PARKER V. E.I. DUPONT DE NEMOURS & CO., 1995-NMCA-086, 121 N.M. 120, 909 P.2d 1 (Ct. App. 1995)

DENISE I. PARKER (f/k/a Denise I. Gillette) and MICHAEL D. PARKER, Plaintiffs-Appellants,
vs.
E.I. Du PONT de NEMOURS & CO., INC., Defendant-Appellee.

No. 15,570

COURT OF APPEALS OF NEW MEXICO

1995-NMCA-086, 121 N.M. 120, 909 P.2d 1

July 06, 1995, FILED

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

Certiorari not Applied for. Released for Publication December 12, 1995.

COUNSEL

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JUDGES

THOMAS A. DONNELLY, Judge. BENNY E. FLORES, Judge, JAMES J. WECHSLER, Judge, concur.

AUTHOR: THOMAS A. DONNELLY

OPINION

*{*123}* **OPINION**

DONNELLY, Judge.

{1} Plaintiffs, Denise I. Parker and Michael D. Parker, husband and wife, appeal from an order of the district court granting summary judgment and dismissing their personal injury claims against Defendant, E.I. Du Pont de Nemours & Co. (Du Pont). The district court found that no genuine issue of material fact existed precluding summary judgment, and the court determined as a matter of law that Du Pont owed no duty to Plaintiffs under strict liability, negligence, or other tort or statutory remedies. We affirm.

FACTUAL AND PROCEDURAL BACKGROUND

{2} Denise Parker underwent bilateral surgery in October 1983 for the implantation of artificial temporomandibular joints (TMJ). The TMJ implants inserted by oral surgeons in Denise Parker's jaw were designed, manufactured, and distributed by Vitek, Inc. (Vitek), utilizing Proplast, a patented and trademarked substance made by Vitek. Vitek is not a party to the present action.

{3} Following the marketing and use of Vitek's TMJ implants, Denise Parker and certain other patients who had received such implants began to experience problems. Plaintiffs alleged in the instant case that Vitek's artificial joints which had been surgically implanted in Denise Parker deteriorated, and, as a result, she suffered severe complications, necessitating that the TMJ implants be removed and replaced by rib grafts. Plaintiffs also alleged that as a result of the defective TMJ implants Denise Parker suffered a granulomatous reaction, giant cell reaction, bone erosion and migration of Teflon particles into her lymph system. After a number of suits were filed against Vitek, it filed for bankruptcy. At all times material hereto, Vitek was an independent corporation that was neither owned nor controlled by Du Pont.

{4} Proplast, the material used in the manufacture of the Vitek TMJ implants, was made by combining polytetrafluoroethylene (PTFE) with carbon or aluminum oxide. The mixture was then subjected to a process that included filtrating, compressing, rolling, drying, and heating the material to temperatures above 600 degrees Fahrenheit under high pressure. Finally, the material was leached and redried. During the application of heat and pressure, the PTFE became a gel and coalesced with other ingredients. In manufacturing its TMJ implants, Vitek also utilized a pure form of fluorinated ethylene propylene (FEP) which was laminated to one part of the prosthesis. Du Pont manufactured and sold PTFE and FEP in bulk to Vitek and others; the PTFE was supplied either in resin, powder, or fiber form. Du Pont sells PTFE and FEP under the trademark "Teflon."

{5} After Vitek filed for bankruptcy, Plaintiffs filed suit against Du Pont. Their amended complaint alleged that Du Pont negligently assisted Vitek in obtaining an exemption from the Food and Drug Administration (FDA) to market the TMJ implants; that the TMJ implants marketed by Vitek were misbranded; that Du Pont had a duty to warn or to ensure that Vitek warned oral surgeons, hospitals, and Plaintiffs concerning the risks of having an implant made from PTFE or FEP inserted in patients' jaws; that Du Pont was liable to Plaintiffs for negligence under the theory of products liability; that Du Pont was negligent per se; that Du Pont was guilty of misrepresentation or fraud; that Du Pont

violated New Mexico's Unfair Trade Practices Act; that Du Pont was strictly liable to Plaintiffs for conducting an ultrahazardous activity; and that Du Pont was jointly and severally liable to Plaintiffs, together with Vitek.

{6} The TMJ implants manufactured by Vitek were designed by Dr. Charles Homsy, Vitek's president. Homsy is a chemical engineer who invented and patented Proplast, the main substance utilized in Vitek's implants. Vitek and the TMJ implants manufactured by it were subject to regulation and control by the FDA. Vitek was required to obtain the FDA's consent before selling medical devices for a particular use, to warn customers, and to obtain FDA authorization for any warnings that were required. Prior to marketing the TMJ implants, Vitek submitted an application to the FDA for approval of the sale of such devices. In March 1983 *{*124}* the FDA granted Vitek an exemption from further testing and authorized the sale of Vitek's TMJ implants. Based on information provided by Vitek to the FDA, the FDA recommended that Proplast be classified as a general and plastic surgery device and noted that the safety and effectiveness of the material had been established through clinical trials.

{7} Prior to trial Du Pont moved for summary judgment. In support of its motion, Du Pont argued that it did not owe Plaintiffs a duty under any of the theories alleged in the first amended complaint. Du Pont asserted that it was only a bulk supplier of the Teflon utilized in the manufacture of Proplast, that the manufacture and sale of the TMJ implants made by Vitek were regulated and approved by the FDA, and that Du Pont as a supplier of bulk raw materials had no duty to warn Plaintiffs or other consumers of products containing Teflon of any potential problems with the medical application of the finished product. Du Pont also contended that although it did in fact provide Vitek with specific disclaimers and warnings concerning the use of Teflon for medical purposes, it had no duty to warn Plaintiffs in the instant case because, among other things, Vitek substantially modified and changed the substance of the raw materials after the substances left Du Pont's control, and that Vitek was a sophisticated user who possessed knowledge of the risks associated with such product. Finally, Du Pont asserted that the duty to warn users of the TMJ implants of any problems rested with Vitek.

{8} Following a hearing on Du Pont's motion for summary judgment the district court granted the motion.

STANDARD OF REVIEW

{9} Summary judgment is proper "if the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." SCRA 1986, 1-056(C) (Repl. 1992). A fact is material for the purpose of determining whether a motion for summary judgment is meritorious if it will affect the outcome of the case. **Graven v. Vail Assocs., Inc.,** 888 P.2d 310, 312 (Colo. Ct. App. 1994), **cert. granted** (Jan. 30, 1995).

{10} It is a familiar precept that a party moving for summary judgment must make a prima facie showing that there are no genuine issues of material fact. **Marquez v. Gomez,** 116 N.M. 626, 630, 866 P.2d 354, 358 (Ct. App. 1991), **cert. quashed,** 116 N.M. 801, 867 P.2d 1183 (1993). A prima facie showing contemplates that the movant will show an absence of a genuine issue of fact, or that the movant is entitled to summary judgment as a matter of law. **Goodman v. Brock,** 83 N.M. 789, 792, 498 P.2d 676, 679 (1972). The movant need not demonstrate beyond all possibility that no genuine factual issue exists. **Koenig v. Perez,** 104 N.M. 664, 666, 726 P.2d 341, 343 (1986). Once a prima facie showing is made, the burden then shifts to the non moving panty to prove the existence of one or more genuine factual issues. **Id.** On appeal, the reviewing court scrutinizes the entire record in the light most favorable to the nonmovant and takes note of any evidence therein which puts a material fact in issue. **DeLisle v. Avallone,** 117 N.M. 602, 607, 874 P.2d 1266, 1271 (Ct. App.), **cert. denied,** 117 N.M. 773, 877 P.2d 579 (1994).

EXISTENCE OF DUTY

Claim of Strict Liability

{11} We first examine Plaintiffs' claim that Du Pont, as the manufacturer and supplier of PTFE and FEP, was strictly liable to them as a supplier of a dangerous product and that Du Pont breached a duty owed to them to warn about the potential danger incident to the use of Vitek's TMJ implants. New Mexico follows Restatement (Second) of Torts Section 402A (1965),[1] and applies the rule of *{*125}* strict liability upon a manufacturer or seller of unreasonably dangerous products where the dangerous condition of the product is shown to exist when it left the manufacturer's or seller's control. SCRA 1986, 13-1406 to -1408; 13-1423 (Repl. 1991); **Stang v. Hertz Corp.,** 83 N.M. 730, 735, 497 P.2d 732, 737 (1972); **First Nat'l Bank v. Nor-Am Agric. Prods., Inc.,** 88 N.M. 74, 85, 537 P.2d 682, 693 (Ct. App.), **cert. denied,** 88 N.M. 29, 536 P.2d 1085 (1975); **see also Trujillo v. Berry,** 106 N.M. 86, 88, 738 P.2d 1331, 1333 (Ct. App.), **cert. denied,** 106 N.M. 24, 738 P.2d 518 (1987); **Tenney v. Seven-Up Co.,** 92 N.M. 158, 159, 584 P.2d 205, 206 (Ct. App.), **cert. denied,** 92 N.M. 180, 585 P.2d 324 (1978).

{12} In support of its contention that the PTFE and FEP supplied by Du Pont was unreasonably dangerous, Plaintiffs rely, in part, upon SCRA 1986, 13-1402 and -1423 (Repl. 1991). SCRA 13-1402 states:

> The supplier of a product has a duty to use ordinary care to avoid a foreseeable risk of injury caused by a condition of the product or manner in which it is used. This duty is owed [to persons who can reasonably be expected to use the product] [and] [to persons who can reasonably be expected to be in the vicinity during the use of the product.]
>
> [The supplier's duty to use ordinary care continues after the product has left [his] [her] [its] possession. A supplier who later learns, or in the exercise of ordinary

care should know, of a risk of injury caused by a condition of the product or manner in which it could be used must then use ordinary care to avoid the risk.]

SCRA 13-1423 states:

> "Products liability" applies to the supplier of [a component part] [material intended for further processing] which proximately causes injury if, when added to or incorporated into the finished product, the [component part] [material] is substantially unchanged or is in a condition in which it could have been reasonably expected to be used.
>
> For substantial change in the [component part] [material] to relieve a supplier of liability, the change itself must be a proximate cause of the harm done.

{13} Responding to Plaintiffs' arguments, Du Pont asserts that the district court correctly determined that the raw materials supplied by Du Pont to Vitek were inert substances, not inherently dangerous in the form sold to Vitek, and that it had no duty to Plaintiffs under a claim of strict liability in the instant case. We agree. The existence and scope of any duty constitutes a question of law. **Saiz v. Belen Sch. Dist.,** 113 N.M. 387, 398, 827 P.2d 102, 113 (1992); **Calkins v. Cox Estates,** 110 N.M. 59, 62-63, 792 P.2d 36, 39-40 (1990); **see also Marquez,** 116 N.M. at 631, 866 P.2d at 359. "A product may be considered 'unreasonably dangerous' due to either a design or manufacturing defect, or the manufacturer's failure to warn of a non-obvious risk.[1] **Apperson v. E.I. du Pont de Nemours & Co.,** 41 F.3d 1103, 1106 (7th Cir. 1994). Determining whether a duty exists necessarily requires that the court assess whether the relationship between the parties is such that the defendant was under a duty or obligation to use some care to avoid injury to the plaintiffs. **Anguiano v. E.I. DuPont de Nemours & Co.,** 808 F. Supp. 719, 722 (D. Ariz. 1992) **(Anguiano I), aff'd,** 44 F.3d 806 (9th Cir. 1995) (**Anguiano II**).

{14} Du Pont's motion for summary judgment was supported by excerpts from several depositions of Homsy, Vitek's founder, affidavits of John S. Lindell, a chemical engineer employed by Du Pont, and the deposition of Edward M. Mansfield, an attorney. Du Pont also relied on correspondence from Du Pont to Vitek. The affidavits submitted by Du Pont state, among other things, that the PTFE and FEP supplied by it to Vitek were inert in nature and were safe for use in a multitude of forms, that the substances were not inherently defective or dangerous, and that no agency relationship existed between Du Pont and Vitek or Homsy. Nothing contained in Plaintiffs' responses to the motion *{*126}* for summary judgment gives rise to a material, disputed factual issue concerning these basic contentions.

{15} Du Pont's motion for summary judgment was also supported by Mansfield's affidavit, together with the correspondence referred to therein, showing that prior to any sale of PTFE or FEP to Vitek, Du Pont notified Vitek that Du Pont made no surgical or medical grades of Teflon and that it had not studied the suitability of such materials for use in the human body. Plaintiffs' response to Du Pont's motion for summary judgment failed to sufficiently controvert these assertions. The burden of coming forward with

evidence showing the existence of material, disputed factual issues is not satisfied by unsupported assertions of fact. **See Dow v. Chilili Coop. Ass'n,** 105 N.M. 52, 54-55, 728 P.2d 462, 464-65 (1986) (party opposing summary judgment may not simply argue that evidentiary facts requiring trial on the merits exist, nor may it rely on allegations of the complaint).

{16} As a general rule, a supplier of a component part or raw material which is not inherently defective or dangerous at the time it leaves the manufacturer's control, and which part or material is used in the manufacture or making of another product, does not owe a duty to an ultimate consumer to issue a warning concerning the suitability or safety of the finished product; in such situation any duty to warn rests upon the manufacturer of the device or finished product. **See Apperson,** 41 F.3d at 1107-08; **Crossfield v. Quality Control Equip. Co.,** 1 F.3d 701, 704 (8th Cir. 1993); **Kealoha v. E.I. Du Pont de Nemours & Co.,** 844 F. Supp. 590, 594 (D. Haw. 1994); **Kellar v. Inductotherm Corp.,** 498 F. Supp. 172, 175 (E.D. Tenn. 1978), **aff'd,** 633 F.2d 216 (6th Cir. 1980); **Shawver v. Roberts Corp.,** 90 Wis. 2d 672, 280 N.W.2d 226, 232-33 (Wis. 1979). Similarly, a supplier of an inert raw material has no duty to foresee all the dangers that may result from the subsequent manufacture by a third party of a product which incorporates such raw materials together with other substances into a finished product. **See Kealoha,** 844 F. Supp. at 594; **Bond v. E.I. Du Pont De Nemours & Co.,** 868 P.2d 1114, 1118 (Colo. Ct. App. 1993), cert. **denied** (Feb. 28, 1994); **see also Childress v. Gresen Mfg. Co.,** 888 F.2d 45, 49 (6th Cir. 1989); **Anguiano I,** 808 F. Supp. at 725-26.

{17} Plaintiffs have not come forward with evidence indicating that the PTFE or FEP in the form sold by Du Pont to Vitek were not safe materials at the time they left Du Pont's control. Thus, we conclude that the district court correctly determined there was no duty on the part of Du Pont to perform further tests concerning the suitability of Vitek's TMJ implants or to provide warnings to other consumers, including Plaintiffs, of the suitability of the TMJ implants. **Anguiano I,** 808 F. Supp. at 725-26 (duty to provide adequate warnings is upon manufacturer of medical product and not upon supplier of inert raw material sold in bulk); **see also Hill v. Wilmington Chem. Corp.,** 279 Minn. 336, 156 N.W.2d 898, 902-04 (Minn. 1968) (supplier of raw material has no duty to warn users of the finished product when manufacturer of finished product is aware of alleged risk); **George v. Parke-Davis,** 107 Wash. 2d 584, 733 P.2d 507, 515 (Wash. 1987) (en banc) (ingredients for prescription drug not inherently harmful; bulk supplier held not liable to ultimate consumer).

{18} While Plaintiffs have alleged that Du Pont knew Vitek intended to use such raw materials in making and marketing the TMJ implants, Plaintiffs' response to the motion for summary judgment fails to show the existence of proper evidence indicating that Du Pont had any role over designing, manufacturing, packaging, marketing, or sale of Vitek's TMJ implants or that there was a manufacturing defect in the Teflon materials at the time they left Du Pont's control. Similarly, Plaintiffs have not shown that Du Pont played any role in the evaluation or determination of the safety or suitability of Vitek's TMJ implants. In fact, affidavits submitted by Du Pont negated Plaintiffs' allegations

relating to these specific claims. Thus, we conclude that Plaintiffs have failed to show the existence of a material, disputed factual issue concerning whether Du Pont's products used in the manufacture of the TMJ implants in question were inherently dangerous and whether Vitek was unaware of problems concerning *{*127}* the use of Teflon in its TMJ implants. **See Miller v. E.I. DuPont de Nemours & Co.,** 811 F. Supp. 1286, 1287-88 (E.D. Tenn. 1992) (Du Pont held not liable for harm caused by Vitek's TMJ implant where the plaintiffs failed to provide evidence that Du Pont negligently manufactured Teflon or supplied defective component part).

{19} In determining whether a raw materials manufacturer may be held liable for failing to warn a physician, a hospital, or an ultimate consumer of a potential danger concerning a product utilizing such raw materials, we find the rationale applied by the court in **Apperson** instructive:

> While manufacturers of inherently dangerous raw materials will be held liable for injury caused by their product, courts have treated differently manufacturers of inherently **safe** components when the final assembly, rather than a manufacturing or design defect in the component itself, renders the component dangerous. "Such a manufacturer will not be held liable if the injury resulted from a dangerous condition created by the party who created the final product. 'The obligation that generates the duty to avoid injury to another which is reasonably foreseeable does not extend to the anticipation of how manufactured components not in and of themselves dangerous or defective can become potentially dangerous dependent upon the nature of their integration into a unit designed, assembled, installed, and sold by another.'"

41 F.3d at 1107 (citations omitted) (quoting **Woods v. Graham Eng'g Corp.,** 539 N.E.2d 316, 319 (Ill. App. Ct. 1989) (quoting **Curry v. Louis Allis Co.,** 100 Ill. App. 3d 910, 427 N.E.2d 254, 258, 56 Ill. Dec. 174 (Ill. App. Ct. 1981))).

{20} Similarly, in **Kalinowski v. E.I. Du Pont de Nemours & Co.,** 851 F. Supp. 149, 159 (E.D. Pa. 1994), the court considered and rejected an argument like that asserted here. The **Kalinowski** court held that the warnings given by Du Pont to Homsy and Vitek, and the latter corporation's assurances that Du Pont's products would not be used except within the guidelines established by the FDA, satisfied Du Pont's duty to warn. **Id.** The court further reasoned: "Imposing upon defendant the obligation to guard against the negligent or intentional conduct of such intermediaries because of the possibility that its products could cause harm as the result of such conduct would permit the imposition of virtually limitless liability." **Id.**

{21} Claims similar to those alleged by Plaintiffs in the instant case have been filed against Du Pont in a number of other jurisdictions. Each of the courts that has considered such claims has concluded that Du Pont is not liable under a strict liability theory for injuries to parties resulting from the alleged failure to warn ultimate consumers of hazards involved in the use of Vitek's TMJ implants. **See, e.g., Anguiano, II**, 44 F.3d at 812; **Kealoha,** 844 F. Supp. at 594-95; **Kalinowski,** 851 F. Supp. at 159;

Bond, 863 P.2d at 1118-19. Plaintiffs, in part, rely on **Hegna v. E.I. du Pont de Nemours & Co.,** 806 F. Supp. 822 (D. Minn. 1992) (**Hegna I,** another case involving claims similar to those presented here, for the proposition that genuine factual issues exist concerning Plaintiffs' strict liability claim. However, the **Hegna** opinion was modified after Du Pont's motion for rehearing was granted and the factual record in that case was more fully developed. **Hegna v. E.I. Du Pont de Nemours & Co.,** 825 F. Supp. 880 (D. Minn. 1993) **(Hegna II).** In **Hegna II** the court reversed itself and granted Du Pont's motion for summary judgment on Hegna's strict liability claim. **Id.** at 885. **Hegna II** was subsequently affirmed on appeal. **Hegna v. E.I. Du Pont De Nemours & Co.,** 27 F.3d 571 (8th Cir. 1994).

{22} Plaintiffs asserted in their response to the motion for summary judgment that a factual issue exists as to whether Du Pont's warnings to Vitek and Homsy were sufficient. In response Du Pont argued that Vitek was a sophisticated purchaser with extensive knowledge concerning prior studies involving the use of Teflon in medical implants, hence Du Pont had no duty beyond the warnings actually given by it to Vitek and Homsy to further warn third parties of potential risks inherent in the use of PTFE and FEP for medical purposes. The affidavits and documentary evidence submitted by Du Pont in support of its motion indicate that Vitek was familiar with the nature and properties of the *{*128}* raw materials furnished by Du Pont, and that Homsy was aware of articles and studies expressing concerns over the use of Teflon in medical implants. Additionally, the affidavit of Lindell filed in support of Du Pont's motion for summary judgment stated that it notified Vitek of the possible hazard of using PTFE and FEP in medical implants and that Vitek agreed to conduct appropriate tests and give adequate warnings to the ultimate consumers. Thus, we do not believe Plaintiffs' contentions on this point are borne out by the record. Moreover, the adequacy of a warning does not become a material, factual issue until it is first determined that a duty to warn exists. **Anguiano I,** 808 F. Supp. at 726.

{23} In advancing their strict liability claims against Du Pont, Plaintiffs also contend that Du Pont was aware that the PTFE and FEP sold by it to Vitek were unreasonably dangerous when used in the TMJ implants, and that Du Pont knew or should have known that Vitek did not intend to give proper warnings to others. Plaintiffs also rely on the provisions of Restatement (Second) of Torts Sections 388 and 391 (1965) as support for their contention that the district court erred in finding that Du Pont did not owe a duty to warn in the instant case.[2]

{24} Although the reach of Section 388 of the Restatement has been held to extend to a party who supplies chattels that are or are likely to be dangerous, as well as those who manufacture them, **Barsness v. General Diesel & Equip. Co.,** 383 N.W.2d 840, 845 (N.D. 1986), Plaintiffs have failed to establish that the bulk supply of raw material used by Vitek in the manufacture of its TMJ implants was inherently defective or unsafe when it left Du Pont's control. It is undisputed that the Teflon supplied by Du Pont to Vitek when it left Du Pont's control was inert, that it was not an inherently dangerous product, and that it was safe for a multitude of uses. In such case, we think it is clear that the provisions of Sections 388 and 391 of the Restatement, **supra,** cannot be said to be so

broadly applied as to extend vertical liability in the present case. Plaintiffs have failed to show that the Teflon sold by Du Pont was a defective product. A manufacturer of a nondefective product has no duty to test the suitability of another's finished product which is assembled from several different components. **See Kealoha,** 844 F. Supp. at 595 (supplier of safe raw material need not insure against conceivable misuse of material); **see also Apperson,** 41 F.3d at 1108 (burden is on manufacturer of medical device to gain FDA approval of that device).

{25} A number of states have recognized the "bulk supplier doctrine" as a defense to a claim that the supplier failed to warn an ultimate consumer about a possible danger associated with a particular product that had been manufactured from a number of component parts and had undergone substantial change. **See Donahue v. Phillips Petroleum Co.,** 866 F.2d 1008, 1012 (8th Cir. 1989); **Veil v. Vitek, Inc.,** 803 F. Supp. 229, 235 (D.N.D. 1992); **Sara Lee Corp. v. Homasote Co.,** 719 F. Supp. 417, 424 (D. Md. 1989); **see also Bond,** 868 P.2d at 1118 (supplier of raw Teflon not liable under strict liability theory where raw material was not shown to be in defective or dangerous condition when it left supplier's control). As noted in **Donahue,** under the bulk supplier doctrine, a bulk supplier is required to warn its immediate purchaser of any known dangers, with the intent that such warning be passed on to the ultimate consumer. *{*129}* **Donahue,** 866 F.2d at 1012. This doctrine is premised on the concept that the intermediary is in a better position to warn ultimate consumers of dangers associated with the completed product.

{26} Plaintiffs additionally argue that there is an issue of fact concerning whether the PTFE provided by Du Pont underwent substantial change during the process of manufacturing Proplast. In support of their argument, Plaintiffs submitted the affidavit of Dr. Myron Spector which stated that the fabrication of Proplast did not substantially change the Teflon. According to Plaintiffs, because there is a factual issue as to whether the material was substantially changed, the bulk supplier doctrine is inapplicable. We need not decide whether Du Pont would prevail on the issue of whether a substantial change in the product occurred because we have already determined that Du Pont owed no duty to Plaintiffs for supplying Vitek with an inert material.

{27} Plaintiffs further argue that according to comments p and q of Restatement, **supra,** Section 402A, Du Pont would be liable even if the PTFE could be shown to have undergone substantial change in the manufacture of Proplast. We disagree. Both comments p and q state that the American Law Institute has refrained from taking a position regarding liability under such circumstances but that in some cases liability might be established. For example, according to comment p, it would not appear that the seller of raw coffee beans contaminated with arsenic would be relieved of liability just because the buyer roasts and packages the beans for the ultimate consumer. **See also Nor-Am Agric. Prods, Inc.,** 88 N.M. at 86, 537 P.2d at 694. Conversely, the manufacturer of pigiron, which is capable of many uses, would not likely be liable for the unsuitability of a bicycle made by the buyer of such iron. Since PTFE has multiple uses,

we believe the pigiron example is more representative of the present case and reject Plaintiffs' argument.

{28} Plaintiffs also argue that the district court erred in failing to find that Restatement (Second) of Torts Section 389 (1965) is applicable to the facts of the instant case. Specifically, they contend that the district court erred in granting summary judgment because Du Pont supplied the PTFE and FEP to Vitek for use in fabricating implants for use in human beings and that Du Pont knew or had reason to know that the "chattel" supplied by it was "unlikely to be made reasonably safe before being put to a use which the supplier should expect it to be put."[3] We think this argument, too, must fail. Du Pont informed Vitek that it was concerned about the efficacy of using PTFE to manufacture implants, that it had performed no testing to determine whether PTFE based implants were appropriate, and that Vitek would have to rely on its own legal and medical judgment regarding its use of PTFE. Furthermore, it is clear that the FDA had regulatory authority over the sale of the TMJ implants and Du Pont received written assurances from Vitek that it would comply with FDA requirements. We therefore find that Section 389 does not aid Plaintiffs in the instant case.

{29} Plaintiffs also cite Restatement (Second) of Torts Section 294 (conduct involving unreasonable risk of harm to third person), Section 302B (risk of direct or indirect harm), Section 305 (preventing protective action), and Section 308 (permitting improper persons to use things or engage in an activity under the control of defendant) (1965), in support of their contention that Du Pont owed Plaintiffs a duty to warn them of the potential hazards inherent in Vitek's TMJ implants. We have examined each of these provisions and find them inapplicable here. The common thread underlying each of these *{*130}* provisions is a showing that the actor had a duty to the plaintiff under the circumstances presented. The district court properly determined that Du Pont did not have a duty in the instant case.

> **{30}** As observed by the court in **Bond,** 868 P.2d at 1120-21:
>
> There is little social utility in placing the burden on a manufacturer of component parts or supplier of raw materials of guarding against injuries caused by the final product when the component parts or raw materials themselves were not unreasonably dangerous.
>
> Further, there is again even less reason to impose such a duty when, as here, the designer of the final product presumably possesses highly specialized knowledge of the field in which the product exists and that designer is under a duty imposed by the government to conduct specific tests and provide particular warnings. [Citations omitted.]

{31} Finally, Plaintiffs argue that under Restatement (Second) of Torts Section 449 (1965) Du Pont permitted and encouraged Vitek to sell medical devices in a negligent and criminal manner, thus giving rise to a duty on Du Pont's part. We find this argument without merit because Plaintiffs have failed to come forward in response to the motion

for summary judgment and submit proper evidence showing that Du Pont permitted or encouraged Vitek to engage in any unlawful activity. **See Dow,** 105 N.M. at 54-55, 728 P.2d at 464-65 (party opposing summary judgment may not argue unsupported evidentiary facts). On the contrary, it is undisputed that Du Pont did not sell PTFE or FEP materials to Vitek until it agreed to comply with FDA regulations.

{32} We conclude that the district court correctly determined that Du Pont, as the supplier of the materials utilized by Vitek in the manufacture of its TMJ implants, had no duty under a strict liability theory to provide a warning to hospitals, physicians, or patients concerning Vitek's TMJ implants. Any duty to warn Plaintiffs of a potential problem with the materials supplied by Du Pont was owed by Vitek, not Du Pont. **See Veil,** 803 F. Supp. at 235.

Claim of Negligence

{33} Plaintiffs assert that the district court erred in ruling that there was an absence of any disputed factual issue concerning whether Du Pont knew or reasonably should have known that the PTFE or FEP manufactured by it and sold to Vitek were unreasonably dangerous when used in Vitek's TMJ implants. Plaintiffs argue that even if the district court properly held that under strict liability Du Pont did not have a duty to warn, nevertheless, Du Pont was negligent in failing to warn hospitals, oral surgeons, and plaintiffs concerning the potential danger of the materials incorporated into the TMJ implants made by Vitek.

{34} Restatement, **supra,** Section 388 sets out the duty of the manufacturer of a product in a negligence action to warn potential customers of such product. Clause (c) states that a supplier who provides a chattel directly or through a third person is subject to liability for physical harm to one who may be expected to use such chattel if the supplier "fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous."

{35} It is fundamental that in order to prevail under Plaintiffs' claim of negligence, they were required to establish (1) the existence of a duty owed to Plaintiffs, (2) a breach of such duty, (3) a causal connection between Du Pont's conduct and the injury to Plaintiffs, and (4) damages resulting from such conduct. **See** SCRA 1986, 13-1601 (Repl. 1991). Whether a person has breached a duty also involves the question of foreseeability. **Torres v. State,** 34 N.M. 131, 894 P.2d 386, 390-91 (1995). Restatement, **supra,** Section 388 comment 1 to Clause (c) states in pertinent part:

> The supplier's duty is to exercise reasonable care to inform those for whose use the article is supplied of dangers which are peculiarly within his knowledge. If he has done so, he is not subject to liability, even though the information never reaches those for whose use the chattel is supplied.

{36} In the instant case, Du Pont supplied the PTFE sold to Vitek in bulk form. Thereafter *{*131}* Vitek subjected the raw materials to extensive processing in order to

fabricate its patented product, Proplast, and to manufacture its TMJ implants. Upon learning of Vitek's intent to use PTFE for medical purposes, Du Pont advised Vitek in writing that its polymers were not made for medical use and that persons proposing to evaluate or use PTFE for medical or surgical purposes must rely on their own medical and legal judgment. Du Pont also advised Homsy in writing that a medical study had indicated that pure PTFE, when fabricated into a cup for a hip replacement, had a tendency to abrade. Homsy signed and returned acknowledgments of those disclaimers on behalf of Vitek and acknowledged a duty on the part of Vitek to keep the FDA advised concerning the safety of its TMJ implants. **See** 21 U.S.C.A. §§ 352(f), 360d(a)(2)(C) (West Cum. Supp. 1995); **Bond,** 868 P.2d at 1120. Vitek assured Du Pont it would comply with these duties. Plaintiffs have not provided this Court with any reported decision supporting their contention that Du Pont, as supplier of bulk materials, is a supplier of chattels within the contemplation of Restatement, **supra,** Section 388. In **Veil** the court examined a similar claim and reached a contrary conclusion. **Veil,** 803 F. Supp. at 233.

{37} Under the record before us, we conclude that the district court correctly found that Du Pont, as the supplier of raw materials used in the TMJ implants designed, manufactured, and sold by Vitek, owed no duty to Plaintiffs under a negligence theory to warn Plaintiffs of the potential dangers of using Vitek's TMJ implants or to refrain from selling its raw materials to Vitek. **See Veil,** 803 F. Supp. at 233; **Bond,** 868 P.2d at 1121.

Plaintiffs' Other Claims

{38} Plaintiffs have asserted that Du Pont is liable under several alternative theories of liability, apart from their claims of strict liability and negligence. They argue that Du Pont is negligent per se, that Du Pont misrepresented the safety of Teflon, that Du Pont was guilty of unfair trade practices, and that Du Pont is jointly and severally liable. The district court found the absence of material, disputed facts to support each of these theories. We agree. The affidavits submitted by Du Pont in support of its motion for summary judgment negated each of these allegations. Nothing in Plaintiffs' responsive affidavits or other materials gives rise to disputed issues of fact relating to any of these contentions.

(a) **Claim of Negligence Per Se**

{39} Plaintiffs assert that the district court erred in granting summary judgment to Du Pont because a material, disputed factual issue existed as to whether Du Pont was independently liable as a supplier of PTFE and FEP to Vitek under Plaintiffs' claim of negligence per se. Plaintiffs contend the FDA declared that the TMJ implants manufactured and sold by Vitek were dangerous because the Teflon material used on articulating surfaces leads to a breakdown of debris particles, giant cell response, bony degeneration and granulomas. Plaintiffs also assert that Vitek's TMJ implants were sold in violation of federal law.

{40} In order to hold a defendant liable under a claim of negligence per se, the defendant must be shown to have violated a specific statute. **See Runge v. Fox,** 110 N.M. 447, 450, 796 P.2d 1143, 1146 (Ct. App. 1990). Such showing has not been made here.

{41} Although Plaintiffs' brief-in-chief asserts that Du Pont aided and abetted criminal acts of Vitek, that Du Pont was aware that the TMJ implants manufactured by Vitek were sold without the required FDA approval, and that the warnings given by Vitek of the potential hazards of the TMJ implants were not given or were inadequate, our review of the record indicates that Plaintiffs' response to Du Pont's motion for summary judgment fails to show that Du Pont itself violated any state or federal statute, or that it assisted or abetted Vitek in violating any law or regulation.

{42} Du Pont insisted as a condition of selling its products to Vitek that it comply with FDA requirements and that Vitek give appropriate warnings to consumers of its TMJ implants. Plaintiffs have failed to show that Du Pont was involved in any of Vitek's presentations to the FDA concerning the safety *{*132}* of its TMJ implants, or that Du Pont prepared any of the warnings given by Vitek. Finally, the district court concluded, and we agree, that Plaintiffs have failed to come forward with facts indicating that any agency or joint relationship existed between Du Pont and Vitek. **Cf. Miller,** 811 F. Supp. at 1287 (placing burden on plaintiffs to present evidence of joint venture between Vitek and Du Pont involving Vitek's TMJ implants).

(b) **Claim of Misrepresentation and Fraud**

{43} Plaintiffs also argue that Vitek's representation to consumers that its TMJ implants utilized medical grade Teflon was untruthful and that Du Pont knew this representation was either a negligent or an intentional misrepresentation. Plaintiffs further contend that Vitek had a duty under federal law to fully inform the FDA of any potential dangers with its product, to obtain FDA consent before selling such implants, and to warn customers of potential dangers related to its product. Plaintiffs assert that George Wilkins, an employee of Du Pont, was aware that Vitek intended to disregard prior studies indicating that PTFE posed a danger if used in articulating joints, and that in 1985 Du Pont had the opportunity to review Vitek's literature.

{44} It is undisputed that Du Pont disclosed to Vitek its concern of potential problems with using PTFE in a hip implant to Vitek. Plaintiffs have failed to show that Du Pont made any express or implied representations to either Dr. Terry L. Carlberg or Dr. Richard L. Farquhar, the oral surgeons who surgically implanted the TMJ devices in Denise Parker, St. Vincent Hospital, the hospital where the surgery was performed, or to either of the Plaintiffs. In order to prevail under a theory of negligent misrepresentation, Plaintiffs are required to show that (1) Du Pont made a material misrepresentation of fact to Plaintiffs, (2) Plaintiffs relied upon such representation, (3) Du Pont knew the representation was false at the time it was made or made it recklessly, and (4) Du Pont intended to induce Plaintiffs to rely on such representation. SCRA 1986, 13-1632 (Repl. 1991); **see also Garcia v. Rodey, Dickason, Sloan, Akin**

& Robb, P.A., 106 N.M. 757, 761-62, 750 P.2d 118, 122-23 (1988); **R.A. Peck, Inc. v. Liberty Fed. Sav. Bank,** 108 N.M. 84, 88, 766 P.2d 928, 932 (Ct. App. 1988). No showing of a factual issue concerning a negligent or intentional misrepresentation on the part of Du Pont has been shown to exist here.

{45} Plaintiffs further contend that Du Pont was guilty of constructive fraud because it allowed the words "Medical Grade Teflon" to appear on Vitek's product label of its TMJ implants, it assisted Vitek in the marketing of the implants, and it purportedly signed a fraudulent statement on behalf of Vitek for submission to the FDA. In order to establish a cause of action based on a claim of constructive fraud, Plaintiffs must prove "a breach of a legal or equitable duty which the law declares fraudulent because of its tendency to deceive others." **Barber's Super Markets, Inc. v. Stryker,** 84 N.M. 181, 186, 500 P.2d 1304, 1309 (Ct. App.), **cert. denied,** 84 N.M. 180, 500 P.2d 1303 (1972); **see also Snell v. Cornehl,** 81 N.M. 248, 249, 466 P.2d 94, 95 (1970).

{46} Our review of the record fails to disclose any evidence giving rise to a material, factual issue supporting these allegations so as to give rise to a duty on the part of Du Pont to either of the Plaintiffs herein.

(c) **Claim of Unfair Trade Practices**

{47} Additionally, Plaintiffs assert that Du Pont's acts and omissions violated this state's Unfair Practices Act, NMSA 1978, §§ 57-12-1 to -21 (Repl. Pamp. 1987 & Cum. Supp. 1994), because it engaged in unfair or deceptive trade practices. In support of their claim, Plaintiffs allege that Du Pont permitted Vitek to use a label with the words "Medical Grade Teflon" on its product and that Du Pont filed a "Good Manufacturing Practices" statement with the FDA that was directly in conflict with its disclaimers to Vitek concerning the use of Teflon for medical purposes. Generally, the Unfair Practices Act is intended to provide a private remedy for individuals who suffer pecuniary harm for conduct involving either misleading identification of a business or goods, or false or deceptive advertising. **Stevenson v. Louis Dreyfus Corp.,** 112 N.M. 97, 100, 811 P.2d *{*133}* 1308, 1311 (1991); **see also Richardson Ford Sales, Inc. v. Johnson,** 100 N.M. 779, 782, 676 P.2d 1344, 1347 (Ct. App. 1984). Nothing in the evidence presented by Plaintiffs in response to Du Pont's motion for summary judgment gives rise to a material issue of fact indicating that Du Pont was involved in the design, manufacture or sale of Vitek's TMJ implants. Nor is there any showing that Du Pont participated in the marketing or labeling of Vitek's products, or made any representations concerning the TMJ implants in question. Plaintiffs' allegations to the contrary, unsupported by affidavits or sworn testimony, are not evidence to be considered in reviewing Du Pont's motion for summary judgment. **See Dow,** 105 N.M. at 54-55, 728 P.2d at 464-65.

(d) **Claim of Joint and Several Liability**

{48} Lastly, Plaintiffs argue that Du Pont may be held jointly and severally liable under the provisions of NMSA 1978, Section 41-3A-1(C)(3), (4) (Repl. Pamp. 1989). These provisions state:

C. The doctrine imposing joint and several liability shall apply:

. . . .

(3) to any persons strictly liable for the manufacture and sale of a defective product, but only to that portion of the total liability attributed to those persons; or

(4) to situations not covered by any of the foregoing and having a sound basis in public policy.

{49} Since we have concluded that the district court correctly determined that Du Pont was not liable under any of the theories advanced by Plaintiffs, their claim of joint and several liability must also fail. Absent a showing that Du Pont owed or breached a duty to Plaintiffs under one or more of the claims asserted by them, joint or several liability does not lie. **See Standhardt v. Flintkote Co.,** 84 N.M. 796, 805, 508 P.2d 1283, 1292 (1973) (non-negligent party cannot be held jointly liable or subject to the right of contribution).

{50} We have carefully examined each of Plaintiffs' other contentions and find them to be without merit. Because we find that Du Pont owed Plaintiffs no duty under any of the tort or statutory theories raised, we need not address Du Pont's assertion that Plaintiffs' claims are preempted by federal law.

CONCLUSION

{51} The decision of the district court is affirmed.

{52} IT IS SO ORDERED.

THOMAS A. DONNELLY, Judge

WE CONCUR:

BENNY E. FLORES, Judge

JAMES J. WECHSLER, Judge

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1 Restatement, **supra,** Section 402A provides:

(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.

2 Restatement, **supra,** Section 388 provides:

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.

Restatement, **supra,** Section 391 provides:

One who supplies directly or through a third person a chattel for another to use for the supplier's business purposes, knowing or having reason to know that it is or is likely to be dangerous for the use for which it is supplied, is subject to liability as stated in §§ 388-390.

3 Restatement, **supra,** Section 389 states:

One who supplies directly or through a third person a chattel for another's use, knowing or having reason to know that the chattel is unlikely to be made reasonably safe before being put to a use which the supplier should expect it to be put, is subject to liability for physical harm caused by such use to those whom the supplier should expect to use the chattel or to be endangered by its probable use, and who are ignorant of the dangerous character of the chattel or whose knowledge thereof does not make them contributorily

negligent, although the supplier has informed the other for whose use the chattel is supplied of its dangerous character.