary doctrine were to be applied in the present case, that exception alone may not provide a complete defense for the defendants. The line of cases in the prescription drug context merely shifted the duty to warn, by requiring the manufacturer to provide an adequate warning to the intermediary. *Basko v. Sterling Drug, Inc.*, 416 F.2d 417, 426 (2d Cir. 1969); *Davis v. Wyeth Laboratories*, 399 F.2d 121, 130 (9th Cir. 1968). The evidence raises genuine issues of material fact as to whether GE provided adequate warnings to the breast implant manufacturers about the risks of harm from silicone gel breast implants. The evidence shows that as early as 1958 and continuing into the 1970s, GE was aware of potential risks to human health posed by silicone breast implants. The material safety data sheets which accompanied the silicone compounds sold by GE merely disclaimed their use in health applications. No evidence has been introduced that GE warned the implant manufacturers about the research and testing GE had done indicating risks posed by the implant devices.

GE relies on *Jacobs v. E.I. DuPont de Nemours & Co*., 67 F.3d 1219 (6th Cir. 1995), where the learned intermediary defense was applied to preclude DuPont's liability for injuries allegedly suffered from a temporomandibular interpositional implant. The court in *Jacobs* held that since DuPont had given adequate warnings to the manufacturer/distributor of the implants, Vitek, and had relied on Vitek to warn the consumer, DuPont had discharged its duty under § 388. This case is unlike *Jacobs*, however, because in *Jacobs* evidence had been introduced showing that DuPont had given several warnings to Vitek, the manufacturer and distributor of the prosthesis. The facts of the present case are more like those of *Adkins v. GAF Corp*., 923 F.2d 1225 (6th Cir. 1991). *Adkins* involved an asbestos manufacturer, ACL, which sold asbestos to Celotex and was sued for injuries suffered by a Celotex employee. The Sixth Circuit, applying Ohio law, declined to apply the learned intermediary defense on behalf of ACL in part because the evidence showed that ACL did not pass on warnings to Celotex, was familiar with Celotex's plant and, therefore, knew exactly how its employees were being exposed, and had knowledge of the dangers that its products posed because it had conducted its own research on the products. *Id.*; *see also Jacobs*, 67 F.3d at 1240 n.36. Similarly, the evidence does not show that GE passed on warnings to the breast implant manufacturers, even though GE chemists consulted frequently with employees of those companies and were familiar with their manufacturing processes and GE had conducted its own

independent research and testing on the effects of silicone implantation.

For the foregoing reasons, it cannot be said as a matter of law under all state laws that GE discharged its duty to warn under § 388. At least in some states, it would be for a jury to determine in light of the factors listed in comment n, whether GE acted reasonably in relying on MEC, Heyer-Schulte, and McGhan to warn the ultimate breast implant consumers about the risks posed by breast implants.

OTHER CLAIMS

The plaintiffs also assert that a reasonable trier of fact could find GE liable under the Restatement (Second) of Torts § 302(b), § 389, and § 324A, and for fraudulent misrepresentation and breach of warranty. Since summary judgment is due to be denied with respect to the plaintiffs' claims under the Restatement (Second) of Torts § 402A and § 388, it is unnecessary to reach these other theories.

CONCLUSION

This decision denying summary judgment is interlocutory, is based on state laws most favorable to the plaintiffs, and does not constitute a holding that GE is liable to the plaintiffs in all or any case. It will not bar a motion for summary judgment or for judgment as a matter of law filed in a case applying the law of a particular state.

ORDER

For the reasons indicated, GE's motion for summary judgment is DENIED.

This the 20th day of March, 1996.

/s/ Sam C. Pointer, Jr.
Chief Judge Sam C. Pointer, Jr.

1As stated in *Scotfoam,* "it may be a misnomer to describe these as defenses, since they are aspects of concepts of defect and causation." *Scotfoam*, 887 F. Supp. 1463, 1466.

2 The learned intermediary theory was first developed in the area of prescription drugs. In that line of cases courts held that a manufacturer of a prescription drug is not obligated to warn the ultimate consumer of dangers involved in using the drug, if the prescribing physician receives adequate warnings. The manufacturer's duty is satisfied because the physician is expected to act as a "learned intermediary" communicating between the manufacturer and the consumer. *See, e.g., Hall v. Ashland Oil Co.,* 625 F. Supp. 1515, 1518-19 (D. Conn. 1986).