

2000-2001

**NATIONAL HEALTH LAW
MOOT COURT COMPETITION**

Transcript of Record
Docket No. 00-2015

SUPREME COURT OF THE UNITED STATES

October Term, 2000

PAULA D. STRAND

Petitioner and Cross Respondent,

v.

RELIEF, INC.,

Respondent and Cross Petitioner.

SPONSORS:

Southern Illinois University School of Law

*Southern Illinois University School of Medicine,
Department of Medical Humanities*

American College of Legal Medicine

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF SHOCK

Paula D. Strand

)

)

Plaintiff

)

Civil No. 98-C-62

v.

Relief, Inc.

)

)

Defendant.

MEMORANDUM OPINION AND ORDER

This matter is before the Court on Defendant's motion for summary judgment and Plaintiff's opposition to this motion.

I. **FACTS**

Relief, Inc. (Relief) is a corporation organized under the laws of the State of Panic where it has its offices and facilities. Relief manufactures medical devices to treat and control pain. In 1984, Relief developed the "Pain Free" Transcutaneous Electrical Nerve Stimulation (TENS) device (Pain Free). The product was originally intended for the relief of chronic, acute and post-traumatic pain. In this application, the Pain Free qualified as a Class II medical device and was subject to the premarket notification requirements of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. ' 360(k).¹ In 1985, Pain, Inc. brought to market the TENS device after clearing it through the 510(k) process. This procedure involved a notice to the Food and Drug Administration (FDA) including information demonstrating that the device was substantially equivalent to another device marketed before May 1976.

In the years since the introduction of the Pain Free device, doctors and therapists observed that the device also appeared to help in the healing of wounds and bone fractures. Relief undertook clinical trials to investigate this possible indication. The clinical trials took 2 years, involved 500 subjects and cost \$15 million. This investigation determined that treatment with Pain Free had a beneficial effect in the treatment of wounds and fractures. Because such application placed the Pain Free in regulatory Class III, Relief was required to submit and obtain the FDA's approval of a premarket approval

¹ This process, which is commonly referred to as the 510(k) process (given its section number in the original Act) mandates a limited form of review for a manufacturer introducing a new medical device. If the device is found by the Food and Drug Administration (FDA) to be substantially equivalent to an existing device, it may be marketed without additional review by the FDA. See 21 C.F.R. ' 814.1(c).

application (APMA) under section 515 of the Act (21 USC ' 360e) before Relief could market the Pain Free with these new intended uses.

The FDA took two years to review Relief's PMA and the additional submissions it required to complete the application, finally granting premarket approval in 1993. Relief immediately began marketing and selling the Pain Free nationwide (including in the State of Shock) for this approved indication, as patients and physicians had eagerly anticipated use of the Pain Free in the treatment of other injuries. The Pain Free became a very popular treatment, with many physicians and patients praising the device's effectiveness in treating injuries and alleviating pain.

Like many patients, the plaintiff Paula Strand, a Shock citizen, welcomed the Pain Free as a part of her rehabilitation. In 1996, Strand suffered massive trauma in an automobile accident and was treated by her physician with the Pain Free. At first, the Pain Free appeared to be effective in treating and healing Strand's wounds and fractures. However, after the second week of treatment, Strand exhibited several severe and permanent injuries resulting from muscle and nerve damage. These included severe burning, muscle cramps, and intermittent sharp, stabbing pain localized to the area where the TENS electrodes were located. Further, Strand experiences almost constant pins-and-needle sensations (medically known as paresthesias) throughout the area. Alleging that the Pain Free caused her injuries, Strand filed a multi-count complaint in this Court stating counts of strict liability, negligence, fraud, failure to warn and breach of implied warranty, seeking in excess of \$75,000 in damages. Jurisdiction is properly based on diversity of citizenship under 28 U.S.C. ' 1332.

Defendant filed a motion for summary judgment under F.R.C.P. 56 in part on the basis that the claims were expressly preempted by the Act. In the alternative, Defendant asserts that the claims are impliedly preempted because the PMA process establishes a comprehensive regulatory scheme to which a state-law tort action stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress in establishing the PMA process. In connection with this motion, the parties stipulated that the Pain Free device used by Strand was properly manufactured by Relief according to the approved design and was properly used by Strand for its intended purpose to help heal her fractures and wounds.

II. ANALYSIS

A. Express Preemption

The basis of preemption is the Supremacy Clause of the Constitution. U.S. Const., art. VI, ch. 2. Under this concept, state law that conflicts with federal law is deemed to be without effect. The

Defendant's argument here that the Act preempts the claims in Plaintiff's Complaint is controlled by the application of section 360k(a) of the Act.²

² (a) **General Rule B** Except as provided in subsection (b), 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 **B** (1) which is different from, or in addition to, any requirement applicable under this Act 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 Act.

21 U.S.C. ' 360k(a).

Relief states that preemption exists because the PMA process is a federal requirement applicable to a particular device. The Supreme Court examined in detail the issue of preemption with respect to the 510(k) "substantially equivalent" process in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Unlike the 510(k) process reviewed in *Medtronic*, the PMA process is substantially different in that it imposes upon the applicant a significant burden to show the safety and effectiveness of a device in order to obtain approval to market and sell it.³ The manufacturer is required to submit an application which includes:

(A) full reports of all information . . . , concerning investigations which have been made to show whether or not such device is safe and effective;

(B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;

(C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device;

(D) an identifying reference to any performance standard under section 514 which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;

(E) such samples of such device and of components thereof as the Secretary may reasonably require, . . . ;

(F) specimens of the labeling proposed to be used for such device; and

(G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 513, may require.⁴

After review, the FDA must approve or deny the application.

This Court holds that the PMA process is a specific requirement as described in *Medtronic* and preempts state common law causes of action. Accordingly, the claims of strict liability based upon an unreasonably dangerous product are preempted. FDA approval includes an evaluation of a device's

³ This court also notes that the opinion in *Medtronic* was highly fragmented and only a very narrow majority was in agreement as to the basis for preemption. See Scott W. Saylor and Steven M. Thomas, *Post-Decision Diagnosis: Medical Device Preemption Alive and Mostly Well After Medtronic, Inc. v. Lohr*, 6 ANN. HEALTH L. 185 (1997).

⁴ 21 U.S.C. ' 360e(c)(1).

design, effectiveness, safety, production processes, and labeling. A judgment based upon strict liability would be a requirement different from or in addition to the federal requirement.⁵

This same analysis applies to the failure to warn claim as far as this claim is based upon labeling reviewed and approved in the PMA process. State law counts of fraud and implied warranty also are precluded in that they would establish requirements different from or in addition to federal requirements.

The Plaintiff is not precluded from asserting claims based upon Relief's negligence in complying with the PMA federal regulatory requirements notwithstanding the preemptive effect of section 360k(a). *Mitchell v. Collagen*, 126 F.3d 902 (7th Cir. 1997).

B. Implied Preemption

Even if the Plaintiff's claims were not preempted under section 360k(a), they are preempted by the comprehensive PMA regulatory scheme in a manner coincidental with the scope of the statutory preemption of section 360k(a) in that a state tort claim would interfere with the accomplishment of congressional objectives. *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995). We recognize that previous court decisions have foregone the implied preemption analysis. *Reeves v. Acromed Corp.*, 44 F.3d 300 (5th Cir. 1995); *Stamps v. Collagen Corp.*, 984 F.2d 1416 (5th Cir. 1993). However, this Court favors the reasoning that, as an obstacle to the accomplishment and execution of the full purposes of Congress, Strand's state law claims may be preempted by the Food and Drug Act. *See English v. General Electric Co.*, 496 U.S. 72 (1990).

The PMA process represents a comprehensive legislative effort to establish a regulatory scheme which would provide reasonable assurances that Class III medical devices, those which present the greatest risk to patients, are safe and effective. This distinguishes it from the 510(k) process review considered in *Medtronic*.

In evaluating the congressional purpose of the PMA process, one must concurrently consider the investigational device requirements of section 520(g). 21 U.S.C. ' 360j(g). Clinical studies submitted in support of a PMA are subject to this provision of the Act and the FDA's implementing regulations.

This section provides an additional layer of assurance for the safety and effectiveness of a medical device. Pursuant to its authority, FDA has established requirements to ensure that individuals involved in clinical tests are protected and that the safety and efficacy data included in the PMA is reliable. 21 C.F.R. Part 812. The comprehensive and pervasive regulatory scheme established for

⁵ Were the PMA requirements deemed to be general requirements, they are of sufficient specificity to preempt state requirements different from or in addition to those imposed by the Act and of the type of requirements contemplated to have preemptive effect. *Medtronic*, 518 U.S. at 500.

Class III medical devices which are subject to the PMA process is manifested in sections 515 and 520(g) of the Act.

The regulatory scheme established to ensure that devices subject to the PMA process are safe and effective, evinces a congressional objective to have a uniform and comprehensive review of these Class III devices performed by the FDA. A state law tort action requirement inconsistent with the PMA process would stand as an obstacle to the accomplishment and execution of this purpose. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

IV. Conclusion

The Defendant's motion for summary judgment is granted as to the Plaintiff's claims arising out of strict liability, failure to warn, fraud and breach of implied warranty. The Clerk of the Court is directed to enter judgment on these counts on which Plaintiff takes nothing. The Defendant's motion is denied with respect to Plaintiff's negligence claim insofar as it is based on non-compliance with PMA federal regulatory requirements. Finally, pursuant to 28 U.S.C. '1292(b), the Court certifies this judgment for interlocutory appeal.

SO ORDERED

Date: July 21, 1998

/s/ George Burwood

Honorable George Burwood

Entered: July 21, 1998

IN THE UNITED STATES COURT OF APPEALS
FOR THE TWELFTH CIRCUIT

No. 99-0905

Paula D. Strand

Plaintiff-Appellant

v.

Relief, Inc.

Defendant-Appellee

Appeal from the United States District Court for the Eastern District of Shock
Civil No. 98-C-62 B George Burwood, District Judge

Argued December 14, 1999 B Decided May 26, 2000

Before KEMMLER, Chief Judge, DAVIS and SOUTHWICK, Circuit Judges.

KEMMLER, Chief Judge. This action comes before the court on plaintiff's appeal of the district court's grant of summary judgment for defendant on the basis of preemption. The district court certified the judgment for appeal under 28 U.S.C. ' 1292(b) and this court granted the petition for this appeal. The district court's judgment is affirmed.

Facts

The district court's opinion adequately sets forth the facts of this case. In 1996, the plaintiff Paula D. Strand sued the defendant Relief, Inc., on theories of strict liability, negligence, fraud, failure to warn and breach of implied warranty for injuries she claims to have sustained from using the Transcutaneous Electrical Nerve Stimulation (TENS) device manufactured and marketed by Relief referred to as the Pain Free. Relief moved for summary judgment on the grounds that Strand's state law claims were preempted by the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. ' 360k. The district court granted Relief's motion as to Strand's claims

of strict liability, fraud, failure to warn and breach of implied warranty, but spared Strand's negligence claim. Strand appeals the district court's holding on preemption. Relief has not appealed the decision with respect to the negligence claim.

Analysis

Express Preemption

We disagree with the district court's conclusion that the Act expressly preempts Strand's state law claims. The linchpin to whether the Act preempts state requirements applicable to medical devices is whether the Act imposes a "specific requirement" within the meaning of section 360k(a). *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). The regulations at issue here simply do not constitute the kind of "specific requirement" that warrants preemption under the Act or *Medtronic. Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999). Although it does vest regulatory authority over devices in the FDA, the premarket approval process required under section 360k(a)(1) imposes no affirmative federal requirements on device manufacturers. Moreover, the Act is not specific to any particular device.

Implied Preemption

Although we cannot affirm the district court's decision with respect to express preemption, we nevertheless arrive at the same result because we agree that plaintiff's claims are barred by implied preemption. As the Eleventh Circuit has recently suggested, state law claims may be preempted by the Food and Drug Act as an obstacle to the accomplishment and execution of the full purposes of Congress. *Goodlin*, 167 F.3d at 1377 n.20. Allowing the various states to impose requirements on devices through tort actions would create an unsystematic and inconsistent regulatory environment which thwarts the objectives of the PMA approval process. Accordingly, Strand's claims, with the exception of those alleging negligence in the failure to comply with the FDA-approved PMA, are preempted because they obstruct the fulfillment of Congress' purposes and objectives in promulgating the Act. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Conclusion

We hold that Strand's state law claims against Relief are preempted by the Act under the doctrine of implied preemption.

The judgment of the district court is affirmed.

No. 00-2015

IN THE SUPREME COURT OF THE UNITED STATES

OCTOBER TERM 2000

PAULA D. STRAND,

PETITIONER AND CROSS RESPONDENT,

v.

RELIEF, INC.,

RESPONDENT AND CROSS PETITIONER.

ORDER GRANTING CERTIORARI

Upon consideration of the Cross Petitions for Certiorari the Court hereby **GRANTS** the petitions as to the following issues:

1. Whether the premarket approval process of the Federal Food, Drug and Cosmetics Act imposes a requirement that expressly preempts state law requirements that are in addition to or different from the Act under 21 U.S.C. '360k.
2. Whether state court tort claims stand as an obstacle to the accomplishment and execution of the purposes and full objectives of Congress as set forth in 21 U.S.C. '360e of the Federal Food, Drug and Cosmetic Act and are therefore impliedly preempted.

IT IS SO ORDERED.

Date: June 26, 2000