PUBLISHED

UNITED STATES COURT OF APPEALS

FOR THE FOURTH CIRCUIT

JOHN M. MARTIN, SR.,
Plaintiff-Appellant,

v.

No. 96-1627

AMERICAN MEDICAL SYSTEMS,
INCORPORATED,
Defendant-Appellee.

Appeal from the United States District Court
for the Eastern District of Virginia, at Norfolk.
Raymond A. Jackson, District Judge.
(CA-96-95-2)

Argued: April 9, 1997

Decided: June 19, 1997

Before HALL and MURNAGHAN, Circuit Judges, and
BUTZNER, Senior Circuit Judge.

Vacated and remanded by published opinion. Judge Hall wrote the
opinion, in which Judge Murnaghan and Senior Judge Butzner joined.

COUNSEL

ARGUED: David Michael Deutsch, DAVID M. DEUTSCH, CO.,
L.P.A., Dayton, Ohio, for Appellant. Barbara Ann Williams,
WRIGHT, ROBINSON, OSTHIMER & TATUM, Richmond, Virginia, for Appellee. **ON BRIEF:** Mark D. Brynteson, DAVID &
BRYNTESON, P.C., Chesapeake, Virginia, for Appellant.

OPINION

HALL, Circuit Judge:

John M. Martin appeals a summary judgment entered for defendant American Medical Systems in Martin's personal injury suit. In light of a recent controlling decision of the Supreme Court, we vacate the judgment and remand.

I.

Martin suffers from erectile dysfunction. He consulted a urologist about his problem, and the urologist recommended that he use an inflatable penile prosthesis. He gave Martin some literature and a videotape about defendant American Medical Systems' prostheses. After reviewing these materials, Martin chose to use defendant's "Dynaflex" product.

On June 2, 1993, the Dynaflex was surgically implanted. Soon thereafter, Martin developed a severe infection. On June 25, his urologist prescribed intravenous antibiotics, but to no avail. Martin then underwent a second surgery to remove the Dynaflex.

The infection raged on, however. He was again treated with intravenous antibiotics in August. From November 29, 1993, through May 13, 1994, he was hospitalized five times for surgery, including debridement of dead tissue, skin grafts, removal of a cyst and an abscess, and subtotal phallic reconstruction. His penis is now disfigured and shortened.

Martin filed this personal injury suit in state court in Chesapeake, Virginia. He alleged several tort and warranty theories against American Medical Systems, the gravamen of all of which was that the defendant failed to ensure that the Dynaflex would be sterile and hence safe for implantation in the human body. The defendant removed the case to district court based on diversity of citizenship.

After limited discovery, American Medical Systems moved for summary judgment. It argued that Martin's claims were preempted by

the Medical Device Amendments of 1976, 21 U.S.C.§ 360. The district court held that all claims were preempted except breach of express warranty. On that claim, it held that Martin could not show that he relied on the express "Limited Warranty" American Medical made to his urologist.**1** To the extent that Virginia law precluded manufacturers from limiting warranties to those in privity of contract, the district court held that it, too, would be preempted. Summary judgment was entered for the defendant.

Martin appeals.

II.

Martin first attacks the district court's holding that his tort and implied warranty claims are preempted. This issue dominates Martin's brief, but, in its response, American Medical Systems concedes that under the Supreme Court's decision in Medtronic, Inc. v. Lohr, 116 S.Ct. 2240 (1996), Martin is right: the Medical Device Amendments of 1976 do not preempt his common-law claims.

For context's sake, we will briefly describe what this issue was all about. Before 1976, the Food and Drug Administration (FDA)'s rigorous premarketing approval did not extend to medical devices. The Dalkon Shield disaster, among others, prompted Congress to change that. Today, the maker of a new "Class III" device -- the most potentially dangerous -- must apply for FDA approval and must cool its heels while the FDA thoroughly investigates the device's effectiveness. 21 U.S.C. § 360e(d)(2). The Dynaflex is a Class III device.

Because the 1976 amendments so abruptly changed the status quo, Congress was compelled to take the existing market into account. Any device on the market at the time was permitted to stay on the market until and unless the FDA, after conducting a review like that for new devices, ordered otherwise. 21 U.S.C. § 360e(b)(1)(A).

This grandfather clause took care of assuring the continued avail-

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1 The relevant warranty is "The AMS Dynaflex Penile Prosthesis ... [is] delivered to the hospital prefilled and sterile."

ability of necessary equipment; on the other hand, it locked up market power in the current manufacturers, and it posed a risk that, if the manufacturer of some device went out of business, a much-needed product might be unavailable during the time it would take a new manufacturer to go through the FDA premarket approval process. Accordingly, Congress also exempted from premarket approval "substantially equivalent devices" to those on the market in 1976. 21 U.S.C. § 360e(b)(1)(B). Under this exemption, a manufacturer need only notify the FDA of its intent to market a device. If the FDA concludes that the device is "substantially equivalent," it notifies the manufacturer, which is then free to market its product. This limited FDA review is called "510(k)" after its section number in the original act.**2** The Dynaflex reached the market in this way.

In assuming federal responsibility for the safety of medical devices, Congress expressly preempted the power of the states:

> Except [where the FDA has exempted a particular state requirement], 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 --
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> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
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> (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.

21 U.S.C. § 360k(a). Manufacturers of medical devices have argued that requirements imposed by state tort law are among the things preempted. This court, in Duvall v. Bristol-Myers-Squibb Co., 65 F.3d 392 (4th Cir. 1995), agreed. The district court relied on Duvall in granting the summary judgment here.

Subsequently, the Supreme Court decided Medtronic. In that case, the Court held that, as regards 510(k) devices, state-law claims are not

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2 "510(k)" is codified at 21 U.S.C. § 360(k).

preempted. The Court reasoned that the 510(k) process does not constitute FDA approval of the safety or effectiveness of the device, but was rather merely the preservation of the pre-1976 status quo, which included potential liability under state law.**3**

Thus, an intervening decision of the Supreme Court requires that we set aside the summary judgment on all of Martin's claims except the one for breach of express warranty. On the latter claim, to which we now turn, the summary judgment did not rest solely on Duvall, and American Medical Systems contends that it can be affirmed notwithstanding Medtronic.

III.

Under Duvall, some warranty claims could be brought against the manufacturer of a 510(k) device. Because the Medical Device preemption provision relates to state laws that add safety and quality requirements in excess of FDA premarket approval, we reasoned that a manufacturer could voluntarily make claims about its product and thereby incur contractual liability; an obligation freely assumed by contract is not one required by general state law.

Here, the district court correctly held that Martin's warranty claim was not preempted per se. However, the court held that summary judgment for the defendant was appropriate, because (1) Martin was unaware of the Limited Warranty when he got the implant, and (2) language in the Limited Warranty restricting it to the direct purchaser and disclaiming liability for consequential damages was effective, notwithstanding contrary Virginia law. On this second point, the court reasoned that any warranty coverage for Martin would be on account of state law, not American Medical Systems' voluntary undertaking, and so the state law was preempted.

Medtronic overturned this analysis; Martin is entitled to rely on state law concerning the scope and validity of the defendant's warranty. Va. Code § 8.2-318 states:

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3 The Court later vacated Duvall, 116 S.Ct. 2575 (1996), and remanded it for our reconsideration. For our decision on remand, see Duvall v. Bristol-Myers-Squibb Co., 103 F.3d 324 (4th Cir. 1996).

> Lack of privity between plaintiff and defendant shall be no defense in any action brought against the manufacturer or seller of goods to recover damages for breach of warranty, express or implied, or for negligence, although the plaintiff did not purchase the goods from the defendant, if the plaintiff was a person whom the manufacturer or seller might reasonably have expected to use, consume, or be affected by the goods[.]

Obviously, American Medical Systems knows that the direct purchaser of its Dynaflex prosthesis -- a surgeon or hospital -- is not the ultimate user. It therefore cannot rely on language in its "Limited Warranty" restricting coverage to the direct purchaser.

Likewise, Virginia law prohibits the exclusion of consequential damages where such an exclusion is unconscionable. Va. Code § 8.2-719(3). The statute explicitly provides that such an exclusion for "injury to the person in the case of consumer goods is prima facie unconscionable." There is nothing in the current record to rebut the prima facie unconscionability of this exclusion.

Having concluded that Virginia law applies and would extend any express warranty to Martin, we turn to whether an express warranty was even made. The district court pointed out that Martin did not know of the express warranty that the prosthesis was sterile until this litigation began; therefore, he could not have relied upon it.

Clear Virginia authority is to the contrary. Any description of the goods, other than the seller's mere opinion about the product, constitutes part of the basis of the bargain and is therefore an express warranty. It is unnecessary that the buyer actually rely upon it. Daughtrey v. Ashe, 243 Va. 73, 413 S.E.2d 336 (1992). In Daughtrey, a jeweler had described a gem as being of higher quality than it actually was. In a subsequent breach of warranty suit, the jeweler asserted that the buyer had not been aware of the description and had not relied upon it. The Virginia Supreme Court held that it did not matter. The express warranty inquiry focuses on what it is that the seller agreed to sell, and, absent clear proof that the parties did not intend their bargain to include the seller's description of the goods, that description is an express warranty. 413 S.E.2d at 338-339.

The facts of this case militate even more strongly in favor of an express warranty than in Daughtrey. In both cases, the seller described the goods, but the buyer was unaware of the description. Here, though, unlike in Daughtrey, Martin surely did rely on and expect the fact warranted to be true: i.e. the implant was sterile. Martin may assert a claim for breach of express warranty.

The judgment of the district court is vacated, and the case is remanded for further proceedings consistent with this opinion.

VACATED AND REMANDED