United States Court of Appeals,

Fifth Circuit.

No. 93-3752.

Dorothy Marie REEVES, Plaintiff-Appellee,

v.

ACROMED CORPORATION, et al., Defendants,

Acromed Corporation, et al., Defendants-Appellants.

Feb. 10, 1995.

Appeal from the United States District Court for the Eastern District of Louisiana.

Before JOHNSON, HIGGINBOTHAM and DAVIS, Circuit Judges.

W. EUGENE DAVIS, Circuit Judge:

This appeal arises from a products liability action filed by the appellee, Dorothy Marie Reeves ("Reeves"), alleging that a metal bone implant manufactured and marketed by the appellant, AcroMed Corporation ("AcroMed") exacerbated injuries in her back. The central issue presented on appeal is whether the Medical Device Amendments (the "MDAs") to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq.* (the "Act"), preempt Reeves' claim that AcroMed failed to adequately warn her and her physician of the implant's dangers. AcroMed also challenges the evidentiary sufficiency of Reeves' defective manufacturing, defective design, and unreasonably dangerous per se claims. For the reasons stated below, we conclude that Reeves' failure-to-warn claim is preempted and that Reeves failed to produce sufficient evidence to recover on her defective manufacturing and defective design theories. We thus vacate the district court's judgment and remand this case for

retrial of Reeves' action predicated on her unreasonably dangerous per se theory of recovery.

I.

In December 1985, Dorothy Marie Reeves seriously injured her back. In an effort to correct Reeves' condition, her neurosurgeon attempted a complicated surgical procedure designed to fuse the vertebrae at the four levels of the spine affected by the injury. As part of this surgery, Reeves' neurosurgeon implanted metal bone plates and screws manufactured by AcroMed to secure Reeves' vertebrae while the bone fused. Reeves' condition initially improved after the surgery. X-rays taken of Reeves' back throughout the two years following surgery revealed no complications. Six months after the surgery, however, Reeves complained of increasing pain in her back that had not existed before the surgery. In December 1991, Reeves filed the present suit contending that AcroMed's metal bone implant broke and prevented the bones in her spine from fusing. She based her claim on a number of theories, including negligence, strict liability, breach of warranty, and battery. However, Reeves' primary theory at trial was that AcroMed failed to warn her that the Food and Drug Administration (the "FDA") never approved AcroMed's implant for use in the spine except as part of a controlled investigational study.

At the close of trial, the district court submitted three special interrogatories on liability to the jury. The jury found AcroMed's device unreasonably dangerous as a spinal implant and that AcroMed did not legally obtain FDA approval to market its

device as a spinal implant. The jury also found that Reeves would not have permitted her surgeon to implant AcroMed's device if she had known that the device was unapproved for use in the spine.[1] The jury assessed Reeves' damages at $475,000, and the district court entered judgment on the verdict against AcroMed for that amount.

The district court instructed the jury that they could find AcroMed's product unreasonably dangerous and answer Interrogatory One "Yes" based on any of Reeves' four theories of recovery: defective design, defective manufacturing, failure-to-warn, and the "unreasonably dangerous *per se*" doctrine. AcroMed contends that the evidence is insufficient to support Reeves' recovery on three of the four theories submitted to the jury: defective

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[1]The jury answered the interrogatories as follows:

> INTERROGATORY NO. ONE:
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> Was the AcroMed product implanted in Dorothy Reeves' spine unreasonably dangerous as a spinal implant?
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> YES _X_ NO ____
>
> INTERROGATORY NO. TWO:
>
> Did AcroMed legally obtain FDA approval for the AcroMed product to be implanted in the spine except in an investigative or experimental program, prior to the time it was implanted in Dorothy Reeves?
>
> YES ____ NO _X_
>
> INTERROGATORY NO. THREE:
>
> If Dorothy Reeves had been informed that the AcroMed product was experimental and under investigation would she have permitted it to be implanted in her back?
>
> YES ____ NO _X_

manufacturing, defective design, and the unreasonably dangerous *per se* doctrine. AcroMed further maintains that the MDAs preempt Reeves' failure-to-warn claim.

II.

When a district court submits two or more alternative grounds for recovery to the jury on a single interrogatory and the plaintiff prevails, we ordinarily order a new trial if one of the grounds for recovery is "legally inadequate." *Walther v. Lone Star Gas Co.,* 952 F.2d 119, 126 (5th Cir.1992); *Pan Eastern Exploration v. Hufo Oils,* 855 F.2d 1106, 1123 (5th Cir.1988). In such a case, "the reviewing court cannot determine whether the jury based its verdict on a sound or unsound theory." *Pan Eastern Exploration,* 855 F.2d at 1123; *Hayes v. Solomon,* 597 F.2d 958, 985 (5th Cir.1979) (holding that "the very real likelihood that the jury may have utilized an unproven or improper theory of liability to reach its verdict mandates reversal"). In the present case, the district court submitted four of Reeves' theories of recovery under the first interrogatory. The first interrogatory inquires whether AcroMed's product was "unreasonably dangerous as a spinal implant." The court instructed the jury that proof of one or more of Reeves' four theories of recovery was sufficient for an affirmative answer to the first interrogatory. Thus, if the court erroneously submitted one of the legal theories of recovery to the jury and the form of the interrogatory prevents us from determining upon which theory the jury based its verdict, we must vacate the judgment. *Hufo,* 855 F.2d at 1123.

AcroMed's primary contention on appeal is that the district court erroneously submitted Reeves' failure-to-warn theory of recovery to the jury. According to AcroMed, Reeves' failure-to-warn claim is legally inadequate because it is preempted by the MDAs. We now turn to the merits of AcroMed's preemption argument.

III.

A.

Reeves' produced evidence at trial that AcroMed failed to warn her or her doctor that its metal bone implant was not FDA approved for use in the spine. This evidence is the basis of her failure-to-warn claim.

The MDAs establish two separate approval processes for medical devices: Pre-Market Approval and Pre-Market Notification. The FDA's Pre-Market Approval process applies to new medical devices introduced after May 28, 1976, the date the MDAs were enacted. This process is lengthy and involves extensive investigation by the FDA. The FDA's Pre-Market Approval application requires manufacturers to submit extensive animal and human data to establish their devices' safety and effectiveness. 21 C.F.R. § 814.20. Frequently, an experimental program under close FDA scrutiny must be successfully completed before FDA approval can be obtained under this process. FDA regulations also require Pre-Market Approval applicants to submit "[c]opies of all proposed labeling for the device." 21 C.F.R. § 814.20(b)(10). The FDA approves a Pre-Market Approval application only after extensive

review by the agency and an advisory committee composed of outside experts. 21 C.F.R. § 814.40.

In contrast to the FDA's Pre-Market Approval process, the agency's Pre-Market Notification process is more abbreviated and involves less FDA oversight. To obtain FDA approval under this procedure, the applicant must demonstrate that its device is "substantially equivalent" to a device on the market prior to May 28, 1976. 21 C.F.R. § 807.87. The Pre-Market Notification process requires applicants to submit descriptions of their devices and other information necessary for the agency to determine whether the devices are substantially equivalent. As with the Pre-Market Approval process, Pre-Market Notification applicants must also submit their proposed labeling. *Id.* If the FDA determines that a device is substantially equivalent to a device that was on the market prior to the enactment of the MDAs in 1976, the applicant is free to market the device.

Reeves produced evidence that AcroMed applied twice to the FDA for approval to market its device as a spinal implant under the FDA's Pre-Market Notification process, and that the FDA rejected both applications. The FDA concluded that the implant was not substantially equivalent to any spinal implant on the market before 1976, and directed AcroMed to obtain additional animal and human data showing that the implant is safe and effective if used as a spinal implant. In December 1985, AcroMed submitted a third Pre-Market Notification application to the FDA covering the same implant, but omitting any statements identifying the spine as one

of the potential uses of the device. In contrast to AcroMed's prior applications, this application stated that AcroMed intended to market its implant for use in "appropriate fractures of long bones of both the upper and lower extremity," and other flat bones. The FDA approved AcroMed's implant for marketing based on the revised application.[2]

B.

AcroMed contends that the MDAs expressly preempt Reeves' failure-to-warn claim. Section 360k(a) of the Act provides:

> [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—
>
> (1) which is different from, or **in addition to,** any requirement applicable under this chapter to this 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) (emphasis added). AcroMed argues that § 360k(a) preempts Reeves' failure-to-warn claim because her claim, if successful, would impose a labeling requirement that is "in addition" to the FDA's labeling regulations.

The touch-stone of preemption analysis is Congressional intent. *Cipollone v. Liggett,* --- U.S. ----, ----, 112 S.Ct. 2608, 2617, 120 L.Ed.2d 407 (1992). Congressional intent may be "explicitly stated in the statute's language or implicitly

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[2]In January 1986, the FDA approved an additional AcroMed application for an investigational study allowing AcroMed to implant its device in the spines of a select group of patients under strict guidelines established by the FDA. Reeves was never a participant in such an investigational study.

contained in its structure and purpose." *Id.* (quoting *Jones v. Rath Packing Co.,* 430 U.S. 519, 525, 97 S.Ct. 1305, 1309, 51 L.Ed.2d 604 (1977)). Where Congress enacts legislation that specifically addresses the issue of preemption, the express language of the statute provides a "reliable indicium of congressional intent with respect to state authority." *Id.* at ----, 112 S.Ct. at 2618 (quoting *Malone v. White Motor Corp.,* 435 U.S. 497, 505, 98 S.Ct. 1185, 1190, 55 L.Ed.2d 443 (1978)). Consequently, the existence of an express preemption provision renders it unnecessary for us "to infer congressional intent to preempt state laws from the substantive provisions" of the MDAs. *Id.* Rather, to determine the precise boundaries of § 360k(a) "we need only identify the domain expressly preempted" by the language of the statute. *Id.*

We have previously held that § 360k(a) of the Act preempts common law failure-to-warn claims involving medical devices subject to the MDAs. In *Moore v. Kimberly-Clark Corp.,* 867 F.2d 243, 246-247 (5th Cir.1989), the court held that § 360k(a) preempted a claim alleging that a tampon manufacturer had failed to provide adequate warnings concerning the dangers of toxic shock syndrome. The court based its decision primarily on the fact that FDA regulations specifically prescribe the form and content of toxic shock warnings on tampons. *Id.* Because the plaintiff's claim would essentially impose labeling requirements beyond those required by the FDA's regulations, the court concluded that § 360k(a) preempted the plaintiff's claim.

In *Stamps v. Collagen Corp.,* 984 F.2d 1416, 1423-24 (5th Cir.), *cert. denied* --- U.S. ----, 114 S.Ct. 86, 126 L.Ed.2d 54 (1993), this court applied the reasoning of *Moore* to hold that preemption barred a failure-to-warn claim brought against the manufacturer of an anti-wrinkle treatment. We reached this conclusion even though the FDA had not promulgated regulations that specifically prescribed the form and content of the product's labeling and warnings. The court reasoned that the FDA's Pre-Market Approval process requires agency review and approval of a device manufacturer's proposed labeling before a medical device can be marketed. *Id.* FDA approval of a device for marketing, therefore, signifies the agency's determination that the manufacturer's labeling is sufficient. Because common law failure-to-warn claims would impose labeling requirements beyond those required by the FDA, the court concluded that § 360k(a) preempted the plaintiff's failure-to-warn claim. *Id.*

C.

We conclude that the reasoning of *Moore* and *Stamps* applies to the present case because Reeves' failure-warn-claim, if successful, would impose labeling requirements "in addition" to the requirements of the MDAs and FDA regulations. 21 U.S.C. § 360k(a). FDA regulations require device manufacturers to submit the proposed labeling and warnings for their devices to the FDA as part of the approval process under the MDAs. 21 C.F.R. § 807.87(e). FDA labeling regulations specifically require labels to disclose a device's uses, hazards, side effects, and any applicable

precautions. 21 C.F.R. § 801.109. Based on its review of the manufacturer's proposed labeling, the agency can impose additional labeling requirements if it determines that a "substantial deception" or unreasonable health danger could be corrected by "labeling or a change in labeling." 21 C.F.R. § 895.25. The FDA thus implicitly approves a manufacturer's proposed labeling when the agency approves a device for marketing. *Stamps,* 984 F.2d at 1123. Because Reeves' failure-to-warn claim would impose labeling requirements beyond those required by the FDA, her claim runs afoul of § 360k(a) of the MDAs. *Id.; see also* 21 C.F.R. § 808.1(d)(6) (the MDAs preempt state requirements that have "the effect of establishing a substantive requirement for a specific device.")

Reeves attempts to distinguish this case from *Moore* and *Stamps* on three grounds. Reeves first argues that we should not give preemptive effect to the FDA's approval of AcroMed's labeling because the FDA approval process involved in this case is considerably less stringent than the review processes involved in *Stamps.* The anti-wrinkle treatment in *Stamps* was approved through the FDA's Pre-Market Approval process. In contrast, AcroMed's implant was approved through the FDA's Pre-Market Notification process. *Stamps,* 984 F.2d at 1123. In support of her argument, Reeves points out that the FDA's approval of a device under the Pre-Market Notification process "does not in any way denote official approval of the device." 21 C.F.R. § 807.97.

Reeves' attempt to distinguish this case on the basis of the type of FDA approval process at issue is unpersuasive. The FDA

labeling requirements that prompted this court to apply preemption in *Stamps* also apply to products approved under the FDA's Pre-Market Notification process. Even if the FDA's Pre-Market Notification process does not result in the FDA's "official approval" of a device, the agency subjects the manufacturer's proposed labeling to extensive scrutiny. As discussed above, FDA regulations required AcroMed to submit its proposed labeling with its Pre-Market Notification application. *See* 21 C.F.R. § 807.87(e). The regulations also required the FDA to review AcroMed's labeling to ensure that it was in compliance with the general labeling regulations set out in 21 C.F.R. §§ 801 *et seq.* Therefore, despite the differences between the FDA's Pre-Market Approval and Pre-Market Notification procedures, our preemption analysis remains the same. The First Circuit used this same reasoning in holding that the preemptive effect of FDA labeling regulations apply equally to devices approved under the FDA's Pre-Market Approval and Pre-Market Notification procedures. *Mendes v. Medtronic, Inc.,* 18 F.3d 13, 17-18 (1st Cir.1994).

Reeves also contends that preemption should not apply in this case because the AcroMed implant was used in the spine—an "off-label" use—rather than in the long bones of the upper or lower extremities, as stated in AcroMed's December 1985 application to the FDA. But, Reeves' attempt to distinguish this case based on the off-label use of AcroMed's implant is also flawed. FDA labeling regulations specifically address off-label uses of medical devices. For example, FDA regulations require manufacturers to

provide appropriate labeling if the manufacturer has reason to believe that its medical device might be used for purposes different from the purposes for which the device is approved. 21 C.F.R. 801.4[3]. Similarly, the FDA can require a manufacturer to provide additional labeling that addresses potential off-label uses. 21 C.F.R. § 895.25. Consequently, the fact that AcroMed's implant might have been used for an off-brand propose is not sufficient to distinguish this case from *Moore* and *Stamps.*

Finally, Reeves argues that preemption should not apply in this case because AcroMed misled the FDA and violated FDA regulations by withholding material information from the FDA concerning the intended uses of its product. Reeves argues that AcroMed failed to inform the FDA that they intended to market their device as a spinal implant. In support of this argument, Reeves produced evidence that AcroMed removed all references to spinal uses from its December 1985 Pre-Market Notification application to gain FDA approval after the FDA had rejected two prior applications to market the device as a spinal implant.

Reeves essentially invites us to create an exception to preemption under § 360k(a) in cases where a manufacturer withholds material information from the FDA during the approval process.

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[3]According to § 801.4:

> [I]f a manufacturer knows, or has knowledge of facts that would give it notice that a device introduced into interstate commerce by a manufacturer is to be used for conditions, or uses other than the ones for which he offers it, he is required to provide adequate labeling ... which accords with such other uses to which the article is to be put.

Whether such an exception is warranted in a case involving a medical device subject to the MDAs is a question of first impression in this circuit. In *Hurley v. Lederle Lab. Div. of American Cyanamid Co.,* 863 F.2d 1173, 1179-1180 (5th Cir.1988) we declined to preempt a failure-to-warn claim brought against a vaccine manufacturer. We based our holding on the plaintiff's allegations that the manufacturer withheld material information from the FDA during the vaccine's approval process.

Our holding in *Hurley* however is distinguishable from the present case. In contrast to the present case, *Hurley* did not involve a medical device subject to approval under the MDAs. More importantly, because the vaccine at issue in *Hurley* was not subject to the express statutory preemption provision in § 360k(a) of the MDAs, we based our analysis on **implied** preemption principles. As the Supreme Court made clear in *Cipollone,* implied preemption analysis is inapplicable where a statute contains an express preemption provision. Therefore, the focus of our preemption analysis must be the language of § 360k(a). --- U.S. at ----, 112 S.Ct. at 2618.

Only one other circuit has specifically addressed whether evidence of fraud on the FDA is sufficient to defeat preemption under § 360k(a) of the MDAs. In *King v. Collagen Corp.,* 983 F.2d 1130, 1139-1140 (1st Cir.1993), the First Circuit declined to create an exception to preemption under the MDAs where the plaintiff alleged that the manufacturer fraudulently withheld material safety information from the FDA during the approval

process. The court reasoned that the FDA was in the best position to determine whether a manufacturer has withheld material information:

> [W]here the FDA was authorized to render the expert decision on Collagen's use and labeling, it, and not some jury or judge, is best suited to determine the factual issues and what their effect would have been on its original conclusions.

Id. at 1140. The court also observed that an erroneous jury finding that a manufacturer failed to disclose material information would be tantamount to imposing a requirement "that is different from, or in addition to, any requirement applicable ... to the device." *Id.* (quoting 21 U.S.C. § 360k(a)). The court concluded, therefore, that a fraud-on-the-FDA exception to preemption would inevitably run afoul of the MDA's express preemption provision in § 360k(a). *See also, Papas v. Upjohn Co.,* 985 F.2d 516, 518-519 (11th Cir.1993) (declining to find an exception to an express preemption provision under the Federal Insecticide, Fungicide, and Rodenticide Act based on allegations that a pesticide manufacturer withheld material information from the Environmental Protection Agency).

Other courts have declined to create an exception to preemption under the MDAs in cases where manufacturers allegedly violated FDA labeling regulations. In *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.,* 38 F.3d 988, 993-94 (8th Cir.1994) the Eighth Circuit held that the plaintiff's failure-to-warn claim was preempted under § 360k(a) even though the plaintiff alleged that the defendant manufacturer had violated FDA labeling regulations. The court reasoned that the MDAs require the

FDA to determine whether a manufacturer's proposed labeling complies with FDA labeling regulations when the agency approves a device for marketing. Accordingly, permitting a state law failure-to-warn claim based on allegations that a manufacturer violated FDA labeling regulations would essentially constitute a collateral attack on the FDA's original determination that the manufacturer was in compliance with all applicable regulations. *Id.* The court concluded that such an attack on the FDA's determination of compliance is preempted by § 360k(a).[4]

We agree with the reasoning of *King* and *El Dorado* and, therefore, decline Reeves' invitation to create a unwieldy exception to *Moore* and *Stamps* in cases where manufacturers attempt to mislead the FDA or violate FDA regulations. The MDAs establish an extensive enforcement scheme under which the FDA bears the primary responsibility for policing violations of its regulations. *El Dorado,* 38 F.3d at 994. In fact, the MDAs specifically proscribe the submission of fraudulent forms to the FDA and establish civil and criminal penalties for intentionally defrauding or misleading the FDA. *See* 21 U.S.C. §§ 331, 333(a)(2), 333(g);

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[4]Other courts have questioned the applicability of preemption in cases where a manufacturer has violated FDA regulations. However, most of the statements favoring an exception to preemption under these circumstances are in dicta. *See Slater v. Optical Radiation Corp.,* 961 F.2d 1330, 1334 (7th Cir.1992) (Posner, J.) (reasoning that preemption under § 360k(a) "is limited to efforts by states to impose sanctions for compliance with federal regulations."); *see also Tarallo v. Searle Pharmaceutical, Inc.,* 704 F.Supp. 653, 655 (D.S.C.1988). However, as of the date of this opinion, no court has squarely held that a violation of FDA labeling regulations defeats preemption of state failure-to-warn claims.

see also United States v. Arlen, 947 F.2d 139, 142-43 (5th Cir.1991).[5] Given the FDA's central role in reviewing and approving devices under the MDAs, the FDA is in the best position to decide whether AcroMed withheld material information from the agency and, if so, the appropriate sanction. Allowing a jury or court to second-guess the FDA's enforcement of its own regulations contravenes Congress' expressly stated intent in § 360k(a) to eliminate attempts by states to impose conflicting requirements on medical device manufacturers. *See* H.R.Report No. 853, 94th Cong., 2d Sess. 9 (1976) (explaining that the principal purpose of § 360k(a) is to eliminate conflicting regulations). For these reasons, we conclude that § 360k(a) of the MDAs preempts Reeves' failure-to-warn claim.

IV.

We conclude, therefore, that the district court erred in

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[5]21 U.S.C. § 331 states:

> The following acts and the causing thereof are prohibited:
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> (q)(2) With respect to any device, the submission of any report that is required by or under this chapter that is false and misleading in any material respect.

21 U.S.C. § 333(a) establishes criminal penalties for violations of § 331:

> (a)(1) Any person who violates a provision of section 331 of this title shall be imprisoned for not more than one year or fined not more than $1,000, or both.
>
> (2) Notwithstanding the provisions of paragraph (1), if any person ... commits such a violation with the intent to defraud or mislead, such person shall be imprisoned for not more than three years or fined not more than $10,000, or both.

submitting Reeves' failure-to-warn theory of recovery to the jury. Because we cannot determine whether the jury based its affirmative answer to Interrogatory One on Reeves' legally inadequate failure-to-warn theory of recovery, we must vacate the district court's judgment and remand the case for retrial. The only remaining issue is which of the three remaining theories of recovery the district court must retry on remand.

AcroMed contends that Reeves failed to introduce sufficient evidence to recover on the basis of a design or manufacturing defect. We have carefully reviewed the record and find no evidence to support a recovery on the basis of a defect in the fabrication or manufacture of AcroMed's implant. On appeal, Reeves points to no evidence that would support a recovery on this theory. Consequently, there is insufficient evidence to retry this theory of recovery on remand.

Reeves also failed to establish all the elements required by Louisiana law to recover on a defective design theory. To prevail on this theory, Louisiana law requires a plaintiff to establish the existence of an alternative safer design for the product. *Halphen v. Johns-Manville Sales Corp.,* 484 So.2d 110, 115 (La.1986). Reeves introduced no evidence of an alternative safer design. Indeed, she does not argue on appeal that she satisfied this requirement.

Finally, AcroMed contends that Reeves failed to produce sufficient evidence at trial to support her recovery under the theory that AcroMed's implant is unreasonably dangerous *per se.* A

product is unreasonably dangerous *per se* if "[a] reasonable person would conclude that the danger-in-fact, whether foreseeable or not, outweighs the utility of the product." *Halphen,* 484 So.2d at 115. While this theory of recovery eliminates the "state of the art" defense, the plaintiff is not relieved of the burden of proving that the product is defective. *Valenti v. Surgiteck-Flash Medical Eng. Corp.,* 875 F.2d 466, 468 (5th Cir.1989). Thus, in order to carry her burden, Reeves must establish that some inherent characteristic of AcroMed's implant renders it unreasonably dangerous for use in the spine.

We conclude that Reeves' evidence is sufficient to support submitting her unreasonably dangerous *per se* claim to the jury. In support of her claim, Reeves points to an October 1985 FDA letter rejecting AcroMed's original application to have its implant approved as a spinal implant. In this letter, the FDA cites several potential health hazards of AcroMed's device as a spinal implant. The FDA specifically referred to its concern about the stability of the device and that the screws could break and damage the bones in the spine. This evidence, together with evidence that allowed the jury to infer that the screws broke and exacerbated Reeves' back pain, is sufficient to create a jury issue. We conclude, therefore, that there is sufficient evidence to retry Reeves' unreasonably dangerous *per se* theory of recovery on remand.

V.

For the reasons stated above, we must VACATE the judgment and REMAND this case for retrial of Reeves' unreasonably dangerous *per*

se theory of recovery. *Pan Eastern Exploration,* 855 F.2d at 1123.

VACATED and REMANDED.

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