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UNITED STATES COURT OF APPEALS
FOR THE THIRD COURT

No. 94-1714

HUGH EDWARD ENGLISH, III; LORRAINE ENGLISH,
Appellants

v.

MENTOR CORPORATION

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA
(D.C. Civil Action No. 93-02725)

Argued January 12, 1995

Before: COWEN, NYGAARD and ALITO, Circuit Judges

(Opinion Filed: September 29, 1995)

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OPINION OF THE COURT

PER CURIAM.

Hugh and Lorraine English sued Mentor Corporation, alleging claims based upon strict product liability, negligence, breach of express and implied warranty, loss of consortium by Mrs. English, and punitive damages. Mr. English had a Mentor inflatable penile prosthesis implanted. The device malfunctioned and appellants sued Mentor in the Pennsylvania Court of Common Pleas. Mentor removed the case to the federal district court, which granted summary judgment in its favor, holding that appellants' claims were preempted by the Medical Device Amendments to the Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. §§ 360c-360rr.

Appellants raise two issues on appeal: (1) whether the Medical Device Amendments of 1976 preempt their state law tort and contract claims against the manufacturer of a Class III medical device; and (2) whether the Amendments also preempt these claims for a medical device cleared for marketing under the "substantial equivalence" exception to the general rule requiring

a full Premarket Approval process. We will affirm in part, reverse in part, and remand the cause. I.

The Medical Device Amendments classify medical devices as Class I, II or III devices, depending upon their potential danger to the public. Class III devices are the most dangerous, the most heavily regulated, and include the prosthesis implanted in Mr. English. Generally with Class III devices, the manufacturer must submit a detailed "Premarket Approval" application to the FDA, 21 U.S.C. § 360e(c)(1), and obtain Premarket Approval before they can be marketed to the public. Id. § 360c(a)(1)(C).

There are two exceptions to this requirement. First, Class III devices may receive an "Investigational Device Exemption" (or "IDE") from the FDA, id. § 360j(g), which permits the device to be tested on human subjects without obtaining Premarket Approval. Id. § 360e(a). Second, absent formal premarket approval, the FDA has permitted manufacturers to market new inflatable penile implants by completing the "510(k) procedure," which requires a demonstration that the new device is "substantially equivalent" to other penile implants already on the market before the passage of the MDA.[1] 21 U.S.C.

[1]In adopting the MDA, Congress drew a distinction between devices that were on the market before its passage (and devices "substantially equivalent" to these devices) and devices marketed after its passage in 1976. Congress realized that it was impracticable to require that devices that were already on the market be withdrawn until they obtained premarket approval from the FDA. See 21 U.S.C. § 360e. Instead, Congress directed the FDA to promulgate regulations to allow manufacturers of these devices to move gradually into compliance with the MDA. Id. This

§360c(f)(3); 21 C.F.R. §§ 807.81-807.100. Absent such a demonstration, a device may not be marketed until obtaining the full premarket approval described above.

Under this 510(k) procedure, the FDA must decide whether a new device is in fact substantially equivalent to a device already on the market prior to 1976. See 21 U.S.C.

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authority also extended to new devices "substantially equivalent" to devices on the market as of 1976. Id.

The FDA relied on this distinction as authorization for its 510(k) process. Thus, the FDA has issued regulations, such as 21 C.F.R. § 876, classifying certain preexisting devices (including inflatable penile implants) as Class III devices, but exempting them from immediate premarket approval (by postponing the date the regulations become effective). The FDA also allows substantial equivalents of these devices to be marketed before obtaining final premarket approval--by completing the 510(k) process. Id. at §§ 807.81-807.100. These devices, however, are required to obtain premarket approval in the future. See 21 C.F.R. § 870.1-870.3. New devices (i.e. devices not in existence before 1976 or substantially equivalent to such a device) must receive premarket approval before they may be marketed. 21 U.S.C. § 360e(a); 21 C.F.R. § 870.3.

With the passage of the Safe Medical Devices Act ("SMDA") in 1990, Pub. L. No. 101-629, Congress explicitly codified these 510(k) procedures. See H.Rep. No. 101-808, 101st Cong., 2d Sess., 1990 U.S.C.C.A.N. 6305, 6319 ("Section 4(b) [of the SMDA] codifies the FDA's current practice regarding the use of the 510(k) procedure for entering the market."). The current approach is found at 26 U.S.C. § 360c(f)(3), which explicitly allows a manufacturer of a Class III device, for which no final regulation requiring premarket approval has been promulgated, to market the device by complying with the FDA's 510(k) notification process. Similarly, the SMDA codified the FDA's definition of substantial equivalence. See 21 U.S.C. § 360c(i)(1)(A). Because Congress in the SMDA codified FDA procedures in place at the time the device implanted into English was approved by the FDA pursuant to the 510(k) process, we make reference to its provisions in determining the extent to which the FDA has regulated the device.

§360c(f)(3). Pursuant to 21 U.S.C. § 360c(i)(1)(A), a device is considered "substantially equivalent" if the device:

> (i) has the same technological characteristics as the predicate device, or
>
> (ii)(I) has different technological characteristics and information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

This substantial equivalence determination therefore requires the manufacturer to provide information to the FDA in order to ensure that "the device is safe, effective and performs as well as or better than the [predicate] device...." 21 C.F.R. § 807.95; see 21 U.S.C. § 360c(i)(3)(A); 21 C.F.R. § 807.92.

The FDA, however, views the 510(k) exception as an intermediate step to obtaining full premarket approval. The FDA will eventually require all Class III devices to obtain full premarket approval.[2]

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[2]Congress has directed the FDA to clear up the backlog of devices that are classified as Class III, but for which the FDA has not issued a final regulation requiring premarket approval. 21 U.S.C. § 360e(i). Congress was concerned that the FDA was using the 510(k) process as a means to avoid having to issue premarket approval on a wide array of devices. See H.Rep. No. 101-808, 101st Cong., 2d Sess., reprinted in 1990 U.S.C.C.A.N. 6305, 6317-20. Under § 360e(i), manufacturers of these Class III devices will have to submit information pertaining to their performance, including safety and effectiveness data. The FDA will then be required promptly to re-categorize these devices as Class II devices or finally issue regulations requiring that they obtain premarket approval. Id.

Before Mr. English's prosthesis was inserted, the FDA determined that Mentor's prosthesis was substantially equivalent to other Class III devices marketed before the Amendments, and allowed Mentor to market its prosthesis to the public without Premarket Approval. The FDA had initially granted an Investigational Device Exemption to Mentor, permitting it to test its prosthesis on human subjects; English, however, did not receive a device as part of an IDE test study and thus Mentor cannot rely on IDE regulations in support of its argument that English's state tort claims are preempted.

II.

Appellants argue first that Congress never intended the Amendments to preempt state law claims. We rejected that argument in Gile v. Optical Radiation Corp., 22 F.3d 540 (3d Cir.), cert. denied, 115 S. Ct. 429 (1994); see also Michael v. Shiley, Inc., 46 F.3d 1316 (3d Cir. 1995). The preemption provision provides:

> (a) Except as provided in subsection (b)[3] 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

[3]Subsection (b) permits a state to apply for an exemption from the preemption of subsection (a) for certain state laws. No such application was made in this case, thus subsection (b) is not at issue.

> matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a).

We opined in Gile that Congress' use of the word "requirement" in § 360k(a) adequately expresses its intent to preempt state law claims that would impose different or additional requirements from those under federal law. 22 F.2d at 542-43. We held that § 360k(a) preempted state law strict liability and negligence claims as impermissible attempts to impose additional safety or effectiveness requirements on medical device manufacturers. Id. at 545. In Michael, we held that § 360k(a) also preempts breach of implied warranty claims because they too arise under state law. 46 F.3d at 1324-25.

Applying Gile and Michael, we hold that the district court correctly adjudged appellants' strict liability, negligence, and breach of implied warranty claims preempted by § 360k(a) of the Medical Device Amendments. Because Gile and Michael explain our rationale with respect to these claims, we need not.

In Michael, we held that breach of express warranty claims are not preempted by § 360k(a) because they are created by the parties and not by state law. 46 F.3d at 1325-26; see also Cipollone v. Liggett Group, Inc., -- U.S. --, 112 S. Ct. 2608, 2622 (1992) ("[R]equirements imposed by an express warranty are not 'imposed under state law,' but rather imposed by the warrantor."). Again, we are satisfied that our opinion in

Michael fully sets forth our analysis. We will reverse the district court's summary judgment on this claim.

The remaining claims are for loss of consortium by Mrs. English and punitive damages. We will uphold summary judgment with respect to the latter, inasmuch as the Pennsylvania courts have held that, absent fraud, punitive damages cannot be awarded for a breach of warranty. See e.g., AM/PM Franchise Ass'n v. Atlantic Richfield, 526 Pa. 110, 584 A.2d 915, 927 (1992).

We have found no Pennsylvania case, however, deciding whether a loss of consortium award can be premised upon a breach of warranty. Pennsylvania has made clear that loss of consortium cannot be based on pure breach of contract. E.g., Thorsen v. Iron and Glass Bank, 328 Pa. Super. 135, 476 A.2d 928, 932 (1984). Other courts, however, have looked to the substance of the breach of warranty claim in deciding whether it will support a loss of consortium award. See, e.g., Scarzella v. Saxon, 436 A.2d 358, 363 (D.C. App. 1981) (allowing loss of consortium premised upon breach of warranty and citing W. Prosser, Law of Torts § 95, at 635 (4th ed. 1971) for the proposition that warranty actions have historically sounded in tort as well as contract); Fernandez v. Union Bookbinding Co., Inc., 400 Mass. 27, 507 N.E.2d 728, 735 (1987) (same); Klein v. Sears, Roebuck and & Co., 92 Md. App. 477, 608 A.2d 1276, 1284, cert. denied, 328 Md. 447, 614 A.2d 973 (1992) (same); Henningsen v. Bloomfield Motors, Inc., 32 N.J. 358, 161 A.2d 69, 100-102 (1960) (same).

Appellants' breach of express warranty claim seeks damages for personal injuries, which are recoverable in

Pennsylvania as consequential damages for breach of warranty. 13 Pa.C.S.A. § 2715(b)(2). Given the substance of appellants' warranty claim and that "a consortium claim is inextricably intertwined with the underlying action for personal injury...[,]" Novelli v. Johns-Manville Corp., 395 Pa. Super. 144, 576 A.2d 1085, 1088 (1990), appeal denied, 527 Pa. 625, 592 A.2d 45 (1991), we think the Pennsylvania Supreme Court would permit Mrs. English to maintain her loss of consortium claim.

Finally, appellants argue that the Amendments do not preempt their claim that Mentor failed to comply with FDA requirements in the design and manufacture of the device. The district court rejected this argument because appellants did not properly allege that Mentor failed to comply with FDA regulations concerning the manufacturing process. Appellants point to no evidence that would support or create an issue of fact with respect to such a claim, even if properly alleged. We find no error in the district court's determination. See also Mendes v. Medtronic, 18 F.3d 13, 20 (1st Cir. 1994) (refusing to consider the same argument where plaintiff's complaint contained no allegations of manufacturer's failure to comply with FDA requirements).

III.

The second issue raised by appellants is whether § 360k(a) preemption also applies to a Class III medical device without Premarket Approval, but cleared for marketing by a "substantial equivalence" determination. To reiterate, a manufacturer can bypass the full-blown Premarket Approval process

if the FDA determines that the device is substantially equivalent to devices on the market before the Amendment became effective in 1976. 21 U.S.C. § 360e(b)(1); see discussion supra part II.

FDA regulations require that a manufacturer seeking a substantial equivalence determination submit a 510(k) Premarket Notification containing "an adequate summary of any information respecting [the] safety and effectiveness [of the device] or state that such information will be made available upon request by any person." 21 U.S.C. § 360c(i)(3)(A). The actual summary regarding the safety and effectiveness of the device must contain "detailed information regarding data concerning adverse health effects and shall be made available to the public by the [FDA] within 30 days of the issuance of a determination that such device is substantially equivalent to another device." Id. §360c(i)(3)(B).

Moreover, the FDA regulates both the format and content of a 510(k) Notification. The Notification must include, among other things: any action taken by the manufacturer to comply with the Amendment's requirements for performance standards; proposed labels, labeling, and advertisements sufficient to describe the device, its intended use, and the directions for its use; where applicable, photos or engineering drawings of the device; a statement that the device is similar to and/or different from other products of comparable type, accompanied by data to support the statement that may include an identification of similar products, materials, design considerations, and a description of the operational principles of the device; and any

additional information requested by the FDA that is necessary for it to make a finding of substantial equivalency. 21 C.F.R. §807.87.

In addition to the requirements pertaining specifically to substantially equivalent devices, the devices are also subject to the FDA's "General Controls," which include labeling requirements and good manufacturing practices. Mendes, 18 F.3d at 14 (citing 21 U.S.C. §§ 360i, 360j). The parallel FDA regulations on labeling govern the content and appearance of prescription medical device labels. 21 C.F.R. §§ 801.1, 801.15, 801.109. As the Mendes court noted, these regulations exempt such devices from the requirement that there be directions to a layperson on how to use the product safely, if the package describes, inter alia, "any relevant hazards, contraindications, side effects, and precautions" for the prescribing physician. Id. at 18 (quoting 21 C.F.R. § 801.109). Furthermore, the FDA has promulgated extensive regulations interpreting the Amendment's good manufacturing practices requirements. 21 C.F.R. §§ 820.1-820.198.

Only a handful of federal courts have considered whether the 510(k) process is a "requirement" that preempts state law tort claims under 21 U.S.C. § 360k(a). The majority of them hold that it is a requirement. For example, in Mendes, supra, the court held that a FDA determination of substantial equivalence carries with it sufficient federal requirements relating to safety and effectiveness to preempt state tort claims. Accord Duvall v. Bristol-Myers Squibb Co., No. S-93-

1072, 1994 WL 591534 (D. Md. Mar. 30, 1994); Bollier v. Medtronic, Inc., No. H-92-2439, 1993 WL 734843 (S.D. Tex. Oct. 28, 1993); Rutland v. Mentor Corp., No. 20235, 1994 WL 454741 (Miss. Cir. Feb. 23, 1994).

With respect to Mentor's penile implants, the Rutland court stated:

> The application procedure under 510(k) includes extensive qualification criteria based upon clinical studies, drawings and procedures in the manufacture of the device, proposed labelings and warnings, extensive product sterility information and documentation, a comparison to other devices on the market and safety and effectiveness status based upon ten (10) years of another similar device. Mentor not only complied with the 510(k) requirements, it continues to comply with post-510(k) requirements imposed by law.

Id. at *3.

Among the few cases suggesting that the 510(k) process does not invoke preemption is Larsen v. Pacesetter Systems, Inc., 74 Haw. 1, 837 P.2d 1273 (1992) (involving pacemaker). Larsen held that the 510(k) process does not preempt state law claims because it does not constitute FDA approval of a device. Id. at 1282. The court cited 21 C.F.R. § 807.97, which states that an FDA determination of substantial equivalence "does not in any way denote official approval of the device. Any representation that creates an impression of official approval of a device because of complying with the [510(k) Notification] regulations is misleading and constitutes misbranding." Id.

Nevertheless, we agree with the district court's well-reasoned rationale that the Amendment's preemption provision is

triggered not by FDA approval of a device's safety and effectiveness, but by federal requirements relating to a device's safety and effectiveness. See 21 U.S.C. § 360k(a). Those regulations include the 510(k) process with which a manufacturer must comply to obtain a determination of substantial equivalence. We are satisfied that this process is sufficiently rigorous to constitute a "requirement...relating to the safety or effectiveness" of Class III medical devices, pursuant to §360k(a).

Implicitly conceding that the FDA regulations discussed above do establish safety requirements, English nevertheless maintains that only regulations specifically covering inflatable penile prostheses have preemptive effect. In support of this argument, English asserts that the FDA has determined that preemption only applies when:

> [T]he [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific [FDA] requirements. There are other State or local requirements that affect devices that are not preempted by section [360k(a)] of the act because they are "not requirements applicable to a device" within the meaning of section [360k(a)] of the act.

21 C.F.R. § 808.1(d) (emphasis added). Indeed, two district courts have followed this logic and ruled that preemption occurs only when there are specific, but not general, regulations pertaining to a device. Ginochio v. Surgikos, Inc., 864 F. Supp.

948, 951-53 (N.D. Cal. 1994); Oja v. Howmedica, Inc., 848 F. Supp. 905, 906 (D. Colo. 1994).

We find this argument unconvincing. First, English attempts to read the phrase "other specific requirements applicable to a particular device" out of the statute. This phrase suggests that a general regulation that is binding on a particular device has preemptive effect. See Hodgon v. Mentor Corp., No. 92-1429, slip. op. at 5 (S.D. Ind. Aug. 8, 1994) (finding premarket approval regulations are "specific requirements" within meaning of § 808.1(d)); Tucker v. Collagen Corp., 1994 U.S. Dist. LEXIS 3101, at *9 (N.D. Ill. Mar. 16, 1994) (rejecting narrow reading of § 808.1(d)). Indeed, other circuits have relied on FDA regulations generally applicable to Class III devices in order to find preemption. See Mendes, 18 F.3d at 17-18 (good manufacturing practice and labeling requirements); Stamps v. Collagen Corp, 984 F.2d 1416, 1422 n.5 (5th Cir.) (good manufacturing practice requirements), cert. denied, -- U.S. --, 114 S. Ct. 86 (1993); King v. Collagen Corp., 983 F.2d 1130, 1131 (1st Cir.) (premarket approval application requirements), cert. denied, -- U.S. --, 114 S.Ct. 84 (1993).

Second, even assuming that the FDA's regulations should be interpreted as English suggests, we believe no deference is owed to that interpretation because it conflicts with the text of the statute. See Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc., 467 U.S. 837, 842-43, 104 S. Ct. 2778, 2781 (1984). Here, Congress directed that state requirements are preempted "which are different from, or in addition to, any

requirement under [the FDCA]." 21 U.S.C. § 360k(a) (emphasis added). Thus, the mere fact that the FDA has promulgated regulations affecting groups of devices, rather than a specific type of device, should not alter whether or not there is preemption. See Talbott v. C.R. Bard, Inc., 865 F. Supp. 37, 49 (D. Mass. 1994) (rejecting FDA's interpretation of preemption provision as contrary to statute); Ministry of Health, Province of Ontario, Canada v. Shirley Inc., 858 F. Supp. 1426, 1436 (C.D. Cal. 1994) (same); see also Stamps, 984 F.2d at 1421 n.2 (interpreting § 360k(a) and § 808.1(d) as announcing "essentially the same test"); King, 983 F.2d at 1130 (ruling that § 360k(a) provides "maximum protection and express preemption....").

Finally, since promulgating § 808.1(d), the FDA has issued an interpretation of § 808.1(d) contradictory to the one advanced by English. The FDA has stated: "[P]reemption is not restricted to State requirements that directly conflict with Federal law, but rather extends to requirements that are different from, or in addition to, any requirement applicable to the device under the act." 45 Fed. Reg. 67,326, 67,328 (1980) (emphasis added). Thus, we conclude that the FDA's labeling and good manufacturing practices regulations establish requirements within the meaning of § 360k(a).

IV.

In conclusion, based on our decisions in Gile and Michael, we hold that appellants' strict product liability, negligence and breach of implied warranty claims are preempted by the Medical Device Amendments of 1976. Furthermore, we hold that

preemption applies even where, as here, a Class III medical device is cleared for marketing under the "substantial equivalence" exception to the MDA Premarket Approval process. We hold, nonetheless, that the district court erred by granting summary judgment in Mentor's favor on appellants' breach of express warranty claim. Under our holding in Michael, such a claim is not preempted by the MDA.[4] We will reverse and remand the cause for further proceedings on this claim.

[4]For the reasons stated, we also remand Mrs. English's loss of consortium claim; however, we affirm summary judgment on appellants' claim for punitive damages.