2-7-1995

Michael v Shiley, Inc.

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 94-1496

NINA MICHAEL,

Appellant

v.

SHILEY, INC.;
HOSPITAL PRODUCTS GROUP, INC.,
(FORMERLY HOWMEDICA, INC.);
PFIZER, INC.

On Appeal from the United States District Court
for the Eastern District of Pennsylvania
(D.C. Civil No. 93-1729)

Argued Monday, October 24, 1994

BEFORE: STAPLETON, HUTCHINSON and GARTH, Circuit Judges

(Opinion filed February 7, 1995)

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OPINION OF THE COURT

GARTH, Circuit Judge:

This appeal requires that we determine how the Medical Devices Amendments of 1976 which amended the Food, Drug and Cosmetics Act of 1938, 21 U.S.C. § 360-360rr, allocates authority between the states and the Food and Drug Administration. To be precise, we must decide whether 21 U.S.C. § 360k pre-empts Nina Michael's state law causes of action for negligent manufacture and design, strict product liability, breach of the implied warranty of merchantability, breach of an express warranty, and common law fraud against Shiley Inc., the manufacturer of the Bjork-Shiley Heart Valve.

Applying the express pre-emption analysis defined by Cipollone v. Liggett Group Inc., 112 S. Ct. 2608 (1992), we conclude that § 360k pre-empts Michael's cause of action for negligence (both manufacturing and design), strict product

liability, and breach of the implied warranty of merchantability. We also hold that Michael's complaint to the extent that it relies on fraud perpetrated by Shiley on the FDA is pre-empted. Finally, we hold that § 360k does not preclude Michael from pursuing common law causes of action for express warranty and for fraud to the extent that the fraud arises from Shiley's efforts to promote its product through letters to doctors and advertisements in medical journals.

Accordingly, while we will affirm the district court's pre-emption rulings as to Michael's negligence, strict product liability, and implied warranty claims, we will reverse the district court's summary judgment to the extent that it entered judgment against Michael on her express warranty and fraud claims.

I

A.

Nina Michael's claims arise from the discovery in the past fifteen years that the outlet strut of the Bjork-Shiley 60 Degree Convexo-Concave Disc Heart Valve ("Shiley valve"), which was designed and manufactured by Shiley Inc., fractures in approximately one percent of the patients who received a Shiley implant. App. 200. These failures result from a weak strut mechanism and from poor manufacturing standards at Shiley's facilities. A strut failure leads inevitably to death or serious injury.

B.

The Shiley valve was one of the first medical devices to be approved under the 1976 Medical Device Amendments to the Food Drug and Cosmetics Act of 1938 (the "MDA"), a comprehensive extension of the FDA's authority beyond medical drug manufacturers to medical device manufacturers. Pub. L. No. 94-295, 90 Stat. 539 (1976). Congress passed the Amendments in response to the harm caused by the Dalkon Shield, an unregulated medical device which resulted in serious injury to a large number of women.[1] Sen. Rep. No. 33, 94th Cong., 1st Sess. 2 reprinted in 1976 U.S. Code Cong. & Admin. News 1070, 1071. Through the MDA, Congress hoped "to assure the reasonable safety and effectiveness of medical devices intended for human use." H. Conf. Rep. No. 1090, 94th Cong., 1st Sess. 51 reprinted in 1976 U.S. Code Cong. & Admin. News 1103, 1103. To do so, it granted the FDA new broad powers to regulate medical devices, which powers are based on three statutory classifications.

Class I devices, such as tongue depressors, are devices which generally pose little or no threat to public health and are subject only to general controls on manufacturing. See 21 U.S.C. § 360c(a)(1)(A). Class II devices, such as oxygen masks, pose a slightly greater risk of injury to patients, and accordingly, the MDA subjects them to performance standards, post market

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[1]. For a history of the harm which resulted from the Dalkon Shield, see In re A.H. Robins Co., 880 F.2d 709, 710-12 (4th Cir.), cert. denied sub nom, Anderson v. Aetna Casualty and Surety Co., 493 U.S. 959 (1989).

surveillance, guidelines for use and other appropriate controls. See id § 360c(a)(1)(B). Class III devices, such as the Shiley valve, include all devices which are to be implanted into people, which are used to sustain life, or which pose a potentially unreasonable risk of injury. See id. § 360c(a)(1)(C).

Class III devices may not be marketed or sold until the sponsoring company obtains Premarket Approval (PMA) from the FDA. Id. § 360e. To obtain a PMA, the sponsor must submit "all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective," id. § 360e(c)(1)(A), a statement of the intended use of the product, a description of the expected manufacturing processes for the device, and any other information requested by the FDA. Id. § 360e(c)(1)(B)-(G). After review by a panel of medical experts, the FDA may approve the PMA.

The FDA retains continuing oversight over approved Class III devices. It requires manufacturers to report any deaths or serious injuries which result from the use of the product. See 21 C.F.R. § 803.24(c). It may require warning or instructions on the labels which accompany the product. 21 C.F.R. § 814.82. Finally, the FDA regulates the manufacture of the devices through the imposition of good manufacturing processes. 21 C.F.R. § 820.100-820.101. The only remedial power granted to the FDA is the power to require the sponsor of the product to notify the public of a newly discovered danger posed by the product, order the company to replace the device, or order the company to refund

the purchase price to the patient. The FDA can take these actions only if it determines that the device presents an unreasonable risk of substantial harm to the public. 21 U.S.C. § 360h(a). The act does not permit the FDA to require companies to compensate victims for their medical expenses or for the pain and suffering resulting from a device failure.

C.

Shortly after the passage of the MDA, Shiley applied for Premarket Approval (PMA) to market the Shiley valve. At the time, the FDA's procedures for PMA applications had not been finalized, see 51 Fed. Reg. 26364 (July 22, 1986) (defining PMA procedures), and thus the Shiley application did not receive the same organized and comprehensive evaluation that might be expected today. Sen. Comm. on Energy & Commerce, 101st Cong., 2d Sess., The Bjork-Shiley Valve: Earn as You Learn 20-22 (Comm. Print 1990) [hereinafter Energy & Commerce Report]. For example, evidence of the first strut fracture was belatedly brought to the FDA's attention and explained as an "isolated incident" even though it was unexplained at the time of the application. Id. at 21. Further, Shiley made claims, based on unsubstantiated data, that reduced heart complications would result from Shiley valve implants.[2] Id. at 22-24. Despite these deficiencies, the FDA

[2]. Specifically, Shiley claimed a reduction in the rate of thromboembolism, the development of potentially dangerous blood clots at the valve's location. The FDA later determined that there was no improvement in the rates of thromboembolism with the new valve and that this information, if known at the time the PMA

approved the PMA on April 27, 1979, without a recorded vote. Id. at 22.

Between 1979 and 1983, the struts which hold the mechanical valves in place in 73 Shiley valves fractured, id at 28, leading to the death of most of the implanted individuals. These fractures were the result of both the valve's design and poor manufacturing processes. In particular, the valves suffered from poor welding and poor quality control. See id. at 5-14; App. 461, 615-16, 623-25. During this period, Shiley sent a set of letters to doctors and to the FDA reassuring them that these incidents did not compromise the integrity, safety, or effectiveness of the device. Energy & Commerce Report at 14-17. Despite a redesign of the manufacturing process, continuing strut fractures forced Shiley to recall those valves which had not been implanted in 1980, 1982, and 1983. Because of continuing problems with valve failures, Shiley recalled its larger size valves and ceased production of those sizes in October 1985. Finally, on November 24, 1986, Shiley withdrew all its remaining valves from the market and ceased production of any heart valves. On March 21, 1990, Shiley asked the FDA to withdraw its Premarket Approval. To date, approximately 501 Shiley valves have fractured, resulting in 347 deaths. App. 691.

D.

(..continued)
was filed, would likely have prevented FDA approval. App. 766-68.

These events first affected Nina Michael in 1981. In that year, Michael was diagnosed with a congenital defect with her mitral heart valve, which controls of the flow of blood between the left atrium and the left ventricle. Because the defect was potentially fatal, Michael underwent surgery to have her natural heart valve replaced with the Shiley valve on November 24, 1982.

The surgery was successful and the valve functioned properly. The valve implanted in Michael came with the following disclosure under the heading "Disclaimer of Warranties":

> Shiley warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties, whether express, implied, written or oral.

App. 680.

In the late 1980s and early 1990s, Michael became aware of the strut fracture problem through media sources and her doctor. Research disclosed that her class of valves was among the Shiley valves with the highest rate of failure. It was estimated that there was a two percent chance per year that a catastrophic valve failure would occur in the Shiley valve implanted in Michael. These disclosures caused Michael significant anxiety, which resulted in sleeplessness and other emotional and physical symptoms.

After consultations with her physicians, Michael had the Shiley valve surgically removed and replaced with a different valve in June 1992. The surgeon visually examined her explanted

valve and found no visible defects. The valve was later discarded.

In March 1993, Michael filed a complaint in the Philadelphia Court of Common Pleas, alleging state law claims of negligence, strict product liability, breach of implied warranties, breach of express warranties, and fraud. App. 10-29. Her complaint named Shiley Inc., the maker of the Shiley valve; Pfizer Inc., Shiley's corporate parent; and Hospital Products Group Inc., another corporate owner of Shiley. Shiley removed the case to the Eastern District of Pennsylvania on the basis of diversity jurisdiction. App. 31. On August 16, 1993, Shiley filed two summary judgment motions. One motion alleged that all claims except the express warranty claim were pre-empted. The second motion alleged that Michael had failed to raise a genuine issue of material fact to support her claims.

Through orders dated February 25, 1994, March 31, 1994, and April 7, 1994, the district court granted judgment on all the claims against Michael and in favor of Shiley. It granted judgment on the negligence, strict product liability, and implied warranty claims on both pre-emption and traditional Rule 56 grounds. See Fed. R. Civ. P. 56(c). It granted judgment on the express warranty claim for failure to raise a genuine issue of material fact. Finally, it granted judgment on the fraud claim solely because it was pre-empted.

Michael filed a timely notice of appeal.

II.

We exercise plenary review of the district court's grant of summary judgment and apply the same test that the district court should have applied initially. Goodman v. Mead Johnson & Co., 534 F.2d 566, 573 (3d Cir. 1976), cert. denied, 429 U.S. 1038 (1977). Thus, we will affirm only if Michael has failed to raise a genuine issue of material fact and Shiley is entitled to a judgment as a matter of law. Id. In examining the record, we give the nonmoving party the benefit of all reasonable inferences from the record. Gray v. York Newspapers, Inc., 957 F.2d 1070, 1078 (3d Cir. 1992). We exercise plenary review over the district court's pre-emption determination, as it is a question of law. Travitz v. Northeast Dep't ILGWU Health & Welfare Fund, 13 F.3d 704, 708 (3d Cir.), cert. denied, 114 S. Ct. 2165 (1994). We also exercise plenary review over the district court's application of state law. Salve Regina College v. Russell, 499 U.S. 225, 231 (1991).

III

A.

The parties' core dispute is whether, or to what extent, the MDA pre-empts Michael's state common law causes of action. Article VI of the Constitution provides that the laws of the United States "shall be the supreme Law of the Land; . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const. art. VI, cl. 2. By virtue of this grant of federal power, Congress can through a sufficiently clear expression of its intent displace state law. Cipollone v.

Liggett Group, Inc., 112 S. Ct. 2608, 2617 (1992);[3] CSX Transp. Inc. v. Easterwood, 113 S. Ct. 1732, 1737 (1993) ("[P]re-emption will not lie unless it is `the clear and manifest purpose of Congress.'") (quoting Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947)). "In the interest of avoiding unintended encroachment on the authority of the States, however, a court interpreting a federal statute pertaining to a subject traditionally governed by state law will be reluctant to find pre-emption." CSX Transp. Inc., 113 S. Ct. at 1737.

Pre-emption may arise explicitly from the statute's language or implicitly from the statute's structure and purpose. Morales v. Trans World Airlines, Inc., 112 S. Ct. 2031, 2036 (1992). Nonetheless, "[w]hen Congress has considered the issue of pre-emption and has included in the enacted legislation a provision explicitly addressing that issue, and when that provision provides a reliable indicium of congressional intent with respect to state authority, there is no need to infer congressional intent to pre-empt state laws from the substantive provisions of legislation." Cipollone, 112 S. Ct. at 2618 (quotations and citations omitted).

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[3]. We recognize that Cipollone was decided by a plurality of the Supreme Court. We are satisfied that the pre-emption discussion and holding represents the Court's current pre-emption analysis. See, e.g., American Airlines, Inc. v. Wolens, 1995 WL 15047 (U.S. 1995); Gile v. Optical Radiation Corp., 22 F.3d 540, 542 (3d Cir. 1994); Weber v. Heaney, 995 F.2d 872, 875 (8th Cir. 1993); Cleveland v. Piper Aircraft Corp., 985 F.2d 1438, 1443 (10th Cir.), cert. denied, 114 S. Ct. 291 (1993).

Because Shiley relies upon the express pre-emptive scope of 21 U.S.C. § 360k, our task is primarily one of statutory construction. Id. at 2621. We must give the language of § 360k "a fair but narrow reading" which will give effect to Congress' purpose without undermining "the strong presumption against pre-emption." Id.

Cipollone illustrates the manner in which we are to apply these doctrines. In Cipollone, the Supreme Court considered whether the Cigarette Labeling and Advertising Act of 1965 or the Public Health Cigarette Smoking Act of 1969 pre-empted Rose Cipollone's state common law causes of action for failure to warn, breach of express warranty, fraudulent misrepresentation, and conspiracy claims. The Court concluded that the limited language of the 1965 act did not prevent a state claimant from recovering damages in a state common law cause of action not otherwise pre-empted. 112 S. Ct. at 2619.

The Court turned to the broader pre-emption provision of the 1965 Act which stated "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of cigarettes . . . ." Id. at 2617. Applying a "fair but narrow" reading of this provision, the Court held that Cipollone could not maintain a failure to warn claim because the statute prevented states from requiring any warning beyond the federally mandated statement "CAUTION: CIGARETTE SMOKING IS DANGEROUS TO YOUR HEALTH." Id. at 2621-22. In contrast, the Court concluded that Cipollone's express warranty and fraud claims could proceed. The contract claim was

not "imposed under State law" and the fraud claim did not impose a requirement "with respect to the advertising or promotion of cigarettes." Id. at 2622-24.

B.

Statutory interpretation begins with an analysis of the statute's language. Section 360k(a) provides:

> Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement --
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

This section pre-empts only state imposed requirements. Further, it pre-empts those requirements only when they differ from or add to a previously established FDA requirement and relate to the safety or efficacy of the regulated device. When a state law differs from or adds to a FDA requirement and when a state law relates to the safety or effectiveness of a device approved by the FDA, the state law is pre-empted. Conversely, when a state law neither imposes requirements nor differs from or adds to a FDA requirement nor relates to the safety or effectiveness of the device or to any other matter included in a FDA requirement, the state law is not pre-empted by § 360k.

C.

We first consider Michael's two threshold arguments: (1) that state common law does not impose "requirements" and (2) that the FDA imposed no "requirements" on Shiley. Either would prevent the MDA from pre-empting any of her claims.

An extended discussion of whether the state common law imposes requirements under the MDA is unnecessary.[4] We have already determined that the term "requirements" as used in § 360k encompasses state common law claims. Gile v. Optical Radiation Corp., 22 F.3d 540, 541-42 (3d Cir.), cert denied, 115 S. Ct. 429 (1994). In Gile, we followed the Supreme Court in its interpretation of the term "requirement" as used in § 5(b) of the Public Health Cigarette Smoking Act of 1969. There the Court "reject[ed Cipollone's] argument that the phrase `requirement or

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[4]. Michael points in particular to the FDA regulations which interpret § 360k. See 21 C.F.R. § 808.1. 21 C.F.R. § 808.1(d)(1) states:

> [Section 360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g. requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

Despite the reference in 21 C.F.R. § 808.1(d)(1) to laws of general applicability, we hold that the statutory language of § 360k preempts Michael's claims for breach of the implied warranties of merchantability and fitness as explained in section IV. A. infra.

We express no view on the validity of § 808.1(d)(1) because Shiley disclaimed all implied warranties as it was entitled to do under the Code.

prohibition' limits the 1969 Act's pre-emptive scope to positive enactments by legislatures and agencies." Cipollone, 112 S. Ct. at 2620.

D.

Michael next argues that, while we could normally conclude that the FDA had imposed requirements on a manufacturer, the unique facts of this case preclude such a determination. Michael's argument is based on failings in the Premarket Approval and oversight process which arose because Shiley's heart valve was among the first mechanical devices approved under the MDA. According to Michael, these failings kept the FDA from imposing any requirements on Shiley.

Michael claims that the lack of FDA requirements is proved by the absence of any specific regulations which govern heart valves as compared with the other medical devices. Cf. 21 C.F.R. § 813.1 - 813.170 (regulating the testing and manufacture of intraocular lenses); 21 C.F.R. § 870.1025 - 870.5925 (classifying and imposing requirements on various cardiovascular devices). To support this claim, Michael points to the FDA's statement that the MDA pre-empts state requirements only when the FDA "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act . . . ." 21 C.F.R. § 808.1(d).

The absence of regulations relating specifically to heart valves is not dispositive as long as the Shiley valve was subject to "any requirement applicable under [the MDA] to the device."

21 U.S.C. § 360k(a)(1). While Shiley's premarket application may indeed have been flawed, there is ample evidence that the Shiley valve was subject to requirements under the MDA. First, it is clear that Shiley had to and did obtain a PMA prior to marketing the device. See 21 U.S.C. § 360e. After Premarket Approval was obtained, Shiley was subject to the labeling requirements of 21 C.F.R. § 801.1 - 801.16, which became effective February 13, 1976, and of 21 C.F.R. § 820.1 - 820.198, which defined the general "good manufacturing practices" ("GMP") required of medical device manufacturers after July 21, 1978. See 41 Fed. Reg. 6896 (1976); 43 Fed. Reg. 31508 (1978). The FDA had the power to force notification of a previously unknown risk under 21 U.S.C. § 360h(a)[5] and at least once threatened to use this power.

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[5]. 21 U.S.C. § 360h(a) reads in relevant part as follows:

> (a) **Notification**
>
> If the Secretary determines that--
>
> (1) a device intended for human use which is introduced or delivered for introduction into interstate commerce for commercial distribution presents an unreasonable risk of substantial harm to the public health, and
>
> (2) notification under this subsection is necessary to eliminate the unreasonable risk of such harm and no more practicable means is available under the provisions of this chapter (other than this section) to eliminate such risk,
>
> the Secretary may issue such order as may be necessary to assure that adequate notification is provided in an appropriate form, by the persons and means best suited under the circumstances involved, to all health professionals who prescribe or use the device and to any other person (including manufacturer, importers, distributors, retailers, and device users) who should

See app. 766-69. Even though these generally applicable regulations do not rise to the level of specificity present in the case of some other devices regulated by the FDA, we conclude that they present "specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d). They therefore constitute proper bases for pre-emption under § 360k.

IV

Having disposed of Michael's general allegations, we consider whether § 360k pre-empts the separate theories of recovery that Michael alleges. See Cipollone, 112 S. Ct. at 2621 (considering each of Cipollone's theories of recovery to determine if they are pre-empted). Because Gile has already determined that state law negligence and strict product liability claims are pre-empted under § 360k on account of the potential conflict with FDA labeling, design, and manufacturing requirements, we will not discuss those claims further than to restate that they are pre-empted. See Gile, 22 F.3d at 543-44.

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properly receive such notification in order to eliminate such risk.

A.

Breach of Implied Warranties -- Pre-empted

Michael brings a claim for breach of the implied warranties of merchantability and fitness for a particular purpose. 13 Penn. Con. Stat. Ann. §§ 2314, 2315. These Uniform Commercial Code causes of action meet the first requirement of pre-emption under § 360k; they are state imposed. They "arise by operation of law" in any transaction in goods in Pennsylvania. Altronics of Bethlehem, Inc. v. Repco, Inc., 957 F.2d 1102, 1105 (3d Cir. 1992). The requirements imposed by §§ 2314 and 2315 also potentially differ from or exceed the FDA's requirements. To decide Michael's implied warranty claims, the jury would have to decide whether the Shiley valve was defective. Id.; see also 13 Penn. Cons. Stat. Ann. § 2314 (Goods must be "fit for the ordinary purpose for which such goods are used."). In Michael's case, this determination would require a finding that the heart valve's design was flawed, unreasonably dangerous, or poorly manufactured. Id.

This conclusion by necessity depends upon the accepted standards for the design and manufacture of products in the state of Pennsylvania. These standards may deviate from the FDA's determinations in the PMA process or from the FDA's "good manufacturing practices," which represent the agency's expert evaluation regarding the design and production of the Shiley valve. Section 360k does not permit this conflict. Accord King v. Collagen Corp., 983 F.2d 1130, 1135 (1st Cir.), cert. denied, 114 S. Ct. 84 (1993).

B.

Express Warranty Based on Shiley's Label -- Not Pre-empted

Michael also brought an express warranty claim based on Shiley's statement on its packaging that it "warrants that reasonable care has been used in the manufacture of this device." App. 680.

Before we address this issue, we must consider, as a threshold issue, whether the district court ruled that this claim was pre-empted. The district court's February 25, 1994 order granted Shiley's motion for partial summary judgment based on pre-emption. Shiley's motion had sought the entry of summary judgment on Michael's claims of negligence, strict product liability, breach of implied warranties, and fraud claims, but not on Michael's breach of express warranty claim. App. 48. However, in ruling on Shiley' motion, the district court stated, "[w]e have held that the MDA has wholly pre-empted plaintiff's state law claims against defendants." App. 1362. On appeal, Shiley has argued that we can reach the question of pre-emption because the district court granted summary judgment on Michael's express warranty claim for failure to raise a genuine issue of material fact and we can affirm on any appropriate ground. Shiley's Br. at 28. Because "[t]he prevailing party may, of course, assert in a reviewing court any ground in support of his judgment, whether or not that ground was relied upon or even considered by the trial court," we will address that issue. Dandridge v. Williams, 397 U.S. 471, 475 n.6 (1970).

Section 360k only pre-empts requirements which the state "establish[es]" or "continue[s] in force." The focus of § 360k is on preventing the States from imposing on medical device manufacturers normative policy choices which conflict with FDA requirements. See Gile, 22 F.3d at 546. This focus is consistent with the limited purpose for which Congress displaced the states' coordinate regulatory role -- to permit efficient and effective FDA regulation of medical devices. The FDA itself has recognized the MDA's limited focus by interpreting § 360k to pre-empt only state requirements "having the force and effect of law," a term normally reserved for binding standards of conduct that operate irrespective of private agreement. 21 C.F.R. § 808.1(d).

1.

Express warranties arise from the representations of the parties which are made the basis of the bargain and do not result from the independent operation of state law. See 13 Penn. Cons. Stat. Ann. § 2313. Implied warranties, on the other hand, "arise by operation of [state] law." Altronics of Bethlehem v. Repco, Inc., 957 F.2d 1102, 1105 (3d Cir. 1992). The parties to a contract, not the state, define the substantive obligations of the contract and hence any express warranties. While the state provides for the enforcement of the parties' bargain, it does not define each party's duties.[6]

[6]. The conceptual difficulty with determining whether, to what extent, and for what purposes contractual obligations arise by

The underlying foundation of contract law is the objectively manifested intentions of the parties. E. Allan Farnsworth, Contracts §§ 1.1 - 1.3 (2d ed. 1990). Shiley, in the representation which appears on the Shiley valve label, clearly manifested an intent to be bound by its one unequivocal promise and to disclaim any other implied warranties. Shiley represented:

> Shiley warrants that reasonable care has been used in the manufacture of this device. This warranty is exclusive and in lieu of all other warranties, whether express, implied, written or oral.

App. 680.

2.

The Supreme Court has twice recognized this same distinction between state-imposed and state-enforced common law remedies. In American Airlines, Inc. v. Wolens, 1995 WL 15047 (U.S. 1995), the

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virtue of state action, on the one hand, or the autonomous actions of the parties, on the other, has been addressed time and again in the literature on the common law. See, e.g., Jay M Feinman & Peter Gabel, Contract Law as Ideology in The Politics of Law 373, 378 (David Kairys ed. 1990); Charles Fried, Contract as Promise 7-27 (1981). Ultimately, contractual obligations result from the confluence of state authority and private actions. While the "binding force" of a properly executed contract derives from state authority, the content of the commitment is determined (absent mandatory or impermissible terms) by the parties themselves. In this way, contractual obligations differ fundamentally from state imposed regulatory requirements, such as the FDA requirement that medical devices meet certain design parameters. Both the content and the effect of these regulations flow from governmental authority.

Court held that the Airline Deregulation Act of 1978, 49 U.S.C. § 1305(a)(1), did not preempt Wolen's common law contract claims, writing:

> We do not read the ADA's preemption clause, however, to shelter airlines from suits alleging no violation of state-imposed obligations, but seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings. As persuasively argued by the United States, terms and conditions airlines offer and passengers accept are privately ordered obligations "and thus do not amount to a state's enact[ment] or enforce[ment] [of] any law rule, regulation, standard, or other provision having the force and effect of law' within the meaning of § 1305(a)(1)." Brief for the United States as Amicus Curiae 9. . . . A remedy confined to a contract's terms simply holds the parties to their agreements -- in this instance to business judgments an airline made public about its rates and services.

1995 WL 15047 at *6.

Previously, in Cipollone, the Court concluded that § 5(b) of the Public Health Cigarette Smoking Act of 1969 did not pre-empt state contract law claims.

> A manufacturer's liability for breach of an express warranty derives from, and is measured by, the terms of that warranty. Accordingly, the "requirements" imposed by an express warranty claim are not "imposed under State law," but rather imposed by the warrantor. . . . In short, a common law remedy for a contractual commitment voluntarily undertaken should not be regarded as a "requirement . . . imposed under State law" within the meaning of § 5(b).

Cipollone, 112 S. Ct. at 2622 (emphasis in original).

Moreover, our conclusion complies with the Supreme Court's admonition that courts should be "reluctant" to find pre-emption when "interpreting a federal statute pertaining to a subject traditionally governed by state law." CSX Trans. Inc. v.

Easterwood, 113 S. Ct. 1732, 1737 (1993). This is especially true here where Congress remained silent as to whether the MDA pre-empted common law contract claims. The elimination of those claims might result in the elimination of all legal remedies to the purchaser. "It is difficult to believe that Congress would, without comment, remove all means of judicial recourse for those injured by illegal conduct." Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984).

In this case, Congress has not only remained silent as to whether it intended to prevent states from enforcing the contractual representations of medical device manufacturers, it gave indications in 21 U.S.C. § 360h that at least some common law remedies would remain in conjunction with FDA regulation. Section 360h(d) defines the effect that a manufacturer's compliance with an FDA notification, reimbursement, or recall order should have:

> Compliance with an order issued under this section shall not relieve any person of liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

While this provision does not delineate the scope of the state law remedies that remain after the MDA's passage, it contemplates that injured persons will be able to pursue a category of claims for economic loss under some circumstances. We conclude that express warranty claims are included in that category.

Shiley points to previous cases that have concluded that the same or similar federal regulatory schemes do pre-empt contract claims because the contract claims conflict with the FDA's supervision over medical device labeling. Worm v. American Cyanamid Co., 5 F.3d 744, 747 (4th Cir. 1993)[7]; King v. Collagen Corp., 983 F.2d 1130 (1st Cir.), cert. denied, 114 S. Ct. 84 (1993)[8]; Kemp v. Pfizer, Inc., 851 F. Supp. 269 (E.D. Mich. 1994).[9] These courts have held that pre-emption was appropriate because the state law causes of action arose from representations made by manufacturers on labels approved by the FDA or EPA. The courts reasoned that because these labels were approved by the relevant regulatory authority, they could not give rise to voluntary obligations undertaken by agreement and so would conflict with federal regulation.

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[7]. In Worm v. Cyanamid Co, the Fourth Circuit decided that the pre-emption provision of the Federal Insecticide Fungicide and Rodenticide Act (FIFRA), 7 U.S.C. § 136v(b), pre-empted the plaintiff's contract claims because the claims were based on instructions for use found on the product label which were required and approved by EPA regulations. 5 F.3d at 749. Because the Fourth Circuit found that these instructions were mandated by the Environmental Protection Agency, the court concluded that the express warranty claims were pre-empted. Id.

[8]. In King v. Collagen Corp., the First Circuit concluded that § 360k pre-empted King's express warranty claims because those claims arose from the language on the packaging approved by the FDA. 983 F.2d at 1135. "Allowing appellant's express warranty claims effectively would impose additional or different requirements on Zyderm's labeling and packaging." Id.

[9]. In Kemp v. Pfizer, Inc., the district court followed the reasoning of King and Worm to hold that § 360k pre-empted a contract claim against Pfizer, Hospital Products Group, and Shiley, the defendants in this case.

If for no other reason, Worm is distinguishable from this case because it deals with a separate statutory scheme. Worm dealt with Federal Insecticide Fungicide and Rodenticide Act (FIFRA), not the MDA. Second, the plaintiff in Worm complained that Cyanamid had provided improper instructions for the use of the insecticide on its label, giving rise to a contract claim. 5 F.3d at 748-49. Michael is not challenging the instructions for the use or the implantation of the Shiley valve. Rather she seeks to enforce the company's explicit warranty which guarantees the product.

King and Kemp are less easily distinguished. The court in King did not indicate the type of language or warning upon which the plaintiff relied in the case before it and so we cannot know if it is distinguishable from Michael's claims. Kemp dealt with the same product and the same warranty as is at issue in the present case.

Neither King nor Kemp are binding on this court and we conclude that the concern expressed in those cases, that warranty obligations would arise from and therefore be in conflict with statements that are required on a regulated label, does not make pre-emption appropriate. First, the fact that third parties dictate or define the terms of a contract does not undermine the doctrine that contractual duties arise from the mutual assent of parties to agreed upon language. For example, organizations that receive government grants to operate social programs frequently agree to include specified language in agreements with contractors and beneficiaries. See, e.g., 24 C.F.R. § 85.36(i)

(1994) (mandating the inclusion of specified terms in contracts between Housing and Urban Development grant recipients and local parties); Ayers v. Philadelphia Housing Authority, 908 F.2d 1184 (3d Cir. 1990) (discussing HUD mandates for contracts between the local housing authority and the local authority's tenants/purchasers). Government contractors must agree to specified compensation and wage terms in their contracts with employees who work on the government projects. See, e.g., 40 U.S.C. §§ 328-29, 323; 41 U.S.C. § 351; 29 C.F.R. §§ 4.1 to 4.51; 29 C.F.R § 5.5. Courts do not thereby conclude that these requirements cause the immediate parties' contractual relationships to arise from the federal mandate. Regardless of the economic and legal pressures that dictate the final terms, the contract still results from the parties' mutual agreement to those terms.

Further, King and Kemp did not adequately consider the extent to which Shiley's label was ultimately a product of its voluntary actions. The FDA does not devise a label of its own making. Rather, Shiley submitted its proposed label to the FDA, which label was then reviewed with the company. Shiley itself drafted the initial language of the label. If Shiley disagreed with FDA recommendations, it could have engaged in negotiation over what statement was proper or, if it did not wish to be bound by the required statement, it could have chosen not to market its device. Despite indications in King and Kemp to the contrary, we believe that Shiley participated actively and meaningfully in the

FDA regulatory process that resulted in the label which we review here.

4.

Even if this were not the case, the enforcement of an express warranty that arises from approved packaging does not establish a requirement that "is different from, or in addition to, . . . any requirement applicable under this chapter to the device." 21 U.S.C. § 360k. Through her express warranty claim, Michael seeks to enforce the very language which the FDA approved on the Shiley valve label. Given the clarity with which that language speaks of warranties, neither the FDA, Shiley, nor Michael could have mistaken this language as creating anything other than an explicit contractual obligation. Thus, it is the FDA's own requirement that Michael would have the state enforce.

If any person, other than Shiley, "established" the warranty, it was the FDA, not the state. Because the obligations imposed arise directly from the FDA's own approved language, the resulting liability does not differ from or add to FDA regulation. Rather it supports the FDA's approval regulation by giving it effect.

Michael's contract claim is not a product of state action; hence, it is not state imposed -- the sine qua non of pre-emption under § 360k. Michael's express warranty claim is not pre-empted and can be prosecuted.

V

Michael also brought fraud claims relying on two theories of recovery. First, she alleges that Shiley fraudulently misled the FDA to her eventual, but foreseeable, detriment. Second, she alleges that Shiley's unregulated promotional and advertising materials fraudulently misrepresented that the Shiley valve was safe and would produce fewer complications than other valves when the company knew that these claims were not supportable. We consider whether § 360k pre-empts each of these claims.

A.

Fraud on the FDA -- Pre-empted

Michael produced substantial evidence that Shiley misled the FDA with false or misleading information when it applied for Premarket Approval. She claims that these fraudulent submissions led to the FDA's approval of the Shiley valve and thus led eventually to the necessity of removing the heart valve implanted in her. Alternatively, she argues that these fraudulent submissions estop Shiley from claiming that the MDA pre-empts its common law claims. Because of the conflict with the FDA's own efforts to monitor and control its PMA application process, we conclude that Michael's claims for Shiley's knowing misrepresentation to the FDA, even if provable, are pre-empted.

A state law cause of action for fraud is a state imposed requirement. By means of its recognized cause of action in fraud, the Commonwealth of Pennsylvania imposes a duty on anyone who sells products. That duty requires the seller to avoid any

material misrepresentation that could induce purchasers to buy its product. See Moser v. DeSetta, 589 A.2d 679, 682 (Pa. 1991)

Michael seeks to use this general prohibition on deception to encourage the district court to review the PMA application Shiley submitted to the FDA. This inquiry could ultimately require that a court determine whether the information Shiley submitted was truthful, whether it was complete, whether FDA procedures sufficed to avoid a material misrepresentation, and whether the FDA should have or would have approved the device despite the misrepresentations. In sum, this claim requires a court, applying state law, to perform the same functions initially entrusted to the FDA.

Section 360k does not permit such a searching state inquiry into the inner workings of FDA procedures. Congress allocated the FDA responsibility to design and manage a process which would result in approval of the safest and most effective medical devices possible. See 21 U.S.C. § 360e (creating the PMA requirement). Congress also assigned the FDA the responsibility to approve or disapprove of applications to market medical devices. Under § 360k, states may not impose different requirements and thereby reach a different conclusion than the FDA. "[W]here the FDA was authorized to render the expert decision . . ., it, and not some jury or judge, is best suited to determine the factual issues and what their effect could have been on its original conclusions." King, 983 F.2d at 1140 (Aldrich & Campbell, J.J. concurring). Under the MDA, states have no authority to police Shiley's compliance with the FDA's

procedures. If Shiley knowingly misled the FDA in its PMA application, it is for the FDA to remedy that situation using the authority Congress gave it in the MDA.

Further, permitting a fraud claim based on false representations to the FDA would conflict with our precedent that plaintiffs may not bring implied causes of action for violations of the Food, Drug and Cosmetic Act. Gile v. Optical Radiation Corp., 22 F.3d 540, 544 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994). Plaintiffs cannot circumvent this bar by characterizing their cause as a claim for state law fraud.

Nor can Michael revive the pre-empted fraud claim by characterizing it as a defense to pre-emption. Michael argues that, though her fraud claim might be pre-empted, her allegations of Shiley's fraud in obtaining its PMA, if proven, should deprive Shiley of the defense of pre-emption. In essence, Michael argues that we should not permit Shiley to invoke the cloak of federal pre-emption when it obtained that cloak through the fraudulent manipulation of the regulatory process.

While we do not condone misconduct by medical device manufacturers, we cannot agree with Michael's theory. If a medical device manufacturer's claim that the MDA pre-empts a plaintiff's cause of action depends in the first instance upon proof that its Premarket Approval was not fraudulently obtained, courts would have to engage in the intrusive inquiry, which we have just demonstrated is forbidden. Only the timing, and not the inquiry itself, would differ from a claim for fraud on the FDA. This argument thus presents not less, but greater

interference with the FDA's decisions. An attempt to reexamine the FDA's approval under state law standards, however pleaded, is pre-empted by § 360k.

B.

Fraud Based on Shiley's Advertisements -- Not Pre-empted

Michael's second fraud claim differs from the first in that it does not rely on conduct which was directly regulated by the FDA. Michael alleges that Shiley sent cardiac surgeons and cardiologists a series of letters and other promotional materials which knowingly misrepresented the extent of the valve fracture problem and knowingly overstated the reduction in serious side effects achieved by the Shiley valve. See FDA and the Medical Device Industry, Hearing Before the House Committee on Energy and Commerce, 101st Cong., 2d Sess. 15-21 (1990) (providing samples of these letters); App. 393-95. Michael alleges that the company's misinformation resulted in the eventual harm she suffered when her valve was explanted.

1.

Having already concluded that state law fraud claims create state-imposed requirements and, when combined with other § 360k elements, are thus pre-empted, see section V. A. supra, we need only consider the other elements of pre-emption under § 360k.[10]

[10]. The Supreme Court recently held that the Airline Deregulation Act of 1978 ("ADA") pre-empted the enforcement of a state consumer fraud statute, the Illinois Consumer Fraud Act, 815 Ill. Comp. Stat. § 505/2. American Airlines, Inc. v. Wolens,

The FDA had not imposed specific requirements related to advertising and promotion of the Shiley valve. Accordingly, we find that, as applied to Michael's circumstances, a state law fraud claim based on Shiley's advertising and promotional activities does not impose a requirement that "is different from, or in addition to" a FDA requirement and "which relates to the safety or effectiveness of the device or to any matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k.

Unlike Michael's strict liability claims which are based on a duty to produce safe products, Michael's fraud claims are based "on a more general obligation -- the duty not to deceive." Cipollone, 112 S. Ct. at 2624. Thus, Michael's fraud claim does not relate to the safety or effectiveness of the Shiley valve. Michael argues that because this duty to avoid deceit does not "relate to the safety or effectiveness of the [Shiley valve]," her claims are not pre-empted.

She relies on Cipollone for this argument. In Cipollone, the Supreme Court concluded that the Cipollone's fraud claims against cigarette manufacturers were only pre-empted to the

(..continued)
1995 WL 15047 *5-*6 (U.S. 1995). In Wolens, the Supreme Court held that state consumer fraud statute was a state imposed law. Id. The Court then found that the Illinois state statute met the other element of pre-emption under the ADA, that is, the statute "relate[d] to [airline] rates, routes, or services." 49 U.S.C. § 1305(a)(1).

Here, of course, the other requirements which dictate pre-emption under § 360k of the MDA differ from the requirements which dictate pre-emption under § 1305(a)(2) of the ADA. As stated in text, we conclude that Michael's common law fraud claim is not pre-empted by § 360k.

extent they sought to impose additional warnings on the cigarette packages. The Court permitted Cipollone's fraud claims for "claims based on allegedly false statements of material fact made in advertisements." Id. at 2623-24. The Court made this distinction because Cipollone's second claim based on "the duty not to deceive" did not conflict with federal requirements of § 5 of the Public Health Cigarette Smoking Act of 1969 which only pre-empts state law claims "based on smoking and health." Id. at 2624.

If § 360k also limited its pre-emptive scope to state requirements "which relate[] to the safety or effectiveness of the device," Michael's argument might be compelling, but § 360k is not so limited. It extends as well to state requirements "which relate[] . . . to any matter included in a requirement applicable to the device under this chapter." Thus, we must determine not only whether Michael's fraud claim relates to "safety and effectiveness" -- which we hold it does not -- but also whether it relates to any other FDA requirement.

2.

This latter inquiry turns on whether the FDA imposed any requirements on Shiley's efforts to promote its heart valve. The record reflects that it did not. Shiley prepared and sent the letters which tout the valve's reliability and superiority as compared to competitors' valves to doctors without the FDA's approval. App. 393-94. The FDA, at that time, was not supervising medical device manufacturers' efforts to promote

their devices outside of a limited category of "restricted devices" defined by the MDA and not relevant to this appeal. Only in the last few years has the FDA actively sought to control the promotional representations which device makers make to the medical community. Sandra J.P. Dennis, Promotion of Devices: An Extension of FDA Drug Regulation or a New Frontier, 48 Food & Drug L.J. 87 (1993). We note, however, that this on-going extension of the FDA's authority has been criticized as exceeding the FDA's statutory mandate. See id; Jeffrey N. Gibbs, Medical Device Promotional Activities and Private Litigation, 47 Food & Drug L.J. 295 (1992).

To be sure, the FDA did regulate the information Shiley placed on its labels. As required by the MDA, Shiley submitted its labels to the FDA and the FDA approved them. (See section IV. B. supra). A deviation from the content of the label approved by the FDA violates the MDA. 21 C.F.R. § 814.39(a)(2). Nonetheless, there is a substantial difference between supervising label content and supervising advertising.

Mindful that the Supreme Court has observed in a slightly different context that "Congress offered no sign that it wished to insulate . . . manufacturers from longstanding rules governing fraud," Cipollone, 112 S. Ct. at 2624, we conclude that Michael's second theory of fraud is not precluded by § 360k and is thus not pre-empted.

Our conclusion does not conflict with First Circuit's determination in King that § 360k pre-empted King's fraud claim. 983 F.2d at 1136. King's fraud claim arose from the absence of

warnings on the label of the medical device. Id. Because the FDA regulates the labeling of medical devices, King's claims were pre-empted. Michael's theory does not depend upon Shiley's representations on its labeling. Unlike in King where the court determined that the plaintiff's fraud claim was, "at bottom, a failure to warn claim," id., and thus pre-empted by the MDA, Michael's fraud claim is, at bottom, a fraudulent promotion claim. As such, it is not pre-empted.

VI

Summary Judgment -- Sufficient Evidence

Although the district court granted summary judgment on the majority of Michael's claims because it believed they were pre-empted, it also analyzed the claims using the traditional standard for summary judgment. We have concluded that Michael's express warranty claim and her fraud claim are not pre-empted. However, our holding in this regard does not address the district court's ruling that Michael had failed to present sufficient evidence to proceed to trial. We address that issue here and hold that, on this record, it was error to grant summary judgment for Shiley.

A.

Our consideration of Michael's contract claims originates with an examination of the contract. The label attached to the heart valve, which was implanted in Michael, included the statement "Shiley warrants that reasonable care has been used in

the manufacture of this device." App. 680. This language clearly created an express warranty with regard to the manner in which Shiley manufactured its heart valves. Shiley does not deny that the sale created a valid contract with an express warranty. See 13 Pa. C.S.A. § 2313. Rather Shiley contends that it never breached the warranty because there is no proof that the valve implanted in Michael was defective.

We agree that there is no evidence in the record that Michael's valve was defective. That does not, however, defeat Michael's cause of action. Shiley's warranty does not simply warrant that the valve which was implanted in Michael was defect-free. The language is less specific, warranting instead that "reasonable care has been taken in the manufacture of this device." App. 680.

We are satisfied that the representation made by the language on this label reaches beyond the valve explanted from Michael to encompass the manufacture of Shiley valves generally. While most consumers of most products have little reason to seek assurances in a contract that any device, other than the product purchased by them, is safe and effective, heart valve purchasers, as perhaps other purchasers of implanted devices, have salient and compelling reasons to seek such assurances.

Shiley's customers rely on Shiley's mechanical heart valves in a manner that differs entirely from the normal buyer's reliance on a consumer product. The Shiley valve sustains customer's lives. Malfunction will result in serious harm, or most likely, death. In this context, the purchaser has reason to

demand a very high degree of assurance that the implanted product presents no substantial risk that it will fail. The existence of a significant risk that the device will fail makes the product unsuitable for its purpose. Therefore, a patient-purchaser has every reason to seek, and Shiley has every reason to give, assurances that reasonable care has been taken in the production of such life sustaining devices generally. It is only such a warranty that can alleviate concerns that an implanted medical device will fail without warning.

Shiley's warranty afforded its patient-purchasers those assurances. Michael proceeded with her implant operation with a justifiable belief that the valve implanted in her heart would not fracture or fail due to deficiencies in the manufacturing process. Because any latent defect in an implanted device may be undetectable after it has entered medical supply channels, the representations made by the manufacturer, which here form the basis of Shiley's warranty, requires an examination, not just of the specific heart valve implanted in Michael, but rather of Shiley's valve production generally.

The evidence in the record suggests that Shiley did not exercise due care in the fabrication of the Bjork-Shiley valve. A number of Shiley valves failed as a result of welding cracks that were not prevented or eliminated at Shiley's factories. Michael also submitted to the court the findings of a House Committee report on the manufacture of Shiley's valves. That report stated that Shiley trained welders inadequately, repaired valves which had previously been deemed not repairable by

inspectors, and masked cracked welds to pass quality inspections. She also produced a letter to Shiley from a medical researcher, stating that "[y]our statement re. strut fracture that I just received only tells me that your manufacturing procedure is not acceptable." App. 461. Former welders stated in affidavits that Shiley trained welders poorly and told welders to force badly welded valves past quality control personnel. App 615-16, App. 623-25. This record could amply support a jury determination that Shiley did not exercise reasonable care in the manufacture of its heart valves.

Michael has also shown that Shiley's alleged manufacturing breaches caused her damage. Shiley's failure to manufacture its heart valves using proper care resulted in a risk that any of its heart valves could fail. Indeed, the weak or improper strut construction has resulted in over 500 documented strut failures. Nor, as we have pointed out, could it be determined without explantation whether the valve implanted in Michael suffered from any of the same defects that affected other valves. Accordingly, Michael's doctors concluded that it was reasonable to explant her Shiley valve and replace it surgically. App. 499-501, 526-29; see also app. 471 (Shiley document sent to doctors noting an investigative article which recommended replacement of heart valves in young patients). Michael understandably took the advice of her medical advisors. The cost, inconvenience, risk, and pain of the surgery to explant and replace the valve occurred because of Shiley's alleged general manufacturing deficiencies

which led to Shiley's alleged breach of its warranty of reasonable care.

Contrary to Shiley's arguments, our conclusion does not conflict with our recent decision in Angus v. Shiley, Inc., 989 F.2d 142 (3d Cir. 1993).[11] In Angus, we concluded that a recipient of a Shiley valve could not recover for intentional infliction of emotional distress and a failure to warn claim where the implanted valve had neither failed nor been explanted. Id. at 147 & n.5. Angus had failed to allege that the valve implanted in Angus was defective. Id. In the absence of a valve failure or explantation surgery, she could not maintain a product liability action. Id. In footnote 5, we explicitly held open the question of whether relief would be appropriate following surgery to explant the valve. Id. at 147 n.5.

Unlike the plaintiff in Angus, Michael has suffered a tangible injury on account of the risks, pain, and emotional trauma associated with explantation of the Shiley valve. Michael's case presents the issue left open in Angus -- what relief may be accorded for physical and emotional trauma occasioned by the need for actual explantation surgery. We conclude that, under the terms of Shiley's express warranty,

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[11]. Shiley claims we had earlier determined that a plaintiff whose valve had not failed could not recover for emotional distress on any product liability theory in Brinkman v. Shiley, Inc., 732 F. Supp. 33 (M.D. Pa.), aff'd without opinion, 902 F.2d 1558 (3d Cir. 1989); see Shiley Brief at 41. We, of course, are not bound by an unpublished disposition of our court. See Third Circuit Internal Operating Procedures § 5.8. Moreover, the plaintiff in Brinkman, unlike the plaintiff here, had not undergone explantation surgery.

sufficient evidence has been shown by Michael to withstand entry of summary judgment for Shiley. Our conclusion is consistent with Pennsylvania's rule that emotional harm may be recovered when it accompanies a physical injury. Houston v. Texaco, Inc., 538 A.2d 502, 504 (Pa. Super. 1988).

B.

Finally, we consider whether Michael produced sufficient evidence to proceed to trial on her fraud claim.[12] In Pennsylvania, the elements of fraud are: (1) a material misrepresentation of fact, (2) which is false and (3) made with knowledge of its falsity, (4) which is intended to induce the receiver to act, and (5) upon which a party justifiably relies. Mellon Bank Corp. v. First Union Real Estate, 951 F.2d 1399, 1409 (3d Cir. 1991).

> It is well established that fraud consists of anything calculated to deceive, whether by single act or combination, or by suppression of truth, or suggestion of what is false, whether it be by direct falsehood or by innuendo, by speech or silence, word of mouth, or look or gesture. We have held that "fraud is composed of a misrepresentation fraudulently uttered with the intent to induce the action undertaken in reliance upon

[12]. The somewhat confusing nature of the district court's orders makes it uncertain that the district court determined that Michael did not raise a genuine issue of material fact on her fraud claim. While the court granted a judgment on her fraud claim on the belief that it was pre-empted, a conclusion which we now reverse, the court granted Shiley's motion for summary judgment for failure to produce sufficient evidence on all claims "except plaintiff's fraud claim." Nonetheless, because we exercise the same review as the district court did in the first instance, we will consider the merits of Shiley's motion, particularly since the two district court orders appear on their face to conflict with one another.

> it, to the damage of its victim." The concealment of a material fact can amount to a culpable misrepresentation no less than does an intentional false statement.

Moser v. DeSetta, 589 A.2d 679, 682 (Pa. 1991) (quoting Thomas v. Seman, 304 A.2d 134, 137 (Pa. 1973)) (other citations omitted).

In support of her claim, Michael points to two sources of fraudulent information: (1) letters written by Shiley to doctors between 1978 and 1983 which attempt to minimize the significance of the prior valve fractures and (2) advertisements and other promotional materials which emphasize a reduction in complications with the Shiley valve that never materialized.

Michael claims that Shiley's representations to doctors in letters, which accompanied its recalls and which Shiley otherwise disseminated to boost the Shiley valve's image following the disclosure of the outlet strut fractures, misrepresented the extent of the strut fracture problem. These letters state that some fractures had occurred but purportedly withheld information on the actual number of strut fractures known to Shiley. Further, the letters asserted that the Shiley valve's original design and the then current manufacturing practices confirm the structural integrity of the Shiley valve.

In contrast to Shiley's reports, the record discloses that Shiley had ample reasons to believe both the heart valve's design and the manufacturing process rendered the heart valve unsafe. Just a month prior to Shiley's distribution of a set of letters to doctors in May 1982, Dr. Bjork, one of the original designers of the Shiley valve, wrote Shiley, "You're circling around with

other solutions is probably a waste of time. At this stage, welding will not be acceptable any more [sic]. . . . Your statement re. strut fractures that I just received only tells me that your manufacturing procedure is not acceptable. You have provided me with absolutely no facts and truthworthy [sic] data for the future." App. 461.

In a prior letter to Dr. Bjork, Shiley had written, "We would prefer that you did not publish the data relative to strut fractures. We expect a few more and until the problem has been corrected, we do not feel comfortable." App. 548. This disclosure contrasts with Shiley's assurances in the letters to doctors that new fractures were very unlikely to occur.

Moreover, Michael has produced affidavits and deposition testimony from employees who worked for Shiley in the late 1970s and early 1980s that state that Shiley supervisors and management ordered them to reweld valves which could not pass inspection, to polish or cover defects in outlet strut welds, and to rework previously scrapped valves in an attempt to hide any defects in the outlet strut welds. App. 555-57, 613-17, 625-29, 635-36. These manufacturing practices likely undermined the structural integrity of the valves and thereby rendered Shiley's representations false.

Michael has also produced samples of advertisements, which Shiley placed in medical journals that circulate to cardiac surgeons, claiming a fifty percent reduction in complications with the Shiley valve over prior valves. App. 678. In prior testimony, Dr. Bjork disagreed that this claim fully represented

the scientific findings. App. 812. By 1984, the FDA, through independent investigation, concluded that scientific tests could not confirm these reductions. App. 766. In fact, the FDA determined that the Shiley valve's design "d[id] not result in meaningful differences in thromboembolic complications in clinical experience . . . . After nearly eight years of clinical use, there is no statistically significant difference between [the Shiley valve and its predecessor] when thromboembolic complication rates are compared." Id.

This record reveals a sufficient pattern of affirmative statements that are contrary to the true information known to Shiley, which, when combined with the withholding of material information as to the integrity and properties of the Shiley valve, is more than sufficient to permit a jury to conclude that Shiley intentionally misrepresented the Shiley valve's performance and the importance of the strut fractures.

Having adduced evidence of the first three elements of a cause of action sounding in fraud, we turn to a consideration of the remaining two elements: inducement and justifiable reliance. We conclude that Shiley had ample reason to expect that its advertisements and letters, although directed to physicians, would induce action by heart patients to accept Shiley's implants on the basis of their physicians' recommendations. We also conclude that the patients' reliance on these recommendations was justifiable.

Pennsylvania has held that "the persons or class of persons whom [a fraudulent declarant] intends or has reason to expect to

act or refrain from action in reliance upon the misrepresentation" may sue in fraud for the damage which results from the declarant's fraudulent statement. Woodward v. Dietrich, 548 A.2d 301, 309, 315 (Pa. Super. 1988) (quoting Restatement (Second) of Torts § 531 (1976)).

In Woodward, the Pennsylvania Superior Court held that a subsequent transferee of a home could sue the prior owner's plumbing contractor, when the plumber had fraudulently misrepresented to the prior owner that his work met the relevant municipal codes. The plumber fraudulently concealed an improper link to the city's sewer system after being hired by the Dietrichs, the former owners of the house, to bring the house up to code. After the Dietrichs sold the home to the Woodwards, the sewer line backed up into the house's basement. The Woodwards brought a cause of action sounding in fraud against the plumber.

The Pennsylvania Superior Court adopted the rule of the Restatement (Second) of Torts § 531 (1976), which reads:

> One who makes a fraudulent misrepresentation is subject to liability to the persons or class of persons whom he intends or has reason to expect to act or refrain from action in reliance upon the misrepresentation, for pecuniary loss suffered by them through their justifiable reliance in the type of transaction in which he intends or has reason to expect their conduct to be influenced.

This provision extends liability beyond those to whom the declarant directs his fraudulent misrepresentation to those whom the declarant has special reason to anticipate will be induced to act. Woodward, 548 F.2d at 313, 315. As comment "e" of the Restatement makes clear, the declarant need not know the identity

of the eventual plaintiff if the plaintiff is a member of a class of persons whom the declarant has reason to expect will act in reliance upon his fraud. Restatement (Second) of Torts § 531 comment e (1976) ("The maker may have reason to expect that his misrepresentation will reach any of a class of persons, although he does not know the identity of the person whom it will reach or indeed of any individual in the class."); Woodward, 548 F.2d at 309 n.9.

After adopting this standard, the court found that the plumber had reason to expect that any subsequent purchaser, such as the Woodwards, would rely on his fraudulent statement that the sewer connection was acceptable, and thus, the court permitted the Woodwards to proceed with their fraud action.[13]

The Superior Court's decision mirrors § 533 of the Restatement (Second) of Torts. Section 533 makes a declarant liable when the declarant "has reason to expect that [the

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[13]. More recently, the Pennsylvania Superior Court relied upon its opinion in Woodward to decide that plaintiffs need not have been in privity with a product manufacturer to bring a claim under Pennsylvania's consumer fraud statute, the Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Con. Stat. Ann. § 209-9.2(a). Valley Forge Towers South Condominium v. Ron-IKE Foam Insulators, Inc., 574 A.2d 641, 646-47 (Pa. Super. 1990), aff'd without opinion, 605 A.2d 798 (Pa. 1992). As a result, a condominium association could sue their roofing contractor's supplier for the supplier's unlawful business practices despite the fact that the association never purchased materials from the supplier. Rather it had only received a warranty from the supplier. "[A]s the materials were intended to become part of a fixture to realty, [the supplier] knew or should have known that its warranty would be relied upon by [the condominium association] covered by the roof it warranted." Id. at 646.

misrepresentation's] terms will be repeated or its substance communicated to the other, and that [the misrepresentation] will influence his conduct in the transaction or type of transaction involved." See Ostano Commerzanstalt v. Telewide Systems, Inc., 794 F.2d 763, 766 (2d Cir. 1986) (holding licensor liable to sublicensee for representations made to licensee with reason to expect that they would influence sublicensee's behavior). As with § 531, the comments to § 533 make it clear that the declarant (here, Shiley) need not be able to identify the party (here, Michael) who eventually relies if the party (here, Michael) who relies is a member of a class of people that the declarant (here, Shiley) would expect to rely on the representation. Restatement (Second) of Torts § 533 comment g (1976).

Michael fits within the rule of Woodward and Restatement § 533. Shiley had ample reason to expect that the patients and eventual recipients of the Shiley valve implants would be affected by the information it published and distributed to doctors. Indeed, that was Shiley's intent. Shiley had to anticipate that its letters and advertisements would lead doctors to recommend, and the physician's patients to choose, the Shiley valve. As § 533 makes clear, the fact that Shiley initially made its representations to Michael's doctors, rather than directly to Michael, does not undermine Michael's claim.

By the same token, Michael's doctors were justified in relying on the medical claims Shiley provided in its promotional materials to determine the proper course of treatment for

Michael.[14] Shiley held a tremendous advantage over the doctors in its knowledge of the facts surrounding the strut fractures and the scientific literature on thromboembolism. The doctors were justified in relying on Shiley to restate honestly the facts and findings pertaining to the valves which Shiley produced. See Aaron Ferer & Sons, Ltd v. Chase Manhattan Bank, 731 F.2d 112, 123 (2d Cir. 1984) (where "one party possesses superior knowledge, not readily available to the other, and knows that the other is acting on the basis of the mistaken information," the second party can justifiably rely on the first party's representations); Daughtrey v. Ashe, 413 S.E.2d 336, 338 (Va. 1992) ("[I]f one who has superior knowledge makes a statement about the goods sold and does not qualify the statement as his opinion, the statement will be treated as a statement of fact."); Restatement (Second) of Torts § 542(a) & comment f (1976).

The information provided by Shiley was intended to affect a doctor's choice of a heart valve for Michael. Shiley distributed its literature containing heart valve information for that very purpose -- to encourage doctors to continue implanting the Shiley valve. The record, read in the light most favorable to Michael,

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[14]. Both her doctors testified that they received letters from Shiley regarding the Shiley valve. App. 495, 524. While they did not retain those letters, it is reasonable to assume, given Shiley's nationwide distribution of the letters, that these letters include the communications discussed above. Both doctors stated that they read standard cardiac journals in which Shiley's advertisements and claims appeared in order to stay current with developments in the field of cardiology and cardiac surgery. App. 500, 535.

suggests that the doctors, who advised Michael, relied on Shiley's disclosures. Accordingly, Shiley's letters and promotional materials likely affected the choice to implant the Shiley valve in Michael.

We conclude that Michael has produced sufficient evidence to raise a genuine issue of fact on her claim of fraud and we will reverse the district court's February 25, 1994 orders of summary judgment on that claim.

VII

Having considered the record and the arguments of the parties, we will affirm the district court's grant of summary judgment on Michael's claims of negligence (both manufacturing and design), strict product liability, and breach of implied warranties -- all of which we hold are pre-empted by 21 U.S.C. § 360k. (See section IV. A. supra). We also hold that Michael's complaint to the extent it relies on fraud perpetrated by Shiley on the FDA is pre-empted. (See section V. A. supra).

We will reverse the district court's February 25, 1994 order granting summary judgment to Shiley on Michael's breach of express warranty claim (see section IV. B. & VI. A. supra) and her fraud claim insofar as she proceeds on the basis of Shiley's representations in its advertising and promotional materials. (See section V. B. & VI. B. supra).

We will remand the case to the district court for further proceedings consistent with the foregoing opinion.