IN THE COURT OF APPEALS OF MISSISSIPPI

NO. 2009-CA-00594

WILLIAM SANDERS **APPELLANT**

V.

ADVANCED NEUROMODULATION SYSTEMS, INC. **APPELLEE**

CERTIFICATE OF INTERESTED PERSONS

The undersigned counsel of record certifies that the following listed persons have an interest in the outcome of this case. These representations are made in order that the justices of the Supreme Court and/or the judges of the Court of Appeals may evaluate possible disqualification or recusal.

WILLIAM SANDERS	APPELLANT
ADVANCED NEUROMODULATION SYSTEMS, INC.	APPELLEE
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TABLE OF CONTENTS

TABLE OF AUTHORITIES

STATEMENT OF ISSUES

I. WHETHER THE FOOD AND DRUG ADMINISTRATION MAY ISSUE AN ORDER THAT IS PLAINLY INCONSISTENT WITH ITS REGULATIONS?

II. WHETHER SANDERS' CLAIMS AGAINST ADVANCED NEUROMODULATION SYSTEMS, INC. ARE BARRED BY MDA'S PRE-EMPTION CLAUSE?

III. WHETHER THE CIRCUIT COURT COMMITTED ERROR IN GRANTING THE MOTION FOR SUMMARY JUDGMENT OF ADVANCED NEUROMODULATION SYSTEMS, INC?

STATEMENT OF THE CASE

i. Nature of the Case, course of proceedings and disposition in the court below.

This is an appeal from the April 3, 2009 Order of the Circuit Court of Lee County, Mississippi granting Advanced Neuromodulation Systems, Inc ("ANS") motion for summary judgment. (Record Excerpt ("RE"), p. 5-7). This Order dismissed the product liability complaint of William Sanders ("Sanders").

On April 8, 2009 Sanders filed his Notice of Appeal of this Judgment. (R., p. 73-74).

ii. Statement of Facts

On or about September 14, 2005, the Plaintiff, William Sanders, was a patient at North Mississippi Medical Center ("NMMC") where he underwent a surgical procedure to remove the left lead of a spinal cord stimulator manufactured by ANS. (R. p. 4-6) During the course of this procedure, the left lead of the spinal cord stimulator broke. Thereafter, on September 7, 2007, Plaintiff filed his Complaint against Advanced and other Defendants.

In his Complaint, Plaintiff alleges that ANS negligently manufactured the spinal cord stimulator, distributed a defective and dangerous product, and that Advanced is strictly liable for injuries sustained by Plaintiff as a result of its manufacture, sale and distribution of a defective product. (R. p. 4-6). After answering the Complaint, ANS filed its motion for summary judgment. (R. p. 7-10).

On April 6, 2009, the Circuit Court granted the Motion of ANS for summary judgment, which dismissed the Complaint of Sanders. (RE 5-7). On April 8, 2009, Sanders filed his notice of appeal. (R. p. 73-74).

SUMMARY OF THE ARGUMENT

The ruling of the trial court is based upon an order of the Food and Drug and Administration ("FDA") that is inconsistent with its own regulations. (RE p. 5-7). The trial court based its ruling on an order of the FDA that determined that the spinal cord stimulator is a Class III device. This order is clearly inconsistent with FDA regulation 21 CFR Part 882.5800, which states:

> 882.5800 Implanted spinal cord stimulator for pain relief:
>
> (a) *Identification:* An implanted cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The simulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

Notwithstanding the fact that the FDA regulations clearly defined the spinal cord stimulator as a Class II device, the trial court relied upon an order of the FDA that said the device is a Class III device. (RE p. 6-7). The importance of whether the device is Class II or III is that a Class III device has FDA premarket approval, and is therefore state law claims challenging there safety are pre-empted by federal law. *Riegel v. Medtronic, Inc.,* 128 S.Ct. 999 (2008).

Court's are required to give substantial deference to an agency's interpretation of its own regulations. *Thomas Jefferson Univ. v. Shalala,* 512 U.S. 504, 512 (1994). In such cases, the "agency's construction of its own regulations is controlling 'unless it is plainly erroneous or inconsistent with the regulation.'" *Wyoming Outdoor Council v. U.S. Forest Service,* 165 F.3d 43, 52 (D.C. Cir. 1999).

The only regulation defining the spinal cord stimulator is 21 CFR Part 882.5800. This regulation states that the spinal cord stimulator is a Class II device. The order of the

FDA classifying it as a Class III device is inconsistent with the regulation and therefore must be ignored.

If the device is a Class II device as state in 21 CFR Part 882.5800, then Sanders action is not pre-empted by federal law, and the motion for summary judgment is without merit. The judgment of the trial court should be reversed.

ARGUMENT

I. WHETHER THE FOOD AND DRUG ADMINISTRATION MAY ISSUE AN ORDER THAT IS PLAINLY INCONSISTENT WITH ITS REGULATIONS?

II. WHETHER SANDERS' CLAIMS AGAINST ADVANCED NEUROMODULATION SYSTEMS, INC. ARE BARRED BY MDA'S PRE-EMPTION CLAUSE?

"A motion for summary judgment should be overruled unless the trial court find, beyond a reasonable doubt, that the plaintiff would be unable to prove any facts to support his claim." *Simpson v. Boyd,* 880 So.2d 1047, 1050 (Miss. 2004); *Palmer v. Anderson Infirmary Benevolent Association,* 656 So.2d 790, 796. In considering a motion for summary judgment, "the evidence must be viewed in a light most favorable to the non-moving party." *Id.*

The basis of the motion for summary judgment of ANS is that the spinal cord stimulator that is the subject of this action was submitted for Pre-market approval ("PMA") from the United States Food and Drug and Administration ("FDA"), and that this approval was obtained. ANS argues that this device is a Class III device that is eligible for such approval. According to ANS, the device received PMA under the Medical Device Amendments ("MDA") of 21 U.S.C. §360k. Citing *Riegel v. Medtronic, Inc.,* 128 S.Ct. 999 (2008), ANS argues that Sanders action is pre-empted under the MDA.

ANS's argument is without merit, because it begins with the premise that the spinal cord stimulator in this action is a Class III device. It is not.

The device that is the subject of this action is found in 21 CFR Part 882.5800, which states:

> 882.5800 Implanted spinal cord stimulator for pain relief:
>
> (b) *Identification:* An implanted cord stimulator for pain relief is a device that that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The simulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.
>
> (c) *Classification:* Class II (performance standards).

It is clear from the regulations of the FDA that the spinal cord stimulator is a Class II device, not a class III device as asserted by Advanced. The significance of this information is that the regulatory scheme of the FDA establishes various levels of oversight for medical devices, depending upon the risks they present. Class I, which includes devices such as elastic bandages and examination gloves, is subject to the lowest level of oversight: "general controls", such as labeling requirements. MDA §360c(a)(1)(A).

Class II, which includes devices such as the spinal cord stimulator, powered wheel chairs and surgical drapes, is subject in addition to "special controls" such as performance standards and postmarked surveillance measures. §360c(a)(1)(B).

Class III devices receive the most federal oversight. These include replacement heart valves, implanted cerebella stimulators and pacemaker pulse generators. In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is purported or represented to be use for a use which is of substantial importance

in preventing impairment of human health or presents a potential unreasonable risk of illness or injury. §360c(a)(1)(C)(ii).

The FDA has established a process for premarket approval of Class III devices. There is no process for exemption of Class I or II devices.

Advanced has characterized the spinal cord stimulator as a Class III device when it is in fact a Class II device. It is not eligible for the premarket approval that would grant it the exemption from litigation articulated in *Riegel v. Medtronic, Inc.,* 128 S.Ct. 999 (2008).

Advanced is asking that the spinal cord stimulator be afforded a protection not provide to it by the FDA. Advanced may have submitted the item in question for premarket approval, and the device may have past the test. However, since it is not a Class III device, the passing of the test does not exempt the device from a lawsuit, because it is a Class II device.

The FDA's order relied upon by the trial court in this action is inconsistent with 21 CFR Part 882.5800. While court's are required to give substantial deference to an agency's interpretation of its own regulations, *Thomas Jefferson Univ. v. Shalala,* 512 U.S. 504, 512 (1994), an "agency's construction of its own regulations is controlling 'unless it is plainly erroneous or inconsistent with the regulation.'" *Wyoming Outdoor Council v. U.S. Forest Service,* 165 F.3d 43, 52 (D.C. Cir. 1999).

In the instant case, the order of the FDA relied upon by the trial court is plainly erroneous and inconsistent with the regulation at 21 CFR Part 882.5800. The decision of the trial court should therefore be reversed, and this action remanded to the circuit court for a trial on the merits.

III. WHETHER THE CIRCUIT COURT COMMITTED ERROR IN GRANTING THE MOTION FOR SUMMARY JUDGMENT OF ADVANCED NEUROMODULATION SYSTEMS, INC?

For summary judgment motion to be granted, there must exist no genuine issue of material fact, and the moving party must be entitled to judgment as a matter of law. MRCP 56(c). The burden of demonstrating that there is no genuine issue of material fact falls on the party that requests summary judgment. *Short v. Columbus Rubber & Gasket Co.,* 535 So.2d 61, 63 (Miss. 1988). In this case there is a genuine issue of fact as to whether the spinal cord stimulator is a Class III devices that may be exempted from litigation pursuant to *Riegel v. Medtronic, Inc.,* 128 S.Ct. 999 (2008).

The evidence in this case establishes that the device in question is not a Class III device, but rather is a Class II device that is not exempted from litigation. There is a genuine issue of fact as to whether the device is exempted from litigation. This Court should reverse the decision of the circuit court, and remanded this matter for a trial.

CONCLUSION

As previously stated, summary judgment motion may only be granted where no genuine issues of material fact exists. MRCP 56(c); *Short v. Columbus Rubber & Gasket Co.*, 535 So.2d 61, 63 (Miss. 1988). In this cause, it is evident that there is a genuine issue of fact as to whether the spinal cord stimulator is a Class III devices that may be exempted from litigation pursuant to *Riegel v. Medtronic, Inc.*, 128 S.Ct. 999 (2008), or whether it is a Class II device as defined by 21 CFR Part 882.5800. It is uncontroverted that 21 CFR Part 882.5800 is the only FDA regulation that deals with a spinal cord stimulator.

Judgment as a matter is precluded by the existence of the question of fact as to whether the device is a Class II device. Sanders asks that on appeal this Court reverse the judgment below, and remand this cause for further proceedings.

Respectfully submitted,
William Sanders

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CERTIFICATE OF SERVICE

I certify that I mailed a copy of this BRIEF OF THE APPELLANT to:

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This the 14th day of December, 2009.

D.L. JONES, JR.