

**DENISE I. PARKER (F/K/A DENISE I. GILLETTE) AND MICHAEL D.
PARKER, Plaintiffs-Appellants,
vs.
ST. VINCENT HOSPITAL, A NEW MEXICO NON-PROFIT CORPORATION,
AND JOHN DOE, AN UNIDENTIFIED PERSON/ENTITY,
Defendants-Appellees.**

Docket No. 15,988

COURT OF APPEALS OF NEW MEXICO

1996-NMCA-070, 122 N.M. 39, 919 P.2d 1104

May 30, 1996, Filed

APPEAL FROM THE DISTRICT COURT OF DONA ANA COUNTY. GRADEN W.
BEAL, District Judge.

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COUNSEL

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JUDGES

HARRIS L HARTZ, Judge. RUDY S. APODACA, Chief Judge, BENNY E. FLORES,
Judge, concur.

AUTHOR: HARRIS L HARTZ

OPINION

{*40} **OPINION**

HARTZ, Judge.

{1} Plaintiffs Denise I. Parker (Denise) and her husband, Michael D. Parker, appeal from an order granting summary judgment in favor of St. Vincent Hospital (the Hospital).

{*41} Their suit arose out of two operations performed on Denise at the Hospital by Dr. Terry Carlberg. In 1983 Dr. Carlberg implanted bilateral interpositional implants (IPIs) in Denise's temporomandibular joint. In 1986 he implanted bilateral artificial temporomandibular joint replacement devices (TJR). The IPIs and TJRs were manufactured by Vitek, Inc., which had declared bankruptcy by the time Plaintiffs filed suit. The implants contained teflon manufactured by E.I. DuPont de Nemours & Company, Inc. (DuPont). Plaintiffs contend that teflon used in the implants abraded and caused granulomatous reactions, giant cell reactions, and bone erosion.

{2} Plaintiffs sued the Hospital and DuPont. The first amended complaint (the Complaint) contends that both implants were defectively designed because of the use of teflon. It alleges that the Hospital supplied the IPIs and TJRs to Dr. Carlberg for use in Denise and breached "a duty to investigate the safety of the Vitek implants before supplying said implants and allowing their use in the Hospital." The district court granted summary judgment to both defendants. We have previously affirmed the judgment in favor of DuPont. **Parker v. E.I. DuPont de Nemours & Co.**, 121 N.M. 120, 909 P.2d 1 .

{3} We now affirm the summary judgment in favor of the Hospital to the extent that it holds that the Hospital is not strictly liable to the Plaintiffs for any design defect in the implants. We reverse and remand, however, on the issue of whether the Hospital may be liable for negligence. Although the Hospital may have had a duty to investigate the safety of the implants and may have failed to exercise due care in performing that duty, we cannot determine on the record before us whether the Hospital had such a duty or whether it exercised due care. Because of our disposition of these issues, we need not address the other issues raised by Plaintiffs' appeal.

STRICT PRODUCTS LIABILITY

{4} Our Supreme Court has recently reaffirmed the doctrine of strict products liability for defectively designed products. **Brooks v. Beech Aircraft Corp.**, 120 N.M. 372, 902 P.2d 54 (1995). Although the tortfeasor in **Brooks** was a manufacturer, liability also extends to others in the chain of distribution. Ordinarily, any entity engaged in the business of selling or otherwise distributing products is strictly liable for distributing a defective product. **See Stang v. Hertz Corp.**, 83 N.M. 730, 497 P.2d 732 (1972); Restatement (Third) of Torts: Products Liability § 1 (Tentative Draft No. 2, 1995) [hereinafter Tentative Draft No. 2].

{5} The Complaint alleges that the Hospital supplied both implants to Denise. But in response to the Hospital's motion for summary judgment, Plaintiffs produced no evidence that the Hospital was in the chain of distribution for the IPIs implanted in 1983. Thus, summary judgment on the claim of strict liability was appropriate with respect to the IPIs. As for the TJRs implanted in 1986, Plaintiffs produced evidence that the Hospital ordered the implants at Dr. Carlberg's request and billed for them at a markup.

{6} The claims regarding the TJRs present the most interesting and challenging issue raised by this appeal: whether a hospital should be strictly liable for supplying a

defectively designed implant selected by the treating physician. We must address whether the Hospital should be treated as a distributor of the implant and, if so, whether there are sound policy reasons not to treat a hospital the same as other distributors for purposes of strict products liability.

{7} According to the weight of authority, a hospital is not a distributor of medical supplies, even though it may bill separately for the item and charge the patient a markup over the hospital's cost. **See Hoff v. Zimmer, Inc.**, 746 F. Supp. 872 (W.D. Wis. 1990) (hip prosthesis); **Hector v. Cedars-Sinai Med. Ctr.**, 180 Cal. App. 3d 493, 225 Cal. Rptr. 595 (1986) (pacemaker); **Fisher v. Sibley Memorial Hosp.**, 403 A.2d 1130 (D.C. 1979) (blood for transfusion); **Roberts v. Suburban Hosp. Ass'n**, 73 Md. App. 1, 532 A.2d 1081 (Md. Ct. Spec. App. 1987) (same); **Baptista v. Saint Barnabas Med. Ctr.**, 109 N.J. Super. 217, 262 A.2d 902 (N.J. Super. Ct. App. Div.) (same), **aff'd**, 57 N.J. 167, 270 A.2d 409 (1970); **Goldfarb v. Teitelbaum**, 149 A.D.2d 566, {*42} 540 N.Y.S.2d 263 (App. Div. 1989) (mandibular prosthesis); **Ayyash v. Henry Ford Health Sys.**, 210 Mich. App. 142, 533 N.W.2d 353 (Mich. Ct. App. 1995) (Vitek implant); **Cafazzo v. Central Med. Health Servs.**, 668 A.2d 521 (Pa. 1995) (same); Tentative Draft No. 2, **supra**, § 5 cmt. c, at 165; **id.**, Reporters' Note c, at 168-69; **contra Cunningham v. MacNeal Memorial Hosp.**, 47 Ill. 2d 443, 266 N.E.2d 897 (Ill. 1970) (blood); **Bell v. Poplar Bluff Physicians Group**, 879 S.W.2d 618 (Mo. Ct. App. 1994). The courts have generally held that the essence of the hospital's role is the provision of services, regardless of whether a product is involved. **See** Tentative Draft No. 2, **supra**, § 5 cmt. c, at 165; **id.**, Reporters' Note c, at 168-69.

{8} We are not convinced by this analysis. **See** William L. Prosser, **The Fall of the Citadel (Strict Liability to the Consumer)**, 50 Minn. L. Rev. 791, 811 & n.107 (1966) (cases rejecting strict liability for hepatitis resulting from blood transfusions have relied "on the rather shaky ground that the transaction is a service, and not a sale of the blood.") (Emphasis added.) To be sure, the chief function of hospitals is to provide a service. But when a product is provided as part of the service, and the service provider bills separately for the product, the rule that has emerged outside of the hospital context is that the provision of the product is a distribution for purposes of strict products liability. **See Newmark v. Gimbel's Inc.**, 54 N.J. 585, 258 A.2d 697 (N.J. 1969) (permanent wave solution used at beauty parlor); Tentative Draft No. 2, **supra**, § 1 cmt. c; **id.**, § 5(c) (one distributes a product when one provides a combination of products and services and the product component is a sale); **id.**, § 5 cmt. c. To depart from this characterization of such a transaction for the special case of hospitals would, in our view, generate unnecessary confusion. If there are sound policy reasons for not imposing strict products liability on hospitals, those policy reasons should be addressed directly, not obscured by artificial semantic distinctions. We now turn to that task.

{9} Although we reject the view that hospitals are never engaged in the business of distributing medical products, we do not ignore the judicial authority in favor of relieving hospitals from exposure to strict products liability for such items. The results of those cases, if not the reasoning, appear to reflect a widely accepted view of public policy. Not only are we aware of no legislative action to overrule those decisions and impose strict

products liability on hospitals, but also the few decisions that imposed such liability on hospitals with respect to blood products resulted in almost universal adoption of state laws removing such liability. **See** Tentative Draft No. 2, **supra**, § 4 cmt. c; **id.**, Reporters' Note to cmt. c; **cf. Hines v. St. Joseph's Hosp.**, 86 N.M. 763, 764-65, 527 P.2d 1075, 1076-77 (Ct. App.) (rejecting strict liability for blood), **cert. denied**, 87 N.M. 111, 529 P.2d 1232 (1974).

{10} On this appeal we need not resolve completely the law regarding hospital exposure to strict products liability. We restrict ourselves to the question whether it is appropriate to impose strict products liability on hospitals with respect to a defectively designed medical product selected by the treating physician.

{11} In **Brooks**, 120 N.M. at 377, 902 P.2d at 59, our Supreme Court recognized "four primary policies supporting the imposition of strict products liability." They were:

[1] placing the cost of injuries caused by **defective** products on the manufacturer who is in a better position to pass the true product cost on to all distributors, retailers, and consumers of the product; [2] relieving the injured plaintiff of the onerous burden of establishing the manufacturer's negligence; [3] providing full chain of supply protection; and, [4] in the interest of fairness, providing relief against the manufacturer who--while perhaps innocent of negligence--cast the defective product into the stream of commerce and profited thereby.

{12} **Id.** The Court also noted, without relying on, a possible fifth policy objective-- "causing manufacturers to take more care in designing and manufacturing a product and in the warnings they give to consumers about using that product." **Id.** at 376 n.1, 902 P.2d at 58 n.1. We will address each of these policies in turn.

{*43} {13} The first policy is to spread the cost of injury. This policy is more precise and more sophisticated than simply identifying a "deep pocket" to reimburse anyone who is injured. It reflects the view that injuries caused by product defects are a true cost of the product. The price of the product should reflect that cost, just as it reflects the cost of manufacturing and marketing the product. The cost of injury caused by a defect in the product is then borne by all purchasers of the product. **See id.** at 377, 902 P.2d at 59; Guido Calabresi, **The Cost of Accidents** 68-75 (1970).

{14} This policy is substantially attenuated as a rationale for imposing strict products liability on non-manufacturer distributors, certainly in the present context. Imposition of strict liability upon the manufacturer presumably suffices to cause the market price of the product to reflect the risk of injury from defects in the product. **See Brooks**, 120 N.M. at 377, 902 P.2d at 59. Because the manufacturer must indemnify the distributor for the distributor's expenses in defending a design-defect claim, **see In re Consol. Vista Hills Retaining Wall Litig.**, 119 N.M. 542, 546, 893 P.2d 438, 442 (1995), the cost to the non-manufacturer distributor for insurance protection against liability for design defects--the cost that the distributor will try to pass on in its retail markup--reflects only the risk that the manufacturer will not be available to pay for both the

consumer's injury and the distributor's legal fees. Moreover, the distributor will not be buying separate insurance policies for each product distributed, nor is it likely to adjust its markup on individual products to reflect the risk that the particular manufacturer will be unable to pay a products-liability claim. Hence, one could expect that the cost of liability arising from defects in a particular product would be shared by those purchasing any product sold by the distributor. For example, the Hospital's liability expenses arising from defective design of an implant would probably be borne by patients using any medical product for which the Hospital is a distributor. The price of pacemakers may go up because of defective jaw implants. To the extent that the cost of injury caused by a defective product is borne by persons who have no occasion to use the product, the first policy is not advanced.

{15} The second policy identified by **Brooks** is to "relieve the injured plaintiff of the onerous burden of establishing the manufacturer's negligence." **Brooks**, 120 N.M. at 377, 902 P.2d at 59. That is, in the absence of strict products liability a person injured by the manufacturer's negligence may well be unable to recover because of the difficulties of proof. This rationale is particularly apropos with respect to manufacturing defects. "[A] product contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product." Tentative Draft No. 2, **supra** § 2(a). When, for example, a product comes off the assembly line with a manufacturing defect, it may be very difficult for a plaintiff to establish what went wrong on the assembly line, much less prove that the error was the result of negligence. In this regard, strict products liability can be viewed as simply an extension of the doctrine of *res ipsa loquitur*. **See Escola v. Coca Cola Bottling Co.**, 24 Cal. 2d 453, 150 P.2d 436, 440-41 (1944) (Traynor, J., concurring). The existence of a manufacturing defect in itself may imply that the manufacturer was negligent. The difference between strict products liability and *res ipsa* doctrine, of course, is that the manufacturer cannot escape strict products liability by convincing the jury of its due care in the manufacturing process.

{16} This rationale can also support liability of **distributors** for manufacturing defects because of the difficulty that may arise in determining whether the defect arose at the time of manufacture or during handling in the distribution chain. It has little force, however, when applied to non-manufacturer liability for design defects. The fact that it is easier to prove that a product is defectively designed than to prove that there was negligence in designing the product, **see Brooks**, 120 N.M. at 378, 902 P.2d at 60, has a perverse effect in that context because ordinarily there is no possibility that a distributor other than the manufacturer created a design defect. That would surely be the case when the hospital does not alter the product {44} and the product is used for its intended purpose. In that event there could be no negligent design by the hospital. Thus, it would not be appropriate to say that "imposing strict liability [would] relieve[] plaintiffs of the burden of proving ordinary negligence under circumstances in which such negligence is likely to be present but difficult to prove." **Id.** at 375, 902 P.2d at 57. Rather, strict liability would impose liability when there is no possibility of negligence.

{17} The third policy is "providing full chain of supply protection." **Brooks** explains that policy as follows: "Suppliers who otherwise might not be liable because of a passive role in the chain of supply should be encouraged to select reputable and responsible manufacturers who generally design and construct safe products and who generally accept financial responsibility for injuries caused by their defective products." **Id.** at 376, 902 P.2d at 58.

{18} Although the rationale makes sense for other products, it encounters a powerful contrary public policy with regard to medical products. Improving medical care is a national priority. Improvement encompasses both advances in treatment and greater access to care, which is impeded by high costs. In this light, should hospitals be encouraged to deal only with the preeminent suppliers of medical products who have a track record of "well-designed" products and have the financial resources to pay for any injuries caused by defective products? Such encouragement could, for example, impact heavily on the use of generic drugs. The California Supreme Court expressed its concern as follows:

If pharmacies were held strictly liable for the drugs they dispense, . . . in order to assure that a pharmacy receives the maximum protection in the event of suit for defects in a drug, the pharmacist may select the more expensive product made by an established manufacturer when he has a choice of several brands of the same drug. As the [board of pharmacy's] amicus brief warns, "Why choose a new company's inexpensive product, which has received excellent reviews in the literature for its quality, over the more expensive product of an established multinational corporation which will certainly have assets available for purpose of indemnification 10, 20, or 30 years down the line?"

{19} **Murphy v. E.R. Squibb & Sons**, 40 Cal. 3d 672, 710 P.2d 247, 253, 221 Cal. Rptr. 447 (Cal. 1985); **cf. Hoff**, 746 F. Supp. at 874-75 (imposition of strict liability would increase cost of medical services and hinder development); **Cafazzo**, 668 A.2d at 527 (research and innovation would be inhibited).

{20} The third policy reason would suggest that when specialty manufacturers develop new, improved, or cheaper medical products, hospitals should refrain from using those products. Yet apparently most medical devices are manufactured by smaller companies.¹ Our perception is that public policy strongly favors medical innovation and the use of less expensive alternative products. Protection to the public comes from the expertise of physicians who select the products and, at least to some extent, from regulation by the Food and Drug Administration (FDA), **see** 1 James T. O'Reilly, **Food and Drug Administration** ch. 18 (2d ed. 1995). Although there is undoubtedly merit to the policy of favoring products from manufacturers with good track records regarding quality and the financial resources to stand behind their products, that policy is countered by the desire for new or less expensive products to improve health and relieve suffering. In short, the third policy has significantly less force with respect to hospitals distributing medical products than with respect to distributors of products that provide mere convenience or entertainment.

{*45} {21} The fourth policy reason for imposing strict products liability--fairness--is more difficult to analyze. A sense of fairness is subjective, although advances in the common law often arise from careful analysis of one's sense of fairness in order to identify the essential elements. **Brooks** stated:

{22} At the heart of this judgment [that liability should be imposed] lies the conclusion that although the manufacturer has provided a valuable service by supplying the public with a product that it wants or needs, it is more fair that the cost of an **unreasonable** risk of harm lie with the product and its possibly innocent manufacturer than it is to visit the entire loss upon the often unsuspecting consumer who has relied upon the expertise of the manufacturer when selecting the injury-producing product.

{23} **Brooks**, 120 N.M. at 376, 902 P.2d at 58. This rationale appears to be based in large part on a composite of the other rationales. In any event, to the extent that we can determine a general societal view regarding whether it is fair to impose strict products liability on hospitals for defectively designed medical products, that view appears to support no liability. The courts and legislatures that have addressed the issue have overwhelmingly relieved hospitals of liability. As for the specifics of this case, the device was selected by the physician, not the Hospital. Thus, one could hardly say that Denise "relied upon the expertise of the [Hospital] when selecting the injury-producing product." **Id.**

{24} Finally, we address what **Brooks** identified as a fifth possible policy objective underlying the imposition of strict products liability, even though **Brooks** did not rely on it. **Id.** at 376 n.1, 902 P.2d at 58 n.1. **Brooks** noted that some courts have suggested that "imposing strict products liability may cause manufacturers to take more care in designing and manufacturing a product and in the warnings they give to consumers about using that product." **Id.** Perhaps our Supreme Court's reluctance to rely on this policy objective is skepticism about whether imposition of strict products liability actually causes manufacturers to exercise more care in such matters as product design. We can provide no empirical evidence one way or the other. We note, however, that to the extent that imposition on hospitals of strict products liability for defective design would cause hospitals to devote more resources to reviewing the designs of products it distributes, that additional effort might be contrary to public policy. If, for example, hospitals were to acquire the expert staff and devote the other resources necessary to evaluate the designs of the medical products used in the hospital, hospitals would incur substantial additional costs that would be passed on to its patients. Yet such measures might well provide little benefit in medical care, and could even cause harm. To make each hospital a mini-FDA could duplicate effort while producing a less reliable result because of the much smaller data base. For example, if a hospital must rely on a small sample of uses of a particular product, random fluctuations may cause the hospital to conclude that a product is unsafe (and should not be used at the hospital) when more extensive, better data establish otherwise.

{25} In light of the reasonable likelihood that strict products liability could cause hospitals to take measures that are not cost-effective and may even be counterproductive, the fifth policy reason is not a persuasive argument for imposing such liability. Rather, to the extent that the law should encourage hospitals to exercise care in permitting the use of medical products at their facilities, that determination should be made under traditional principles of negligence law. With an adequate record regarding the benefits and costs of various steps that could be taken by hospitals, courts can determine what duties of care should be imposed on hospitals. A jury can then determine whether due care was exercised in a particular case. We will address liability for negligence again in the next part of this opinion.

{26} Having analyzed the policies favoring strict products liability in the context of potential hospital liability for defectively designed medical products selected by treating physicians, we conclude that such liability is inappropriate. Although we have not followed other jurisdictions which have held that hospitals are not distributors of medical {46} products, we find support for our conclusion in the results reached by the majority of courts that have considered strict-products- liability claims against hospitals. In addition, we find support in Tentative Draft No. 2, **supra**, § 8(e), which states that retail sellers and other distributors of prescription drugs and medical devices are subject to liability only for manufacturing defects or their own negligence.

NEGLIGENCE CLAIMS

{27} In addition to their claim that the Hospital is strictly liable as a distributor of a defectively designed product, Plaintiffs also contend that the Hospital is liable on a negligence theory. The gist of the theory is that the Hospital violated a duty to investigate the safety of the implants before permitting their use on its premises. The Hospital responds that (1) the only claim stated in the Complaint was for products liability and (2) the district court properly refused to permit Plaintiffs to amend their Complaint to expand their theories of liability in response to the Hospital's motion for summary judgment.

{28} The strongest point in favor of the Hospital's first contention is that Plaintiffs attempted to amend their complaint after the Hospital filed its motion for summary judgment. The proposed amended complaint contained a new count entitled "Negligence of St. Vincent Hospital." The Hospital points out that both counts seeking relief against it in the Complaint--counts entitled "Strict Products Liability" and "Negligence in Products Liability"--were still included in the proposed amended complaint. From Plaintiffs' desire to amend the Complaint to add the negligence count, one could infer that the Complaint had not included a claim predicated on the theory raised by the proposed negligence count. Thus, goes the argument, because the proposed count explicitly raises the claim that the Hospital negligently failed to investigate the safety of the implants, that claim must not have been in the Complaint.

{29} Nevertheless, the issue cannot be resolved by focusing just on Plaintiffs' conduct in response to the motion for summary judgment. What is determinative is whether the

Complaint fairly put the Hospital on notice of the negligent-investigation theory argued on appeal. If there was adequate notice, Plaintiffs' later effort to clarify, and expand upon, the claim in their proposed amended complaint cannot retroactively delete the claim from the Complaint.

{30} In finding that there was adequate notice, we first observe that the captions of the counts in the Complaint do not rule out Plaintiffs' negligence theory. There is an overlap between claims for products liability and claims for ordinary negligence. Entitling a count as "Negligence in Products Liability" does not foreclose the possibility that the allegations stated in the count would also state a cause of action in common-law negligence. We note for example some language of Tentative Draft No. 2. Although the subject matter of the Tentative Draft is "Torts: Products Liability," Section 8(e) states that a retail distributor of a prescription drug or medical device may be subject to liability if "during the period leading up to the sale or other distribution of the drug or medical device the . . . distributor fails to exercise reasonable care and such failure causes harm to persons." Such liability is indistinguishable from ordinary liability for negligence. Perhaps it would be theoretically "cleaner" to avoid any discussion of reasonable care or negligence when addressing products liability. But potential confusion is avoided when a discussion of the general topic of products liability recognizes that a distributor of a product may be liable for negligence as well as for strict products liability. In other words, the title "Negligence in Products Liability" comfortably bears the interpretation "negligence with respect to a product." This title can encompass the negligent-investigation theory Plaintiffs raise on appeal.

{31} Thus, the question becomes whether the theory raised on appeal is summarized adequately in the specific allegations of the Complaint. In our view, it is. The Complaint contains the following two paragraphs:

47. St. Vincent Hospital had a duty to investigate the safety of the Vitek implants before supplying said implants and allowing their use in the hospital.

{*47} 48. Defendants Dupont, Vitek and St. Vincent Hospital breached the duties set forth herein.

{32} To the extent that the Hospital contends that it was surprised by the theory of negligence being raised on appeal, we disagree. At a hearing on a motion to intervene conducted the same month as the hearing on Plaintiffs' motion to permit the filing of the Complaint (which amended an earlier complaint), Plaintiffs' attorney stated that one of the issues in the case was "whether the hospital adequately reviewed the use of that device in their hospital before Dr. Carlberg was allowed to implant it." Later in the hearing, the following exchange occurred:

{33} THE COURT: Where does the duty arise on the part of St. Vincent in that case?

MS. MERCHANT: It has to do with federal regulations as well as a general duty to protect the people within the hospital and keep those people safe. . . . I believe that St. Vincent's did nothing to - - in the hospital, prior to allowing an oral surgeon who is a dentist use their operating facility and to implant experimental devices and therein rises their duty as the trier and as the individual to screen[] those devices [to] make sure [that] they do have adequate FDA approval and that they are safe. And if they are new and innovative, that they have experimental device committees to review that use and to continue to review that when they continue to have failures with those devices.

{34} Likewise, at a subsequent hearing six months before the Hospital filed its motion for summary judgment, Plaintiffs' attorney again spoke of the duty of the Hospital to follow federal regulations and conduct review of the implants.

{35} Given the language in the Complaint and the statements by Plaintiffs' attorney at hearings well before the Hospital filed its motion for summary judgment, we believe that the legal theory raised on appeal was adequately pleaded and that the Hospital was not misled. Plaintiffs' attempt to file a second amended complaint explicitly containing a claim of common-law negligence was unnecessary to preserve the negligent-investigation theory raised on appeal.

{36} Having decided that Plaintiffs' legal theory was adequately raised, we must next address its merits. First, we must consider whether the Hospital in fact owed Plaintiffs a duty to investigate the safety of the implants and, if so, the scope of such a duty. The duty of a hospital to its patients is not unlimited. **See Cooper v. Curry**, 92 N.M. 417, 419-20, 589 P.2d 201, 203-04 (Ct. App.), **cert. quashed**, 92 N.M. 353, 588 P.2d 554 (1978). Should a hospital conduct its own research study regarding the efficacy and safety of implants; should it review the medical literature for pertinent findings by researchers elsewhere; should it monitor the experience of patients who receive implants at the hospital? The existence and scope of such a duty is a matter of policy to be determined by the court when the legislature has not spoken. **See Torres v. State**, 119 N.M. 609, 612, 894 P.2d 386, 389 (1995).

{37} On the record before us, however, we cannot confidently make that determination. We are unable to determine whether imposition on a hospital of any particular duty to investigate the safety of implants or other medical devices promotes or retards public policy. If a duty to investigate would require considerable effort and expense by hospitals, resulting in higher costs for medical care, but would add little to patient safety, it would be unwise to impose the duty. Safety would not be enhanced, for example, if the hospital were merely duplicating efforts by the FDA, particularly given that the hospital would have a far smaller data base to work from, which could lead it to draw inaccurate inferences. On the other hand, if, as alleged by an expert witness provided by Plaintiffs, hospitals already have a duty under federal law to conduct the sort of investigation Plaintiffs would require, then there may be little reason not to impose liability on a hospital that injures a patient because of failure to perform that duty with due care. On remand these matters can be explored and a record prepared that is

adequate for the court to make a proper judgment on the existence and scope of any duty to investigate.

{*48} **CONCLUSION**

{38} We affirm the summary judgment in favor of Hospital on the claim based on strict products liability. We reverse the summary judgment to the extent that it disposes of Plaintiffs' claim that the Hospital breached "a duty to investigate the safety of the Vitek implants before supplying said implants and allowing their use in the Hospital." We remand for further proceedings consistent with this opinion.

IT IS SO ORDERED.

HARRIS L HARTZ, Judge

WE CONCUR:

RUDY S. APODACA, Chief Judge

BENNY E. FLORES, Judge

¹ In 1982 the chairman of the FDA testified that 95% of manufacturers of medical devices had fewer than 500 employees and half of those had fewer than 50. **FDA Oversight: Medical Devices, 1982: Hearings before the Subcommittee on Oversight and Investigations of the House Energy and Commerce Committee**, 97th Cong., 2d Sess. 5 (1982) (testimony of Dr. Arthur Hayes, Commissioner, FDA). Congressman John Dingell said that there were 7000 manufacturers making over 41,000 devices. *Id.* at 2. A 1976 Congressional Report stated that "small manufacturers of medical devices . . . have been responsible for the development of a host of important and innovative devices." H.R. Rep. No. 94-853, 94th Cong., 2d Sess. 12 (1976).