No.	95-1394	
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In re: Temporomandibular Joint (TMJ) Implants Products Liability Litigation	* * *
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Temporomandibular Joint (TMJ)	*
Implant Recipients,	* Appeal from the United States
	* District Court for the
Appellants,	* District of Minnesota.
	*
v.	*
	*
E.I. Du Pont De Nemours and	*
Company; American Durafilm	*
Company, Inc.,	*
	*
Appellees.	*

Submitted: October 19, 1995 Filed: October 4, 1996

Before BOWMAN, HEANEY, and WOLLMAN, Circuit Judges.

BOWMAN, Circuit Judge.

This appeal arises from a multidistrict litigation proceeding, consolidating approximately 280 products liability actions for pretrial purposes under 28 U.S.C. § 1407 (1994) ("When civil actions involving one or more common questions of fact are pending in different districts, such actions may be transferred to any district for coordinated or consolidated pretrial proceedings."). Temporomandibular Joint Implant Recipients (Recipients) appeal from the judgment of the District Court,¹ which granted summary judgment in favor of defendants E.I. Du Pont de Nemours & Company (Du Pont) and American Durafilm Company, Inc. (Durafilm). <u>In re TMJ Implants Prods.</u> <u>Liab. Litig.</u>, 872 F. Supp. 1019 (D. Minn. 1995). We affirm.

I.

Plaintiffs-appellants are the recipients of the Proplast TMJ prosthetic device Interpositional Implant, а used to correct temporomandibular joint (TMJ) disorders. The TMJ connects the upper and lower jaw; it facilitates normal movement of the jawbone. When the articulating surface of the jawbone that fits into the TMJ becomes diseased, normal mobility can be restored by implanting a prosthetic device like the Proplast TMJ Interpositional Implant. The gravamen of the complaint is that the implants failed, abrading the surrounding bone and causing pain to the Recipients. The implants were invented, designed, tested, manufactured, packaged, and sold by Vitek, Inc., a now bankrupt company founded by Dr. Charles Homsy. Du Pont and Durafilm are the named defendants in this action, however, because they manufactured and supplied some of the raw materials that were used to construct the implants -including polytetrafluoroethylene powder and fiber (PTFE resin) and fluorinated ethylene propylene film (FEP film). Du Pont manufactured both of these materials and sold them under the familiar Teflon trademark. Durafilm distributed FEP film, but did not manufacture it.² PTFE resin and FEP film are chemically inert with a wide variety of safe industrial uses. PTFE is used to manufacture everything from bearings in jet aircraft to non-stick

¹The Honorable Paul A. Magnuson, Chief Judge, United States District Court for the District of Minnesota.

²Durafilm merely facilitated the distribution of FEP film to purchasers like Vitek who desired to buy less FEP film than Du Pont was willing to sell directly.

surfaces on frying pans. FEP film is used in applications ranging from pipe insulation to solar collectors.

In the late 1960s, Dr. Homsy invented the implant biomaterial Proplast while conducting prosthesis research at Methodist Hospital in Houston, Texas. Proplast is a spongy and highly porous coalesceable gel designed to promote tissue attachment. Dr. Homsy founded Vitek in 1969 to manufacture and distribute his Proplast prosthetic devices while he continued his research at Methodist Hospital. To make Proplast, Vitek combined PTFE resin with carbons and solvents and then subjected this mixture to an eight-step patented process of heating, compressing, and The implant itself is formed by molding the Proplast into the drying. required shape and laminating one side of it with translucent FEP film. The FEP film layer replaced the meniscus or articulating surface of the TMJ and was designed to protect the underlying Proplast from wear in loadbearing joints like the TMJ. Surgeons positioned the implant so that the Proplast side would be anchored eventually by tissue growth while the FEP film side abutted the lower jaw to shield against wear. The chain of distribution for PTFE resin and FEP film thus began with Du Pont or Durafilm as the initial suppliers, then continued on to Vitek as the finished product manufacturer, and finally ended with the Recipients as the ultimate users of the finished product. Each implant, while selling for at least fifty dollars, contained only a few cents' worth of PTFE resin and FEP film.

When Du Pont learned that Dr. Homsy intended to use its Teflon products for medical purposes, Du Pont advised the purchasing agent at Methodist Hospital by a March 13, 1967, letter that its Teflon products were not made for medical applications and that Du Pont had not conducted the necessary long-term studies to determine the suitability of fluorocarbons for medical use. Du Pont's letter also noted several published scientific reports indicating that pure Teflon implants wore badly and had a tendency to disintegrate

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in load-bearing joints. Consequently, Du Pont required the hospital to sign a disclaimer, acknowledging Du Pont's warnings and agreeing to use its own independent medical and legal judgment as to the safety of Teflon in the implants.

One week later, an agent for Methodist Hospital executed the disclaimer. Dr. Homsy explained in a separate letter that he was familiar with the implant studies that Du Pont mentioned in its disclaimer; he characterized Du Pont's references to the medical literature as "crucially incomplete." Letter from Charles A. Homsy, Orthopedic Prosthesis Laboratory, Methodist Hospital, to George A. Wilkins, Du Pont Consultant 1 (Mar. 20, 1967). He distinguished each study and stated that his own research and subsequent scientific studies had discovered solutions to the problems with earlier Teflon implants. Based on Dr. Homsy's letter and the executed disclaimer, Du Pont agreed to fill Methodist Hospital's requests for Teflon.

In 1977, after the passage of the Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act, Pub. L. No. 94-295, 90 Stat. 539, Du Pont advised Vitek once again that it did not market surgical grades of Teflon. In a policy statement sent to Vitek, Du Pont wrote:

Du Pont Teflon® fluorocarbon resins . . . are made for industrial purposes only. We conduct such tests as are needed to protect the ordinary users of these products but do not perform the detailed, long-term studies which should be made before they are used for medical or surgical purposes. We make no medical or surgical grades and have not sought or received any rulings from the Federal Food and Drug Administration or from any governmental agency as to the safety or effectiveness of these products for such purposes.

Persons proposing to evaluate or to use these products for medical or surgical purposes must rely on their own medical and legal judgment without any representation on our part. They must accept full responsibility for all consequences, either direct or indirect. Any data or other information from Du Pont is supplied in good faith but its applicability in any particular situation must be determined by the recipient.

Statement of Policy Regarding Medical or Surgical Uses of Plastic Materials 1 (May 13, 1977).

Du Pont required Dr. Homsy to sign this policy statement, which also included his agreement to use Du Pont's materials in compliance with FDA regulations and to conduct any clinical tests on humans in accordance with the federal Food, Drug, and Cosmetic Act.

Based on years of clinical studies with Proplast implants in animals and humans and his extensive experience in the manufacturing and marketing of prosthetic devices, Dr. Homsy believed that Proplast was an excellent implant material. Indeed, two FDA advisory committees stated that "the safety and effectiveness of [Proplast] has been established through longterm clinical trials." 47 Fed. Reg. 2810, 2818 (1982) (to be codified at 21 C.F.R. pt. 878) (proposed Jan. 19, 1982). The FDA authorized the sale of Proplast TMJ implants in 1983. By the late 1980s, however, it had become apparent that the FEP film abraded into particles despite the additional precautions Vitek had taken to ensure that this would not In November 1989, Du Pont informed Vitek and Dr. Homsy that it happen. would no longer fill Vitek's orders for Teflon because of concerns about lawsuits spawned by the disintegrating implants. In January 1991, the FDA ordered Proplast implants removed from the market because of their fragmentation and irritation to human tissue.

The Recipients filed this action against the defendants, asserting strict liability and negligence claims. In particular, their case is grounded on two theories of liability: design defect and failure to warn. The Recipients contend that while FEP film may have many safe industrial applications, it was designed defectively for its specific use in the implants because it caused the implants to function in an unreasonably dangerous manner.³ The Recipients also claim that the defendants breached duties owed to them by failing to warn of dangers associated with the implants, insisting that the defendants should have conveyed warnings directly to physicians and patients concerning the dangers of the implants even though the defendants had no direct role in designing or selling the implants.

The District Court granted summary judgment to the defendants, rejecting the design defect claim as well as the failure to warn claim. With respect to the design defect claim, the court concluded that the defendants were entitled to summary judgment because "the undisputed evidence demonstrates that the PTFE and FEP film used in the Vitek TMJ Implants were not `defective products.'" <u>In re TMJ Implants</u>, 872 F. Supp. at 1024.⁴ With respect to the failure to warn claim, the court held that the defendants were entitled to summary judgment because no duty to warn was owed to the Recipients under the raw material/component part supplier doctrine. The court proceeded on the premise that the law refuses

³On appeal, the Recipients have abandoned all claims relating to PTFE resin and instead focus their efforts entirely on FEP film.

⁴The District Court found that PTFE resin and FEP film were not defective products because "[a] manufacturing defect exists only where an item is substandard when compared to other identical units off of the assembly line." In re TMJ Implants Prods. Liab. <u>Litiq.</u>, 872 F. Supp. 1019, 1024 (D. Minn. 1995). The court reasoned that because the Recipients made no claim that the PTFE and FEP film "were somehow inferior to the typical PTFE and FEP film," they were not defective products. Id. Although this "deviation from the norm test" may be appropriate for analyzing claims of manufacturing defect, it is inappropriate to use this test in a design defect case, *i.e.*, where the plaintiff contends that the entire product line is defectively designed. Despite the trial court's error, Du Pont still is entitled to summary judgment once the correct test is applied. This Court may "affirm the district court's judgment on any grounds supported by the record." United States v. Lohman, 74 F.3d 863, 866 (8th Cir.), cert. denied, 116 S. Ct. 2549 (1996).

to hold suppliers of inherently safe and multi-use raw materials responsible for injuries resulting from a dangerous condition created by a finished product manufacturer. Alternatively, the court held that, even assuming that the defendants owed a duty to warn the Recipients, the defendants had discharged their duty as a matter of law under the bulk supplier/sophisticated purchaser doctrine. The court reasoned that, as bulk suppliers to a sophisticated purchaser like Vitek, the defendants discharged any duty to warn the Recipients by making sure that Vitek understood the risks of using Teflon materials in the implants. We affirm the grant of summary judgment to the defendants on both the design defect and failure to warn claims on the basis of the raw material/component part supplier doctrine.⁵

II.

A transferee court has the authority to enter dispositive orders terminating cases consolidated under 28 U.S.C. § 1407. <u>See In re Donald</u> <u>J. Trump Casino Sec. Litig.--Taj Mahal Litig.</u>, 7 F.3d 357, 367-68 (3d Cir. 1993) (Rule 12(b)(6) order), <u>cert. denied</u>, 510 U.S. 1178 (1994). We review <u>de novo</u> the decision to grant summary judgment. <u>Southern Technical</u> <u>College, Inc. v. Hood</u>, 89 F.3d 1381, 1383 (8th Cir. 1996).

When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. <u>See In re Korean Air</u> <u>Lines Disaster</u>, 829 F.2d 1171, 1176 (D.C. Cir. 1987), <u>aff'd</u>, 490 U.S. 122 (1989). When considering questions of state law, however, the transferee court must apply the state law that

⁵The defendants also argue that they are entitled to summary judgment because (1) the Medical Device Amendments of 1976 preempt state actions against manufacturers of bulk medical supplies; and (2) as a bulk supplier to a medical products manufacturer, the FDA and Vitek had the duty to develop adequate warnings. We need not and do not consider these arguments because we affirm the summary judgment in favor of the defendants on other grounds.

would have applied to the individual cases had they not been transferred for consolidation. <u>See In re Air Crash Disaster Near Chicago, Ill.</u>, 644 F.2d 594, 610 (7th Cir.) (holding transferee court must apply the "choiceof-law rules of the states where the actions were originally filed"), <u>cert.</u> <u>denied</u>, 454 U.S. 878 (1981). Products liability claims are, of course, state law tort actions. With approximately 280 cases from across the nation consolidated in this action, we would normally face the daunting task of analyzing the law of each state where the actions were originally filed. The parties, however, have conceded on appeal that "the basis of component part liability law is constant in all jurisdictions." Recipients' Br. at i.

A. Strict Liability Claims

The Restatement (Second) of Torts § 402A (1965) imposes strict liability on sellers of "unreasonably dangerous" products. A product may be considered "unreasonably dangerous" because of (1) a manufacturing defect, (2) a design defect, or (3) a failure to warn of dangers in the product's use. <u>Rynders v. E.I. Du Pont, de Nemours & Co.</u>, 21 F.3d 835, 842 (8th Cir. 1994). As noted above, the Recipients assert that the defendants' FEP film is unreasonably dangerous under the design defect and failure to warn theories.

We first address the design defect claim. The Recipients argue that the District Court erred in granting summary judgment against them because they have raised factual issues as to whether FEP film was defectively designed. The Recipients insist that, even though FEP film has many safe industrial uses and is not inherently dangerous or defective for all uses, the film was defectively designed for its "reasonably foreseeable" use in the implants. Recipients' Br. at 12. In other words, they claim that FEP film was designed defectively, not because it malfunctioned, but because when incorporated into the implants it caused the implants to function in an unreasonably dangerous manner. We reject this argument because suppliers of inherently safe "component parts are not responsible for accidents that result when the parts are integrated into a larger system that the component part supplier did not design or Sperry v. Bauermeister, Inc., 4 F.3d 596, 598 (8th Cir. 1993) build." (discussing a district court's previous application of Missouri law).⁶ After carefully reviewing the record, we are convinced that the undisputed facts show as a matter of law that the defect was in the overall design of the implants and not in the FEP film. FEP film is a mere building-block material suitable for many safe uses. The Recipients' argument boils down to nothing more than the fact that Vitek decided to use what proved to be an unsuitable material to manufacture its implants. The erroneous and unfortunate decision to use FEP film in the design of the implant was made by Vitek, however, not by Du Pont or Durafilm. "[A] component part supplier should not be cast in the role of insurer for any accident that may arise after that component part leaves the supplier's hands." Crossfield v. Quality Control Equip. Co., 1 F.3d 701, 705 (8th Cir. 1993) (discussing a district court's previous application of Missouri law). Therefore, as courts in other TMJ implant cases already have held,⁷ we hold that the defendants were entitled to summary judgment on the design defect claim.

While the law of design defect clearly extends liability to finished product manufacturers like Vitek, it rarely imposes strict liability on component part suppliers who merely sell their multi-use parts to manufacturers of finished products. <u>See</u> W. Page Keeton et al., <u>Prosser and Keeton on the Law of Torts</u> § 100, at 705

⁶We believe it makes no difference whether FEP film is characterized as a "component part" or a "raw material." <u>See Bond</u> <u>v. E.I. Du Pont De Nemours & Co.</u>, 868 P.2d 1114, 1118 (Colo. Ct. App. 1993), <u>cert. denied</u> (Colo. Feb. 28, 1994).

⁷<u>See</u>, <u>e.g.</u>, <u>Jacobs v. E.I. du Pont de Nemours & Co.</u>, 67 F.3d 1219, 1241 (6th Cir. 1995); <u>Hoyt v. Vitek, Inc.</u>, 894 P.2d 1225, 1231 (Or. Ct. App. 1995).

(5th ed. 1984 & Supp. 1988) (citing cases). The critical inquiry focuses on determining the reason why the component part turned out to be unsuitable for use in the finished product. "If the failure was due to a flaw in the component part, then the component part is itself defective and the cause for the assembled product being defective." Id. at 705-06. In such cases, the component part maker may be held strictly liable. Apperson v. E. I. du Pont de Nemours & Co., 41 F.3d 1103, 1106 (7th Cir. 1994) ("Strict liability may extend to manufacturers of component parts for injuries caused by design or manufacturing defects in the component part itself."); Bond v. E.I. Du Pont De Nemours & Co., 868 P.2d 1114, 1119 (Colo. Ct. App. 1993) ("[A] plaintiff must present evidence from which a jury could find that any `defect' was in the `design' of the component part, not the final product."), cert. denied (Colo. Feb. 28, 1994); see also Klem v. E.I. Du Pont De Nemours Co., 19 F.3d 997, 1002-03 (5th Cir. 1994).⁸ If, on the other hand, the finished product was unreasonably dangerous because the component part was unsuited for the particular use that the finished product manufacturer chose to make of it, then the defect is in the design of the finished product rather than in the design of the component part. In these cases, it is the finished product

⁸A supplier of component parts may also be held strictly liable if the parts it supplies were specially designed for a particular use, see Fleck v. KDI Sylvan Pools, Inc., 981 F.2d 107, 118 (3d Cir. 1992) (replacement pool liner in failure to warn case), cert. denied, 507 U.S. 1005 (1993); Maake v. Ross Operating Valve Co., 717 P.2d 923, 926 (Ariz. Ct. App. 1985) (valve designed to limit machine on which it was installed to one cycle for each activation in failure to warn case), review denied (Ariz. Apr. 15, 1986); or if the component supplier exercised some control over the design of the final product, <u>DeSantis v. Parker Feeders, Inc.</u>, 547 F.2d 357, 361 (7th Cir. 1976) (cattle feeder); Estate of Carey by <u>Carey v. Hy-Temp Mfg., Inc.</u>, 702 F. Supp. 666, 670 (N.D. Ill. 1988) (furnace vent damper); Rourke v. Garza, 530 S.W.2d 794, 801 (Tex. 1975) (leased scaffolding supplied to construction company). In this case, it is undisputed that FEP film was designed to be useful in a broad, nonparticularized range of applications and that the defendants did not exercise any control over the design of the implants.

manufacturer and not the component part supplier that may be held strictly liable. Sperry, 4 F.3d at 598 (affirming summary judgment for component airlock supplier where part was "integrated into a larger [spice milling] system that the component part supplier did not design or build"); Childress v. Gresen Mfg. Co., 888 F.2d 45, 49 (6th Cir. 1989) (affirming summary judgment for component valve supplier where design defect was in the finished log-splitter); see also Lee v. Butcher Boy, 215 Cal. Rptr. 195, 198-99 (Cal. Ct. App. 1985) (no design defect in component motor; design defect was in finished meat grinder); Moor v. Iowa Mfg. Co., 320 N.W.2d 927, 928 (S.D. 1982) (no design defect in component roller; design defect was in finished conveyor). In this case, the undisputed facts show as a matter of law that the defect was in the overall design of the implants and not in the design of FEP film. The Recipients simply have failed to show that the disintegration of the implants was due to any design defect in the FEP film itself rather than to Vitek's erroneous decision to incorporate what turned out to be an unsuitable material into its implants.

The Recipients argue that our focus should not be "on the general uses of FEP film but rather on the defective nature of FEP film for its reasonably foreseeable use in TMJ implants." Recipients' Reply Br. at 5. We disagree. "While manufacturers of inherently dangerous raw materials will be held liable for injury caused by their product, courts have treated differently manufacturers of inherently <u>safe</u> components when the final assembly, rather than a manufacturing or design defect in the component itself, renders the component dangerous." <u>Apperson</u>, 41 F.3d at 1107 (citation omitted). Indeed, "[t]he alleged foreseeability of the risk of the finished product is irrelevant to determining the liability of the component part manufacturer because imposing such a duty would force the supplier to retain an expert in every finished product manufacturer's line of business and second-guess the finished product manufacturer whenever any of its employees received any information about any potential problems." Kealoha v. E.I. Du Pont de Nemours & Co., 844 F. Supp. 590, 594 (D. Haw. 1994), aff'd, 82 F.3d 894, 901 (9th Cir. 1996) ("Since the district court's application of the raw material supplier defense is reasonable and supported by the record, we hold that the district court did not err in declining to consider the issue of foreseeability."). Making suppliers of inherently safe raw materials and component parts pay for the mistakes of the finished product manufacturer would not only be unfair, but it also would impose an intolerable burden on the business world, especially where, as here, the raw material or component part (the FEP film) accounts for only a few cents' worth of the cost of the entire finished product (the Proplast TMJ implant). See Kealoha, 844 F. Supp. at 595 ("[T]he cost to a manufacturer of an inherently safe raw material to insure against all conceivable misuse of his product would be prohibitively expensive."). As another panel of this Court has determined in a previous TMJ case, "[i]t would be unreasonable and impractical to place the burden of testing and developing all devices that incorporate Teflon as a component on Du Pont." <u>Rynders</u>, 21 F.3d at 842. Suppliers of versatile materials like chains, valves, sand, gravel, etc., cannot be expected to become experts in the infinite number of finished products that might conceivably incorporate their multi-use raw materials or components. Kealoha, 844 F. Supp. at 594 ("[T]here would be no end to potential liability if every manufacturer of nuts, bolts and screws could be held liable when their hardware was used in a defective product."). We thus believe that the Recipients' argument must be rejected.

While the Recipients may allege that FEP film was unreasonably dangerous or defective as incorporated in the implant, the Recipients' real complaint is that FEP film turned out to be an unsuitable material to use in the implant. Thus, the defect was in the design of the implant rather than in the design of the defendants' Teflon products. If Du Pont had designed FEP film differently, it simply would not have been FEP film. As the Fifth Circuit recently noted in another TMJ case:

If Du Pont had designed Teflon otherwise, it would not have been Teflon. Similarly, if a different product would have served more safely in its stead, Dr. Homsy erred by choosing Teflon for use in TMJ implants. The design of Teflon was not, in this context, defective. Any fault lay with Homsy's selection. Teflon therefore is not unreasonably dangerous in design.

Klem, 19 F.3d at 1003; accord Hoyt v. Vitek, Inc., 894 P.2d 1225, 1231 (Or. Ct. App. 1995) ("In short, if Teflon were designed differently, it would not have the properties that make it useful in so many applications."); Longo v. E.I. Dupont De Nemours & Co., 632 So. 2d 1193, 1197 (La. Ct. App.) ("[B]ecause of its unique and peculiar qualities, there appears to be no question but that Teflon could not have been designed with less harmful consequences. If so, it would not have been Teflon."), writ denied, 637 So. 2d 464 (La. 1994). There is no allegation that FEP film, in and of itself, is inherently dangerous. Indeed, the Recipients concede that FEP film has many safe industrial uses. As the Seventh Circuit noted, "Clearly, Teflon is a raw material with many safe uses; it only became dangerous when Vitek incorporated it into a highly specialized medical device, the Proplast TMJ Implant." Apperson, 41 F.3d at 1106; see also Jacobs v. E.I. du Pont de Nemours & Co., 67 F.3d 1219, 1241 (6th Cir. 1995); Hoyt, 894 P.2d at 1232. In these circumstances, the responsibility to design a safe medical device is Vitek's alone because, as the finished product manufacturer, it knew the specific end-use it intended to make of the FEP film and was in a far better position to evaluate the film's safety for that particular end-use. Summary judgment thus was properly granted for the defendants on the design defect claim.

We next turn to the failure to warn claim. The Recipients contend that the District Court erred in granting summary judgment to the defendants because there is a genuine issue of material fact as to whether the defendants had a duty to warn them of the dangers posed by the FEP film in the implants. Whether the defendants owed a duty to warn the Recipients is a question of law. <u>See Schaffer v. A.O. Smith Harvestore</u> <u>Prods., Inc.</u>, 74 F.3d 722, 729 (6th Cir. 1996). Under the raw material/component part supplier doctrine, suppliers of inherently safe raw materials have no duty to warn end-users of a finished product about dangers posed by the incorporation of the raw materials into that product.⁹

A failure to warn claim brought against suppliers of multi-purpose components is precluded by the same raw material/component part supplier analysis that forecloses design defect claims. For example, in Crossfield v. Quality Control Equipment Co., 1 F.3d 701 (applying Missouri law), we held that raw material or component part suppliers have no duty to warn the ultimate consumer of other companies' finished products if the raw materials or components have multiple safe uses and are not inherently dangerous. Id. at 706. In that case, a supplier sold a chain to a finished product manufacturer who subsequently incorporated the chain into a chitterlings cleaning machine. Even though the chain itself was not defective, a worker was severely injured when her hand was caught in the chain-sprocket mechanism of the machine. This Court refused to hold the chain supplier liable, finding "the primary duty [to warn] was owed by the designer of the machine, not the supplier of only one component part, in itself a non-defective element." <u>Id.</u> at 704. We reasoned that the dangerousness stemmed from the overall design of the chitterlings machine as a finished

⁹Several courts have reached this conclusion in other TMJ implant cases. <u>See</u>, <u>e.g.</u>, <u>Kealoha v. E.I. du Pont de Nemours &</u> <u>Co.</u>, 82 F.3d 894, 899-901 (9th Cir. 1996); <u>Jacobs</u>, 67 F.3d at 1236-38; <u>Klem v. E.I. Du Pont De Nemours & Co.</u>, 19 F.3d 997, 1003 (5th Cir. 1994); <u>Longo v. E.I. Dupont De Nemours & Co.</u>, 632 So. 2d 1193, 1197 (La. Ct. App.), <u>writ denied</u>, 637 So. 2d 464 (La. 1994); <u>Westphal v. E.I. du Pont de Nemours & Co.</u>, 531 N.W.2d 386, 391 (Wis. Ct. App.), <u>review denied</u>, 537 N.W.2d 571 (Wis. 1995).

product and not from the chain alone as a mere component part. We placed particular emphasis on the fact that "the chain, standing alone, is not an inherently dangerous product," <u>id.</u> at 703-704, and that the chain supplier had no role in designing or building the finished product, <u>id.</u> at 705.

Like the chain in <u>Crossfield</u>, the defendants' FEP film is safe for As we already have noted in our discussion of the multiple uses. Recipients' design defect claim, any danger associated with FEP film stemmed from Vitek's overall design of the Proplast implant. FEP film, in and of itself, is not an inherently dangerous product. Moreover, Du Pont exercised no control over the design, testing, or manufacturing of Proplast or the implants. Accordingly, as the manufacturer of a perfectly good material that Vitek put to a use for which the material, as we now know, was unsuited, Du Pont had no duty to warn the Recipients. "To impose responsibility on the supplier of [a nondefective component] in the context of the larger defectively designed machine system would simply extend liability too far." Id. at 704; see also Childress, 888 F.2d at 49 ("[E]xtending the duty to make a product safe to the manufacturer of a nondefective component part would be tantamount to charging a component part manufacturer with knowledge that is superior to that of the completed product manufacturer."); Bond, 868 P.2d at 1120-21 ("[T]here 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."). As we said in <u>Crossfield</u>, "Mere suppliers cannot be expected to guarantee the safety of other manufacturers' machinery." 1 F.3d at 704. Similarly, the defendants, as mere suppliers of FEP film, cannot be expected to guarantee the safety of Vitek's medical devices. We therefore agree with the District Court that the defendants owed no duty to warn the Recipients. Summary judgment thus was properly granted for the defendants on the failure to warn claim.

B. Negligence Claims

The Recipients also argue that the defendants negligently failed to warn them of FEP film's dangerous propensities when used in the implants. This argument must fail, however, because "the same analysis which leads us to the conclusion that [the defendants] had no duty to warn plaintiffs under a theory of strict liability leads us to conclude that [they] had no duty to warn under a theory of negligence." <u>Bond</u>, 868 P.2d at 1120; <u>accord Klem</u>, 19 F.3d at 1003 (holding negligence and strict liability claims "duplicate" each other); <u>Veil v. Vitek, Inc.</u>, 803 F. Supp. 229, 234 (D.N.D. 1992) ("there is no significant difference between the theories"); <u>see also</u> Keeton et al., <u>supra</u>, § 99, at 697. Consequently, whether the Recipients frame their argument in terms of negligence or strict liability, the result is the same: suppliers of safe, multi-purpose raw materials have no duty to warn the ultimate consumer of a finished product about dangers that may exist when the raw materials are integrated into the final product.

III.

The District Court articulated two additional reasons why Durafilm was entitled to prevail on its summary judgment motion. First, a distributor, acting as a mere conduit of a product, is only liable for known dangers. <u>See American Law of Products Liability 3d</u> § 5.23, at 43 (Matthew J. Canavan, ed. pt. 3, 1994). If a product has at most a latent defect, "there is no duty on the distributor to inspect for possibly inherent defects." <u>Id.</u> at 43-44. Based on these legal principles, the District Court concluded that even if it "were to accept Plaintiffs' argument that DuPont's products were defective, such defect would surely be considered latent." <u>In re TMJ Implants</u>, 872 F. Supp. at 1034. We agree with this analysis. Consequently, Durafilm had no duty to inspect for and warn of such defects.

Second, several state statutory schemes explicitly exempt mer distributors from strict liability. ____, e.g. 106(b) (Supp. 1996) (stating seller not subject to strict liability unless is also the manufacturer); Mo. Rev. Stat. § 537.762 (1994) (allowin dismissal of seller in products liability defendant). Such statutory exemptions also for gr ______ d actions.

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For affirmed.
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I respectfully dissent. The majority expands the component par supplier doctrine to shield from liability knew how their product was going to be used and knew d grave er to the ultimate consumers. I cannot accept such blanket In this case, I would permit the Recipients' claims to go to a jury for a determination of what DuPont

¹I recognize that the majority is in our sister circuits in its expansive application of the component This t. decision. Both _ _, 21 F.3d 835 8th Cir. 1994) and our summary affirmance of Hegna v. E.I <u>DuPont De Nemours & Co.</u>, 825 F. Supp. 880 (D. Minn. 1993) <u>f'd</u>, 27 d 571 (8th Cir. 1994) involved PTFE resin--the Teflon produc that underwent substantial change after leaving DuPont's control-the TMJ implan Moreover, in <u>Rynders</u> 1 F.3d at 84, and in _____, summary judgment was premised on DuPont's gs to Vitek, 825 F. Supp. at 884. Our court has no previously 1 manufacturers of component parts.

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whether it had a duty to prohibit the sale of Teflon for use in human implants, or at least to provide adequate warnings to Vitek of those known risks.

Underlying the component part supplier doctrine is the premise that the manufacturer of a finished product is generally in a better position to detect its potential dangers than the manufacturer of only a part of the product. Certainly, a finished product manufacturer is responsible for dangers that result from the product design or from the manner in which a component part is integrated into the finished product. As a corollary, manufacturers of a component part generally will not know about such dangers and should not be required to research every possible application of its nondefective, multi-use product. <u>See Crossfield v. Quality Control Equip. Co.</u>, 1 F.3d 701, 705 (8th Cir. 1993) ("[M]anufacturers of component parts which are not defective standing alone cannot be liable for accidents taking place after the part has been integrated into a larger system which they played no part in building.").

But the facts of this case place it outside the parameters of the general component part supplier doctrine. The Recipients have presented evidence sufficient for a jury to find that DuPont knew Vitek was going to use the Teflon in the TMJ implants. There is also evidence that Dupont knew that Teflon, used in load-bearing human implants, <u>no matter how the implants were designed</u>, can disintegrate and cause injury to implant recipients. DuPont was aware of several studies demonstrating this precise risk. Moreover, a chemist who worked for DuPont for over thirty years testified that a known characteristic of all Teflon, including FEP film, is that it severely fragments after constant contact with and pressure from sharp edges. (Appellants' App. at 370 (Tab 61) (Dep. of Dr. James Fang).)

This is not a case, as the majority contends, of an "erroneous decision to incorporate what <u>turned out</u> to be an unsuitable material." Maj. Op., <u>supra</u> at 11. Rather, the evidence suggests that DuPont was fully aware of the serious risk of harm Teflon posed when used in human implants. To hold DuPont responsible for these known risks would not require component part suppliers to research every possible application of its product; it recognizes DuPont's actual knowledge, without any further research or speculation. Nor are the Recipients claiming that DuPont should have designed FEP film differently, as the majority suggests, but that if DuPont knew the film was inappropriate for use in human implants, it should not have continued to supply the film.

There is significant "social utility" in making DuPont accountable for what it knew and for its failure to prevent harm to the ultimate consumers. While Vitek may have been in the better position to evaluate the film's safety for the particular use, DuPont's position may well have been sufficient for it to have known of the harm Teflon posed in the human implants. It is my position that where the component part manufacturer knows that its product is going to be used in a particular fashion and knows that, no matter what the design, the product poses a danger to the ultimate consumer, it cannot escape from liability.

A true copy.

Attest:

CLERK, U. S. COURT OF APPEALS, EIGHTH CIRCUIT.

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