United States Court of Appeals,

Fifth Circuit.

No. 94-20592.

Sam FELDT, Plaintiff-Appellant,

v.

MENTOR CORPORATION, Defendant-Appellee.

Aug. 21, 1995.

Appeal from the United States District Court for the Southern District of Texas.

Before WISDOM, GARWOOD and DAVIS, Circuit Judges.

GARWOOD, Circuit Judge:

In this products liability suit, plaintiff-appellant Sam Feldt (Feldt) appeals the district court's award of summary judgment, on the basis of preemption, for defendant-appellee Mentor Corporation (Mentor). We affirm in part, reverse in part, and remand.

Facts and Proceedings Below

On October 19, 1988, in an effort to cure erectile impotency, Feldt, then 68 years old, had implanted a pump-activated, Mentor GFS inflatable penile prosthesis (the prosthesis or the GFS), which had been approved by the Food and Drug Administration (the FDA) for marketing because of its substantial equivalence to prior devices. Feldt's prosthesis worked until June 1991 when, because of a flaw in the connection between the penile cylinders and the scrotal pump reservoir, it would no longer inflate and had to be removed and replaced. Feldt claims that, as a result of this defect, he suffered from embarrassment, trauma, and decreased sexual desire. He also claims that the defect contributed to the end of his

relationship with his fiancee.

Seeking recovery for these and other injuries, Feldt filed suit against Mentor, the product manufacturer, in Texas state court on June 17, 1993, alleging negligence, strict products liability, breach of express and implied warranties, and violations of the Texas Deceptive Trade Practices Act (DTPA). In its answer, Mentor raised eighteen affirmative defenses, among them the complete preemption of Feldt's state law claims. Asserting diversity and federal question jurisdiction, Mentor removed the suit to federal court, where on May 20, 1994, it filed a motion for summary judgment based only on the preemption defense. Feldt opposed the motion but dropped his negligence and strict liability claims with regard to the GFS's manufacture. On July 11, 1994, the district court awarded Mentor summary judgment, from which Feldt now appeals.

Discussion

The only issue in this appeal is whether 21 U.S.C. § 360k(a), part of the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug and Cosmetic Act, expressly preempts Feldt's remaining state law claims.[1] When the field alleged to be preempted by federal law has been traditionally occupied by the states, there is a presumption against preemption that can be rebutted only by a "clear and manifest" congressional purpose, be it express or

[1]Although Feldt dropped his negligence and strict liability claims based on defective manufacture, he preserved his failure-to-warn and defective-design claims, which are also grounded on theories of negligence and strict liability.

implied. *Jones v. Rath Packing Co.,* 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977). When Congress explicitly displaces state law, however, as it has here, congressional intent is determined with reference only to the express language of the statute; preemption will not be implied. *Cipollone v. Liggett Group, Inc.,* --- U.S. ----, ----, 112 S.Ct. 2608, 2618, 120 L.Ed.2d 407 (1992); *Stamps v. Collagen Corp.,* 984 F.2d 1416, 1420 (5th Cir.) (rejecting the argument that the language of the MDA permits a finding of implied preemption), *cert. denied,* --- U.S. ----, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993). The federal statute at issue, section 360k(a) of the MDA, provides as follows:

> "[N]o 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
> >
> > (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).

The parties dispute whether Texas law establishes, with respect to the GFS, "any requirement different from, or in addition to, any requirement applicable under this chapter to the device."[2] *Id.*

Since the enactment of the MDA in 1976, the FDA has had authority to regulate the entry of medical devices into the market.

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[2]We have held that state requirements subject to preemption by the MDA may be positive enactments or common law duties. *Stamps,* 984 F.2d at 1420; *see also Cipollone,* --- U.S. at ----, 112 S.Ct. at 2620. Feldt thus draws no distinction between his statutory and common law claims.

Pursuant to this authority, the FDA groups medical devices into three classes (Classes I-III) according to the amount of regulation necessary to ensure their safety and effectiveness. Although all classes of medical devices are subject to general controls, including labeling requirements and so-called good manufacturing practices (GMPs), Class II and Class III devices are subject to additional regulations. Moreover, because Class III devices are deemed to pose the greatest threat of illness or injury, they are subject to the most stringent regulation of the three classes. The GFS is a Class III device. 21 C.F.R. § 876.3350(b).

Before being marketed and sold, Class III devices must undergo the rigors of Pre-Market Approval (PMA), a lengthy, comprehensive process, at the end of which the FDA determines whether there is "reasonable assurance" that the device under consideration is safe and effective. *See* 21 U.S.C. § 360d(c)(1), (d); *see also Reeves v. AcroMed Corp.,* 44 F.3d 300, 303 (5th Cir.), *cert. denied,* --- U.S. ----, 115 S.Ct. 2251, 132 L.Ed.2d 258 (1995). As this Court recently summarized,

> "The FDA's [PMA] application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20.... FDA regulations also require [PMA] applicants to submit "[c]opies of all proposed labeling for the device.' 21 C.F.R. § 814.20(b)(10). The FDA approves a [PMA] application only after extensive review by the agency and an advisory committee composed of outside experts." *Id.*

Although as a general rule a Class III device must obtain PMA before it can be marketed to the public, 21 U.S.C. § 360e(c)(2), there are two exceptions. First, Class III devices found by the FDA to be "substantially equivalent" to devices on the market

before May 28, 1976, the MDA's effective date, are entitled to bypass the PMA process. *Id.* § 360e(b)(1). Second, Class III devices that obtain an investigational device exemption (IDE) from the FDA, *id.* § 360j(g), may be clinically tested on humans without first obtaining PMA. *Id.* § 360e(a). At any time, however, the FDA may issue a regulation requiring an exempted device to undergo the formal PMA process, *see id.* § 351(f)(2), but to date has not done so for inflatable penile prostheses.

It is undisputed that Mentor never obtained PMA for the GFS. The prosthesis was instead found by the FDA to be substantially equivalent to devices marketed before the MDA's effective date. A finding of substantial equivalence is based on a section 510(k) statement submitted as part of a pre-market notification application, a process significantly more abbreviated and less involved than PMA.[3] *Reeves,* 44 F.3d at 303. Applicants for pre-market notification must submit device descriptions and other information sufficient for the FDA to determine whether the device in question is substantially equivalent to pre-MDA marketed devices. As with the application for PMA, applicants must also submit their proposed labeling, 21 C.F.R. § 807.87, for the FDA to determine compliance with general labeling regulations. *See* 21 C.F.R. § 801 *et seq.; Reeves,* 44 F.3d at 305. In this case,

[3]Mentor was also granted an IDE, pursuant to which it conducted clinical trials of the prosthesis. Approval for the implant of Feldt's GFS, however, was not connected to this clinical program, but was instead based only on Mentor's pre-market notification and the subsequent FDA determination of substantial equivalence.

Mentor filed a 510k notification for the GFS on June 9, 1987, and included a variety of information relating to the design of the product as well as a summary of a nine-month clinical evaluation performed pursuant to a previously approved IDE. *See English v. Mentor Corp.,* 1994 WL 263353 at 4-5 (E.D.Pa. June 13, 1994) (unpublished) (describing the content of Mentor's 510k statement). The FDA approved the pre-market notification application on August 26, 1987, thereby allowing the GFS to enter the market subject only to general controls, at least until the FDA requires by regulation that the prosthesis undergo PMA.

Whether the pre-market notification procedures and general controls, like the PMA process, constitute "any requirement[s] applicable ... to the device" so as to displace any additional or different state requirements (relating to the product's safety or effectiveness), 21 U.S.C. § 360k(a), is the central question in this case. The test for section 360k preemption in this Circuit tracks the statutory language:

> "A state tort cause of action will be preempted if, in the context of the particular case, it (1) constitutes a requirement different from, or in addition to, any requirement the MDA makes applicable to the device at issue and (2) relates either to (a) the safety or effectiveness of the device or (b) any other matter included in a requirement made applicable to the device by the MDA." *Stamps,* 984 F.2d at 1421.

There is no question that the state law duties in question are requirements relating to safety and effectiveness. The only issue, then, is whether there is "any requirement the MDA makes applicable to the device at issue."

Below and on appeal, Feldt has argued that, although state law

imposes duties on manufacturers of medical devices, these duties are not "in addition to" any federal requirements because no such requirements exist until the FDA requires PMA for penile prostheses. Rejecting this contention, the district court determined that the FDA's regulations relating to pre-market notification were requirements to which all Mentor's state law duties were "in addition" and therefore preempted. On appeal, Feldt argues mainly that the regulations now applicable to the GFS are for identification and classification only and therefore should not, in light of the MDA's purpose of consumer protection, be construed as federal requirements within the meaning of section 360k. Instead, Feldt contends, consumers should be allowed to pursue state law claims until the FDA promulgates requirements specifically applicable to the GFS.

This Court has considered the preemptive scope of the MDA in a trio of opinions, beginning with *Moore v. Kimberly-Clark Corp.,* 867 F.2d 243, 246-47 (5th Cir.1989). In *Moore,* we held that section 360k(a) preempted a claim that the manufacturer of a Class II device, a tampon, had failed to adequately warn plaintiff of the dangers of toxic shock syndrome. We reasoned that because FDA regulations specifically prescribe the form and content of toxic shock warnings on tampons, the recognition of a state law tort duty would in effect impose labeling requirements on the manufacturer beyond those required by the FDA. The plaintiff, however, also brought a strict liability claim premised on the manufacturer's allegedly defective construction and design of the tampon. Because

"[t]here are no federal regulations on tampon design, composition, or construction," we held that plaintiff's defective design claims were not preempted. *Id.* at 246.

In *Stamps v. Collagen Corp.,* 984 F.2d 1416 (5th Cir.), *cert. denied,* --- U.S. ----, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993), we held that section 360k(a) preempted a plaintiff's failure-to-warn claim against a manufacturer of a Class III device (anti-wrinkle cream) even though the FDA had not promulgated device-specific regulations prescribing the form and content of the product's labels and warnings. *Id.* at 1423-24. According to the Court, the "Class III regulatory structure, no less than that of Class II," imposed general requirements on the proposed labeling and warnings of the device that were "different from, or in addition to" those under Texas tort law. *Id.* at 1422. We also determined that the plaintiff's defective design and manufacturing claims were preempted because of the PMA process and the generally applicable GMPs. *Id.* at 1422 & n. 5. Together, these regulations left us "with little doubt as to whether the MDA tolerates different or additional state requirements, respecting design or manufacture...." *Id.* at 1422 n. 5.

Finally, in *Reeves,* we held that section 360k(a) preempted the plaintiff's failure-to-warn claim against a manufacturer of a Class III device (metal bone implant) marketed without PMA. 44 F.3d at 305. Because the plaintiff's failure-to-warn claim would impose "labeling requirements beyond those required by the FDA," we concluded, the claim "runs afoul of § 360k(a) of the MDAs." *Id.*

We rejected the plaintiff's basis for distinguishing *Stamps:* that the device at issue had not undergone the rigors of PMA but was instead marketed on the basis of substantial equivalence, an FDA finding that does not brand the product with official approval. We focused instead on the fact that pre-market notification, like PMA, imposes some requirements on labeling and warning, and held that it is the existence of any federal requirement that triggers the preemption analysis.[4] *Id.* Although the plaintiff in *Reeves* also brought claims relating to design and manufacturing defects, the defendant did not contend that these were preempted; the Court therefore did not address this issue.

Reeves forecloses Feldt's principal basis for distinguishing *Stamps:* that the pre-market notification process, unlike PMA, does not invoke the preemption provision of section 360k. Preemption does not depend on the route the product takes to the market, but on whether there are any specific federal requirements applicable to the device. *See Reeves,* 44 F.3d at 305 (holding that, "despite the differences between" PMA and pre-market notification, "our preemption analysis remains the same"). Furthermore, since *Moore,* it has become clear that these regulations need not be device-specific; they need only apply generally to the device at issue. In *Stamps,* this Court ruled that the test is whether there

[4]In so holding, we agreed with an earlier decision of the First Circuit, *Mendes v. Medtronic, Inc.,* 18 F.3d 13 (1st Cir.1994). Under facts virtually identical to these here, the court in *Mendes* concluded that section 360k(a) preempted the plaintiff's claims of implied warranty and failure to warn. The Court did not consider preemption of plaintiff's defective design claims because the plaintiff had abandoned them. *Id.* at 17-18.

is "any requirement the MDA makes applicable to the device at issue." 984 F.2d at 1421.[5] Both *Reeves* and *Stamps,* moreover, identified as federal requirements certain general controls applicable to the Class III device, including the GMPs. *See Reeves,* 44 F.3d at 305; *Stamps,* 984 F.2d at 1422 n. 5 (describing the GMPs of section 360j(f) as "further requirements").

In his reply brief, filed after this Court's decision in *Reeves,* Feldt appears to concede, as he must, that his failure-to-warn claims are preempted by regulations, both general and specific, on labels and warnings applicable to the GFS. *See* 21 C.F.R. § 801.1 *et seq.; id.* § 895.25; *see also id.* § 801.109 (relating only to prescription devices). In *Reeves,* this Court relied on the same non-PMA provisions relating to labels and warnings that apply to the prosthesis in this case. *Reeves,* 44 F.3d at 305. We therefore hold that Feldt's claims are preempted

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[5]Citing the following provision, Feldt suggests, and amicus Public Citizen Inc. argues, that the FDA's own gloss on section 360k(a) requires device-specific regulation:

> "State or local requirements are preempted only when the [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." 21 C.F.R. § 808.1(d).

Although the requirements must be "specific" and applicable to a "particular" device, there is no language mandating that such requirements be *specifically applicable* to the device. In *Stamps,* this Court labelled the FDA's test "essentially the same" as the one set forth in that opinion. 984 F.2d at 1421 n. 2. Moreover, this Court in *Reeves* based preemption on labeling regulations generally applicable to all Class III devices. 44 F.3d at 305.

to the extent they are grounded on allegations of inadequate warnings or labeling. *See also Mendes,* 18 F.3d at 18. The district court did not err in finding preempted Feldt's failure-to-warn claim.[6]

That there are some specific requirements applicable to the GFS, however, does not necessarily mean that all Feldt's claims are thereby preempted. As *Moore* and even *Reeves* make plain, there must be some nexus between the state and federal requirements to trigger section 360k preemption. *See also Cipollone,* --- U.S. at ---- - ----, 112 S.Ct. at 2621-23. In *Reeves,* for instance, the plaintiff's inadequate warning claims were preempted not because of the FDA's GMPs, but only because of its specific regulations on labels and warnings. Furthermore, in *Moore,* we determined that there was no preemption of the plaintiff's defective construction and design claims because there were "no federal regulations on [the device's] design, composition, or construction." 867 F.2d at 246. The district court thus erred in relying on the labeling regulations and GMPs as adequate grounds to automatically preempt *all* Feldt's claims. We therefore consider Feldt's remaining claims, those based on implied warranty, defective design, and the DTPA.

With regard to his implied warranty claim, Feldt alleges that Mentor impliedly represented that the GFS was merchantable and fit

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[6]Although Feldt does not discuss his claim of negligent marketing, the claim is essentially based on a failure to warn and is likewise preempted. *See Lujan v. Tampo Mfg. Co., Inc.,* 825 S.W.2d 505, 510 (Tex.App.—El Paso 1992, no writ) (a claim of negligent marketing "involves a failure to warn, or warn adequately, of dangers or risks of harm or the failure to provide instructions for safe use of the particular product").

for its intended purpose. *See* Tex.Bus. & Com.Code §§ 2.314, 2.315. In Texas, these warranties arise by operation of law for any sale of goods in Texas.[7] *Dennis v. T.H. Allison,* 698 S.W.2d 94, 94-95 (Tex.1985). Liability under these provisions depends on a finding that the goods are defective, meaning that they are "unfit for the ordinary purposes for which they are used because of a lack of something necessary for adequacy." *Plas-Tex, Inc. v. U.S. Steel Corp.,* 772 S.W.2d 442, 444 (Tex.1989). The defect, moreover, may be one of "design, material, or manufacture." *Clark v. DeLaval Separator Corp.,* 639 F.2d 1320, 1326 (5th Cir.1981). At oral argument, Feldt maintained that he is not pursuing a warranty claim based on defective manufacture, but only on defective design.[8]

With respect to the design of the GFS, Mentor has not cited, nor can we find, any specific, applicable FDA regulations. Pre-market notification, as mentioned earlier, does not necessarily

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[7]Although Feldt also alleged a breach of an express warranty based on advertising and product literature, he does not specifically discuss any express warranty claim, as such, in his brief. We therefore deem abandoned any contentions on appeal regarding the preemption of this particular claim, *L & A Contracting v. Southern Concrete Services,* 17 F.3d 106 (5th Cir.1994) (issues not adequately briefed deemed abandoned on appeal), and as a result do not decide whether express warranties are preempted by section 360k, given that they arise not by operation of law but by agreement. *See American Airlines, Inc. v. Wolens,* --- U.S. ----, ----, 115 S.Ct. 817, 824, 130 L.Ed.2d 715 (1995) (distinguishing state-imposed from contractually imposed obligations); *Cipollone,* --- U.S. at ----, 112 S.Ct. at 2622 (same). *See also Michael,* 46 F.3d at 1325-28 (holding that section 360k(a) does not preempt claims relating to the breach of express warranties).

[8]The First Circuit has explicitly held that the GMPs preempt implied warranty claims based on defective manufacture. *Mendes,* 18 F.3d at 19.

entail an assessment, and certainly not an affirmation, of the adequacy or quality of the product's design. Although the generally applicable GMPs regulate the manufacture of the GFS, and although PMA devices are deemed "safe and effective," Mentor has identified no comparable regulations relating specifically to the design quality of non-PMA Class III devices generally or of the GFS in particular. Because the design of the device is not specifically addressed by regulation, we hold that Feldt may proceed with so much of his implied warranty claim as relates to the allegedly defective design of the prosthesis.[9]

The same conclusion holds for Feldt's tort-based claims of defective design.[10] In *Moore,* this Court specifically held that, because there were no regulations concerning the tampon's "design, composition, or construction," the plaintiff could proceed with a

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[9]We acknowledge that our holding in this respect is perhaps in tension with a recent decision from the Third Circuit, *Michael v. Shiley, Inc.,* 46 F.3d 1316 (3d Cir.1995). In *Michael,* the court relied in part on the GMPs to conclude that the plaintiff's design-related implied warranty claim was preempted. *Id.* at 1325. *Michael* is distinguishable, however, because the decision was clearly grounded on the fact that the device had undergone PMA; indeed, it is not certain that the Third Circuit would have found the GMPs to be an independently adequate basis for the preemption of claims relating to design. The same can be said of our decision in *Stamps,* where we mentioned in passing the GMPs in reference to claims relating to both design and manufacturing. *See Stamps,* 984 F.2d at 1422 n. 4. It is clear that *Stamps,* especially when viewed in light of *Moore,* premised the preemption of the plaintiff's defective-design claims on the fact that the device had undergone PMA.

[10]In contrast, the term "defect" under Texas *tort* law "means a condition of the product that renders it unreasonably dangerous." *Plas-Tex,* 772 S.W.2d at 444. Whether a product is unreasonably dangerous or inadequately fit for its intended purpose may be, in either case, a question of the product's design.

defective design claim. Although *Moore* concerned a Class II device that apparently did not have to comply with the procedures for pre-market notification, there is no indication here of any general Class III regulations specifically concerning the safety or adequacy of the GFS's design. We recognize that at least two district courts, on virtually identical facts, have held that the plaintiffs' defective design claims were preempted, in part because of the pre-market notification process. *See Bokis v. American Medical Systems, Inc.,* 875 F.Supp. 748, 755 (W.D.Ok.1995); *English v. Mentor Corp.,* 1994 WL 263353 (E.D.Pa. June 13, 1994) (unpublished). Neither court, however, explained how pre-market notification imposes requirements regarding the device's design. Indeed, the most the manufacturer is required to do in its 510k statement is describe the device in a way that establishes that the device "has the same technological characteristics" or, if not, that it is "as safe and effective" as a predicate device, 21 U.S.C. § 360c(i)(1)(A);[11] there are, in short, no requirements or

[11]At oral argument, Mentor contended that a finding of substantial equivalence *necessarily* means that an approved device is no less safe than the predicate device. Consequently, the question arises whether Feldt's design claims should be preempted at least to the extent they rely on allegations that the device is defective *because of* differences between it and the predicate device. Although 21 U.S.C. § 360c(i) is the law today and has been since 1990, it is unclear what necessarily went into a finding of substantial equivalence at the time the GFS was approved for marketing in 1987. At that time, what determined substantial equivalence was not controlled by statute, and Mentor has not cited, nor can we find, any regulations or case law to support its position that the GFS has necessarily been found to be as safe and effective as predicate devices. With regard to design, the FDA regulations applicable in 1987 appear to have required only "[a] statement indicating the device is similar to and/or different from other products of comparable type, ...

prohibitions specifically regarding the design of non-PMA Class III devices. Indeed, in the letter approving Mentor's 510k statement, the FDA stated that its finding of substantial equivalence did not necessarily indicate approval of the GFS's design. At the very least, then, the nexus between the state and federal requirements is much weaker with respect to design defects than it is with respect to manufacturing and labeling, and we find this nexus inadequate to justify the displacement of state law regarding defective design.[12]

Finally, Feldt has alleged violations of the DTPA. With regard to this claim, Feldt's complaint focuses on representations regarding the GFS's design quality. To the extent Feldt's DTPA claims relate to general marketing or advertising of the device, they are preempted by the FDA's explicit regulations on labels and

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accompanied by data to support the statement." 21 C.F.R. § 807.87(f). Safety information was required only if the new device "has undergone a significant change or modification that could significantly affect the safety or effectiveness of the device." *Id.* § 807.87(g). There is nothing in the record that clearly indicates whether the GFS is technologically different from the predicate devices to which it was found to be substantially equivalent. In any event, it does not appear that Feldt has grounded his defective design claims on any differences in design between the GFS and its predicates.

[12]According to one district court, a jury finding that the GFS is unreasonably dangerous "would be contrary to the determinations necessarily made by the FDA" under its procedures for pre-market notification. *Bokis,* 875 F.Supp. at 755. The FDA, however, may approve an unreasonably dangerous device so long as the device has the same technological characteristics or, if the device has different technological characteristics, is as safe and effective as the predicate device. 21 U.S.C. § 360c(i). To say that a new device is as safe as its predicate thus indicates nothing, absolutely, about how safe either product is; a new device may be as safe as a predicate device that itself is unreasonably dangerous.

warnings. To the extent the DTPA claims are based on the breach of an implied warranty, however, the preemptive effect is the same as for Feldt's implied warranty claim under the Texas Business and Commerce Code, discussed above.

Conclusion

For the foregoing reasons, we reverse the district court's judgment insofar as it holds that Feldt's state law claims of design defect are preempted; we affirm the remainder of the judgment and remand the cause for further proceedings consistent with this opinion.

AFFIRMED in part, REVERSED in part, and REMANDED.