IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
HATTIESBURG DIVISION

JAN HUGHES	**PLAINTIFF**
VERSUS	**CIVIL ACTION NO. 2:08cv79KS-MTP**
BOSTON SCIENTIFIC CORPORATION	**DEFENDANT**

MEMORANDUM OPINION AND ORDER

This matter is before the court on a Motion for Summary Judgment **[#79]** filed on behalf of the defendant, Boston Scientific Corporation ("BSC"). The court, having reviewed the motion, the response, the briefs of counsel, the authorities cited, the pleadings and exhibits on file and being otherwise fully advised in the premises finds that the defendant's motion for summary judgment is well taken and should be granted. The court specifically finds as follows:

FACTUAL BACKGROUND AND FINDINGS

Boston Scientific is the designer, manufacturer, marketer and seller of a medical device known as the HydroTherm Ablator ("HTA") which was designed for the treatment of patients who have a condition called menorrhagia (excess uterine bleeding). The defendant describes the HTA procedure as a minimally invasive alternative to hysterectomy or other surgical procedure. The medical procedure the HTA was designed to perform (known as a hydrothermal ablation of the endometrium) is accomplished by circulating heated saline solution through a closed cycle into and then

flushing it from the uterus causing the lining of the uterus, or endometrium to be destroyed and slough off and discharge in simulation of the occurrences during a normal menstrual cycle. The HTA is a Class III medical device which has received Pre-Market Approval (“PMA”) by the Food and Drug Administration ("FDA").

One of the disclosed risks associated with the procedure is a potential for leakage of hot fluid, which may result in thermal injury to the surrounding tissue. To minimize this risk, the HTA is equipped with a leakage detection system which will sound an alarm and automatically shut down the procedure if a leak is detected. This risk is explained in the HTA System User’s Manual and through Boston Scientific’s patient literature.

On October 25, 2006, Mrs. Hughes, who had been diagnosed with, and unsuccessfully treated with available medications for menorrhagia, was admitted as an out-patient by her treating physician, Dr. Michael Weber ("Dr. Weber"), to South Central Regional Medical Center ("SCRMC") in Laurel, Mississippi for a diagnostic hysteroscopy, dilation and curettage and hydrothermal ablation of the endometrium. The procedure was performed by Dr. Weber using a "refurbished" Boston Scientific HTA 5600 purchased from Boston Scientific by SCRMC.

According to the specifications and instructions supplied by Boston Scientific, the hydrothermal ablation procedure was to work as follows: The endometrial ablation procedure begins by slightly dilating the patient's cervix for the purpose of allowing the introduction of the HTA sheath[1], which attaches to a hysteroscope, into the vagina so

[1] The HTA sheath is an insulated continuous flow sheath intended to protect the cervical canal from the thermal effect of the saline solution.

that the physician performing the procedure may view the inside of the uterus to ensure proper positioning of the instrument. After this task is completed, the uterus is filled with room temperature saline solution to gently clean and flush the uterus. The fluid is then heated to ninety degrees Celsius (90º C)[2] and circulated throughout the uterus for ten minutes in order to treat the endometrium, i.e., the lining of the uterus. Once the treatment is complete, room temperature saline solution automatically flushes hot saline from the sheath and cools the uterine cavity. All saline is removed from the uterus once the cooling phase of the procedure is complete. Thereafter, the uterine lining is expected to slough off in a fashion similar to the patient's menstrual period over the course of a few weeks following the procedure.

It appears to be undisputed that Dr. Weber performed the procedure in accordance with Boston Scientific's specifications and instructions and did not move the HTA sheath or otherwise compromise the cervical seal during the procedure. It also appears undisputed that Mrs. Hughes was under general anesthesia during the procedure and did not make any movements or otherwise compromise the cervical seal.

However, Mrs. Hughes' procedure apparently did not go as specified by Boston Scientific in its Users Manual. The plaintiff alleges that through no fault of Dr. Weber or Mrs. Hughes, the HTA malfunctioned during the eighth minute of the heating and circulation phase of the procedure. At that point in the procedure, Dr. Weber heard a beep and simultaneously noticed hot fluid leaking from Mrs. Hughes' cervix. The alarm

[2] This is the equivalent of 194º Fahrenheit. Water boils at 100º Celsius or 212º Fahrenheit.

on the device sounded and it shut down, as it is designed to do.

Immediately following the procedure, Dr. Weber noted that Mrs. Hughes suffered a "3 x 2 burn on her outer perineal body" and "an area of similar size inside the vaginal introitus." *See* Ex. 7 to Plaintiffs' Response, (Mrs. Hughes' medical records). Dr. Weber categorized the burns at that time as either second or third degree burns. *See* Ex. 5 to Plaintiff's Response at 20 (Mrs. Hughes' Dep.). Dr. Weber applied Silvadene cream to the burns and Mrs. Hughes was awakened from anesthesia and taken to the recovery room.

The day following the procedure, Mrs. Hughes returned for follow-up treatment of the burns she suffered. At this visit, Dr. Weber noted the severity of her burns and categorized them as second degree in nature. Dr. Weber ordered Mrs. Hughes to return for treatment of her burns every other day for two weeks, and thereafter once a week for six to eight weeks.

In the weeks that followed, Mrs. Hughes' menorrhagia returned and she alleges that she was forced to explore other alternatives and undergo additional treatment in an attempt to correct the problem. Despite having undergone a tubal ligation after the birth of her last child, Mrs. Hughes has been prescribed birth control pills in an effort to control her bleeding and she asserts that this is precisely the treatment option that Dr. Weber wished to avoid and what precipitated discussions with Mrs. Hughes about treatment with the HTA. She contends that her only other treatment options at this time are another ablation procedure, which she states that she is reluctant to undergo, or a hysterectomy.

The HTA User Manual that was provided to SCRMC with the subject HTA

provides that there are basically three ways that a leak could occur which would cause burn injuries to patients. First, physicians are warned not to "place the procedure sheath tubing over the patient's leg or in contact with any part of the patient or operators anatomy, as the tubing carries hot fluid and contact with it could result in thermal injury." Second, "after the procedure sheath has been placed in the patient during the startup phase," physicians are warned not to remove the sheath "until the post-treatment cooling cycle has been completed, as heated fluid may cause thermal injury to the patient." Third, "a physician must maintain control of the procedure sheath for the duration of the treatment to avoid a compromise of the cervical seal," because "a compromise of the cervical seal could result in fluid leakage through the cervix, which could result in thermal injury to surrounding tissue." The plaintiff asserts that all three of these thermal injuries, each of which occurred during the HTA clinical trials, are attributed to external factors such as user error.

The plaintiff contends that the only mention of risks related to leaks found in the patient pamphlet entitled "Your Period doesn't have to be a sentence" states:

> Treatment with the HTA may involve some rare but potential risks that include perforation (creation of a hole) in the wall of the uterus, a hot fluid bowel or other internal organ burn or leakage of hot fluid into the cervix or vagina.

The plaintiff emphasizes that In deposition testimony, Boston Scientific's corporate representative concedes this warning relates to the risk of leaks caused by user error, not device malfunction. *See* Dep., Donna Mare Gardner, Ex. 9 to Plaintiff's Response at page 406.

STANDARD OF REVIEW

The Federal Rules of Civil Procedure, Rule 56(c) authorizes summary judgment where "the pleadings, depositions, answers to interrogatories and admissions on file, together with affidavits, if any, show that there is no genuine dispute as to any material fact and that the moving party is entitled to judgment as a matter of law." *Celotex Corporation v. Catrett*, 477 U.S. 317, 322, 91 L.Ed.2d 265, 106 S.Ct. 2548 (1986). The existence of a material question of fact is itself a question of law that the district court is bound to consider before granting summary judgment. *John v. State of La. (Bd. of T. for State C. & U.)*, 757 F.2d 698, 712 (5th Cir. 1985).

A Judge's function at the summary judgment stage is not himself to weigh the evidence and determine the truth of the matter, but to determine whether there is a genuine issue for trial. There is no issue for trial unless there is sufficient evidence favoring the non-moving party for a jury to return a verdict for that party. If the evidence is merely colorable, or is not significantly probative, summary judgment is appropriate. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 91 L.Ed.2d 202, 106 S.Ct. 2505 (1986).

Although Rule 56 is peculiarly adapted to the disposition of legal questions, it is not limited to that role. *Professional Managers, Inc. v. Fawer, Brian, Hardy & Zatzkis*, 799 F.2d 218, 222 (5th Cir. 1986). "The mere existence of a disputed factual issue, therefore, does not foreclose summary judgment. The dispute must be genuine, and the facts must be material." *Id.* "With regard to 'materiality', only those disputes over facts that might affect the outcome of the lawsuit under the governing substantive law will preclude summary judgment." *Phillips Oil Company v. OKC Corporation*, 812 F.2d 265, 272 (5th Cir. 1987). Where "the summary judgment evidence establishes that one

of the essential elements of the plaintiff's cause of action does not exist as a matter of law, . . . all other contested issues of fact are rendered immaterial. *See Celotex*, 477 U.S. at 323, 106 S.Ct at 2552." *Topalian v. Ehrman*, 954 F.2d 1125, 1138 (5th Cir. 1992). In making its determinations of fact on a motion for summary judgment, the Court must view the evidence submitted by the parties in a light most favorable to the non-moving party. *McPherson v. Rankin*, 736 F.2d 175, 178 (5th Cir. 1984).

The moving party has the duty to demonstrate the lack of a genuine issue of material fact and the appropriateness of judgment as a matter of law to prevail on his motion. *Union Planters Nat. Leasing v. Woods*, 687 F.2d 117 (5th Cir. 1982). The movant accomplishes this by informing the court of the basis of its motion, and by identifying portions of the record which highlight the absence of genuine factual issues. *Topalian*, 954 F.2d at 1131.

"Rule 56 contemplates a shifting burden: the nonmovant is under no obligation to respond unless the movant discharges [its] initial burden of demonstrating [entitlement to summary judgment]." *John*, 757 F.2d at 708. "Summary judgment cannot be supported solely on the ground that [plaintiff] failed to respond to defendants' motion for summary judgment," even in light of a Local Rule of the court mandating such for failure to respond to an opposed motion. *Id.* at 709.

However, once a properly supported motion for summary judgment is presented, the nonmoving party must rebut with "significant probative" evidence. *Ferguson v. National Broadcasting Co., Inc.*, 584 F.2d 111, 114 (5th Cir. 1978). In other words, "the nonmoving litigant is required to bring forward 'significant probative evidence' demonstrating the existence of a triable issue of fact." *In Re Municipal Bond Reporting*

Antitrust Lit. , 672 F.2d 436, 440 (5th Cir. 1982). To defend against a proper summary judgment motion, one may not rely on mere denial of material facts nor on unsworn allegations in the pleadings or arguments and assertions in briefs or legal memoranda. The nonmoving party's response, by affidavit or otherwise, must set forth specific facts showing that there is a genuine issue for trial. Rule 56(e), Fed.R.Civ.P. *See also, Union Planters Nat. Leasing v. Woods*, 687 F.2d at 119.

While generally "'[t]he burden to discover a genuine issue of fact is not on [the] court,' (*Topalian* 954 F.2d at 1137), 'Rule 56 does not distinguish between documents merely filed and those singled out by counsel for special attention-the court must consider both before granting a summary judgment.'" *John*, 757 F.2d at 712 (quoting *Keiser v. Coliseum Properties, Inc.*, 614 F.2d 406, 410 (5th Cir. 1980)).

ANALYSIS

In response to advances in medical technology and the advent of various artificial and technologically advanced medical devises, Congress enacted the Medical Device Amendments of 1976 (MDA or Act), 90 Stat. 539 to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"), §§ 501, 502, 52 Stat. 1049-1051. The Act classifies medical devices in three categories based on the risk that they pose to the public. Medical devices that present little, or at least no unreasonable, risk of illness or injury are designated Class I and are subject only to minimal regulation by "general controls." 21 U.S.C. § 360c(a)(1)(A). Devices that are deemed to be potentially more harmful are designated Class II. These devices may be marketed without advance approval by the FDA. However, the manufacturers of such devices must comply with federal

performance regulations known as "special controls." 21 U.S.C. § 360c(a)(1)(B).

Pertinent to the analysis here, devices that either "presen[t] a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are designated Class III. 21 U.S.C. § 360c(a)(1)(C). The HTA is a Class III device.

As the Supreme Court explained in *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996):

> Before a new Class III device may be introduced to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. *See* 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance," which is known as the "premarket approval," or "PMA" process, is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission. Hearings before the Subcommittee on Health and the Environment of the House Committee on Energy & Commerce, 100th Cong., 1st Sess. (Ser. No. 100-34), p. 384 (1987) (hereinafter 1987 Hearings); *see generally* Kahan, Premarket Approval Versus Premarket Notification: Different Routes to the Same Market, 39 Food Drug Cosm. L.J. 510, 512-514 (1984).

518 U.S. at 477, 116 S.Ct. at 2246-47.

The information submitted in support of the PMA includes, among other things, full reports of all information that is known by the applicant, samples of both labeling and the device itself, and a full description of the methods and facilities used for manufacturing and installation of the device. *See* 21 U.S.C. § 360e(c)(1) (describing the components of a PMA application). After receipt of the required documentation, the FDA reviews the application, and as stated in *Lohr*, spends an average of 1,200 hours on each submission before granting marketing approval.

A manufacturer is prohibited from producing or labeling any device in any manner inconsistent with the conditions of approval specified by the FDA. *See* 21 C.F.R. § 814.80. Any proposed changes to the device or the accompanying warnings or labeling must be approved through the submission of a supplemental application to the FDA and must be approved by the Agency prior to implementation of the proposed changes. *See* 21 C.F.R. § 814.39.

After a Class III medical device has received pre-market approval and is marketed, the manufacturer has a continuing obligation to report certain adverse events and other safety related issues to the FDA, to submit to FDA inspections, and to respond to FDA requests for information. The FDA requires additional post-market controls, including manufacturing controls and record keeping and reporting requirements. *See* 21 C.F.R. § Parts 803 and 820. The FDA has the power to inspect the companies to ensure regulatory requirements are met and the authority to impose appropriate remedies, such as warnings, corrective labeling, notification to doctors or patients, and recall of products if it believes a product poses a hazard. *See, e.g.,* 21 U.S.C. §§ 351, 352, 360(h), 374.

In this case, the plaintiff contends that the following regulations are particularly pertinent:

1. PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of unanticipated adverse effects, or device failures necessitate a labeling, manufacturing or device modification;

2. ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified,

as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center..... within 10 days after the applicant receives or has knowledge of information concerning ... (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and (a) has not been addressed by the device's labeling or (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

3. REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION ... This regulation...requires that all manufacturers and importers of medical devices ... report to the FDA whenever they receive or otherwise become aware of information from any source, that reasonably suggests that a device marketed by the manufacturer or importer: (1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and such device or similar device marketed by the manufacturer or importer would likely cause or contribute to a death or serious injury if the malfunction were to recur.

See, *e.g.*, 21 U.S.C. § 360i.

The HTA device at issue was originally manufactured by BEI Medical Systems. The FDA granted pre-market approval to the HTA System on April 21, 2001. The PMA Order issued by the FDA informed BEl that the "failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act."

Boston Scientific acquired the HTA technology from BEI in 2002. According to the plaintiff, since Boston Scientific acquired the HTA technology and the PMA in 2002, it has engaged in a practice of violating its PMA Order, the Conditions of Approval, and various federal regulations governing Class III medical devices. Specifically, the plaintiff asserts that the most egregious of Boston Scientific's violations are its failure to adhere to those conditions of approval and FDA regulations that govern its reporting obligations and quality management systems.

The present case calls upon the court to address the question of federal

preemption: *i.e.,* whether Boston Scientific's alleged compliance with the FDA's rigorous pre-market approval procedure preempts the plaintiff's Mississippi common law products liability tort claims pursuant to 21 U.S.C. § 360k, the Medical Devices Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA").

One of the Conditions of Approval for the PMA Order was that Boston Scientific was to report to the FDA via a Medical Device Report ("MDR") any and all incidents of (1) a "malfunction"[3] or "serious" injury,"[4] as those terms are defined by the FDA regulations, and (2) any and all incidents that might reasonably be expected to result in death or serious injury, if a similar malfunction were to recur. However, the plaintiff asserts that rather than report incidents that are required to be reported by applicable FDA regulations, Boston Scientific developed an "algorithm" for determining whether a given incident was one for which they would submit an MDR. The algorithm developed by Boston Scientific as to how burn related incidents were to be reported is as follows:

1. 1st degree burns are not reportable.

2. 2nd degree burns are reportable depending on the extensiveness and intervention required to treat the injury. A 2nd degree burn is MDR reportable if any of the following criteria are met:

    a. the burn is classified as extensive by the physician;

    b. the burn involves both internal anatomy such as the vagina and cervix and external anatomy such as the vulva, perineum and

[3] "Malfunction" is defined in the MDR regulation as "the failure of a device to meet the performance specifications or otherwise perform as intended." Exs. 13 and 14 (Mr. Kyper's supplemental expert report, dated July 20,2009, and 21 C.F.R. § 803,3).

[4] "Serious Injury" is defined in the MDR regulation as "an injury or illness that is life-threatening, results in permanent impairment of a body function or permanent damage to a body structure or necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure." *Id.*

buttocks;

c. the burn requires intervention involving a medical or surgical procedure that cannot be administered by the patient (such as: systemic antibiotics, debridement, skin grafting, etc.).

3. Other 2nd degree burns that can be effectively managed by application of cream or ointment are not considered to be MDR reportable.

4. 3rd degree burns are reportable.

Boston Scientific included this algorithm in its PMA annual reports for the HTA to the Division of Reproductive, Abdominal, and Radiological Devices in the CDRH Office of Device Evaluation. The plaintiff asserts that BSC interpreted the absence of a response as constituting FDA ratification and approval of the algorithm. However, the plaintiff argues that pursuant to 21 C.F.R. § 803.19, a device manufacturer is required to submit a written request for an exemption, variance or an alternative form of MDR reporting to a completely different division of the FDA, housed in a different office building, in a different location, called the CDRH Office of Surveillance and Biometrics - which Boston Scientific apparently did not do. Thus, the plaintiff asserts that not only did Boston Scientific fail to obtain a reporting variance or exemption for approval of its algorithm, that algorithm, by design, excluded hundreds of "malfunctions" and "serious injuries" as those terms are defined by 21 C.F.R. § 803.3.

In April 2008, the FDA conducted an audit of the Boston Scientific facility that handles complaints for the HTA in Marlborough, Massachusetts (the "Marlborough Facility"). As a result of that audit, Boston Scientific changed its algorithm and now reports all burns regardless of severity. If this information had been available to Dr. Weber, the plaintiff argues that he would not have used the HTA on the plaintiff. While

this looks much like a subsequent remedial measure, the plaintiff argues that it is relevant on the issue of notice. The court will consider this argument in the context of the plaintiff's relevant claims.

Part I of Boston Scientific's motion is composed of three parts. First, Boston Scientific argues that because the HTA device at issue in this case is a Class III medical device that has received PMA by the FDA, all of Mrs. Hughes' claims are preempted by federal law pursuant to *Riegel v. Medtronic, Inc.,* 552 U.S. 312, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008). The plaintiff argues that Boston Scientific's analysis of *Riegel* is in error because *Reigel* does not immunize the manufacturer of a Class III device from all civil liability. She asserts that instead, it carves out an exception to the doctrine of preemption, allowing an injured plaintiff to pursue claims that do not impose obligations that are "different than or in addition to" the requirements imposed by the FDA pursuant to its regulations. *Riegel*, 128 S.Ct. at 1011.

Second, Boston Scientific argues that Mrs. Hughes' negligence *per se* claim is expressly preempted pursuant to the pre-*Riegel* cases of *Buckman Co. v. Plaintiff's Legal Committee*, 531 U.S. 341, 121 S. Ct. 1012, 148 L.Ed.2d 854 (2001), and *Webster v. Pacesetter, Inc.,* 259 F. Supp. 2d. 27 (Dist. Ct. DC 2003). However, the plaintiff argues that both *Buckman* and *Webste*r concern a "fraud on the FDA claim" which she asserts is altogether different from a claim for negligence *per se.*

Third, Boston Scientific argues that it is entitled to summary judgment on Mrs. Hughes' remaining common law theories of relief pursuant to the Supreme Court's holding in *Riegel*. The plaintiff contends that this argument is without merit in view of the fact that (a) preemption is an affirmative defense on which Boston Scientific bears

the burden of proof, and (b) the summary judgment evidence presents fact issues as to whether Boston scientific is entitled to assert preemption as an affirmative defense.

In *Riegel*, the Supreme Court held that pursuant to the Medical Device Amendments to the Act, 21 U.S.C. § 360, *et seq*., medical devices that are in compliance with the federal regulations governing their PMA status are not subject to state regulations or requirements that are "different from, or in addition to" the requirements imposed by federal law. 128 S.Ct. at 1011.

The Court's holding in *Riegel* resolved a split of authority among the circuit courts as to whether a common law civil claim imposes "requirements" upon manufacturers that triggers the preemptive language of the Act. However, the Supreme Court also held that its decision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.*

The *Riegel* Court held that the PMA process imposes “requirements” under the MDA which are specific to the individual device seeking such approval. These “requirements” include finding that the device “offers a reasonable assurance of safety and effectiveness.” 128 S.Ct. at 1007. Further, “premarket approval is focused on safety . . ..” *Id.* The Court went on to find that New York common-law tort claims of negligence and strict liability imposed requirements which “would be preempted by federal requirements specific to a medical device.” *Id.*, citing *Medtronic, Inc. v. Lohr,* 518 U.S. 470, 512, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996).

The plaintiff here has asserted tort claims of strict liability, negligence and breach of implied warranty of merchantability and fitness for a particular purpose. The

defendant argues that such claims clearly relate to and revolve around the safety and effectiveness of the HTA device and are thus preempted by the MDA pursuant to the holding in *Riegel*. Do the Mississippi tort law duties impose requirements that are different from or in addition to the federal ones espoused in the MDA and federal regulations governing the Act? The court concludes in the affirmative and thus, the plaintiff's claims are clearly preempted as hereinafter discussed in detail.

The Supreme Court has unequivocally held that state tort duties do impose requirements that are different from and in addition to the MDA requirements because they allow juries to impose standards upon manufactures which have already been considered and imposed by the Agency through the PMA process. *See Riegel*, 128 S. Ct. at 1007-08. Specifically, the plaintiff's design defect claim is preempted because the FDA has already assessed the risk and utility of the design of the HTA through this process. *Id.* at 1004 (quoting 21 U.S.C. § 360e(c)(1))(noting that a PMA application must included a full statement of a Class III device's components, ingredients, and properties and of the principle or principles of operation).

Likewise, a manufacturing defect claim would be preempted if the manufacturer followed the federally-approved manufacturing process for a device. *Id.* at 1006. (quoting 21 U.S.C. § 360e(c)(1)(noting that a PMA application includes a full description of the methods used in, and the facilities and controls used for, the manufacture of a medical device). However, such a claim is not preempted if the plaintiff makes an allegation that the manufacturer failed to followed the FDA approved manufacturing process *Id*. at 1010-11. Claims for failure to warn or to properly label the device would be preempted to the extent they challenge the sufficiency of the FDA-approved

warnings and labels. *Id*. at 1011. *See also* 21 U.S.C. § 360c(a)(2)(B) and 21 U.S.C. § 360e(d)(1)(A). However, like the manufacturing defect claims, they are not preempted if the plaintiff claims that the manufacturer failed to follow the FDA-approved process for providing the appropriate warnings or failed to label the device in conformity with the FDA-approved PMA application. *Id.* Thus, it is clear, that the plaintiff's state tort claims are preempted by *Reigel*.

The plaintiffs' main argument in rebuttal is that the defendant is liable for negligence *per se* for allegedly acquiring pre-market approval improperly and in violating the conditions of the HTA's pre-market approval. Specifically, the plaintiff asserts that the defendant failed to report or did not properly report required incidences of injuries and malfunctions to the FDA by utilizing a faulty algorithm protocol, in violation of 21 C.F.R. § 803.50 and 21 C.F.R. § 814.82. The plaintiff also alleges that the defendant failed to make full disclosure in its labeling regarding the extent and severity of burns in patients pursuant to 21 C.F.R. § 801.109. Thus, according to the plaintiff, *Riegel* does not preempt Mrs. Hughes' claim for negligence *per se*, as she contends that she has, at a minimum, presented genuine issues of material fact that preclude the entry of summary judgment on these claims.

The plaintiff tries to draw a distinction between the claims barred in *Buckman Co. v. Plaintiff's Legal Comm*., 531 U.S. 341, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001), and those she has pled here. However, the defendant argues that regardless of whether the plaintiff alleges that BSC made misrepresentations to the FDA that were intentional (i.e., fraudulent) or that were negligent, *Buckman* operates to preempt any cause of action for failure to communicate properly with the FDA pursuant to its rules and regulations.

In *Buckman*, the plaintiff claimed that the manufacturer of bone screws had made intentional misrepresentations to the FDA in the course of obtaining pre-market approval. *Buckman*, 531 U.S. at 341. In the present case, the defendant contends that the plaintiff is claiming that 1) BSC made negligent misrepresentations to the FDA, thus improperly acquiring pre-market approval for the HTA, and 2) that BSC negligently misrepresented the occurrence of adverse events to the FDA.

However, as the United States Supreme Court clearly stated, claims alleging misrepresentations to the FDA "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Id*. at 350. "The relationship between a federal agency and the entity it regulates is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id*. at 347.

The Court went on to say that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and the Administration uses this authority to achieve a delicate balance of statutory objectives that can be skewed" by allowing the type of claim being asserted here. *Id*. at 348. If these claims are allowed, potential applicants would be forced into the burdensome dilemma of trying to of comply with the FDA's detailed rules while "in the shadow of 50 States' tort regimes." *Id*. at 350. The end-product of this dual regulatory scheme is both a deterrence to potential applicants and a flood of gratuitous information being submitted to the FDA. *Id.* at 351.

The defendant argues that the plaintiff attempts to distinguish her case from *Buckman* by claiming that BSC is guilty of negligent misrepresentations, rather than the

intentional misrepresentations claimed in *Buckman*. However, the plaintiff contends that she has pled neither. Instead, she argues that she has deliberately pled claims based on violations of the MDA as authorized in *Riegel*. The court concludes that this is a distinction without a difference. The claims asserted seem, to this court, to be garden variety misrepresentation claims and should be analyzed as such under controlling law.

What it seems to the court that the plaintiff is ultimately arguing is that she is making a claim of manufacturing defect wherein she alleges that BSC failed to comply with the federal regulations governing the HTA's design, manufacture and use by deviating from, and failing to conform to, in a material way, the BSC's manufacturing specifications and those specifications required by the FDA as part of the PMA process. In other words, this so-called "manufacturing defect" manifests itself through BSC's failure to properly label, warn and correct perceived faults in the HTA because BSC failed to provide proper injury and malfunction data to the FDA. Under the plaintiff's theory, if BSC had properly informed the FDA of the HTA's fault rate and malfunction errors, then the FDA would have required different or supplemental warnings and labeling and perhaps manufacturing changes. This is a novel and intriguing theory advanced by the plaintiff. However, it does not seem warranted under *Riegel* in the face of *Buckman*.

The *Buckman* holding did not turn on intentional versus negligent violation of FDA regulations, but on the principle of maintaining a "federal statutory scheme" put in place by Congress. *Id.* at 352 ("In the present case . . . we have clear evidence that Congress intended that the MDA be enforced exclusively by the Federal Government."). The Supreme Court found that allowing the *Buckman* plaintiffs' claim would "exert an

extraneous pull on the scheme established by Congress, and it [was] therefore preempted by that scheme." *Id*. at 353. Under this rationale, claims asserting misrepresentations, intentional or otherwise, made to the FDA regarding Class III medical devices are preempted by federal law. *Id*. at 348.

The defendant contends that like the manufacturer in *Buckman*, BSC's dealings with the FDA were controlled by the MDA and the very subject matter of BSC's statements were dictated by federal requirements. *See id.* at 347-348. In such a case, preemption of the state tort claim will apply. *Id*. at 348. The way the plaintiff characterizes her cause of action, and the alleged intent level of BSC, does not change the outcome.

The plaintiff is alleging that BSC made misrepresentations to the FDA. State tort claims alleging misrepresentation to the FDA are preempted under *Buckman*. The defendant contends that couching one's claim to focus on the basis of the FDA's decision (i.e. the information provided to the FDA by the manufacturer) as opposed to the decision itself (i.e. the approval of the design, manufacturing process, labeling, etc.) is nothing but an attempt to allow each of the 50 states to usurp the role of the FDA and call into question the regulatory process in place. The court finds that this is the exact concern of the *Buckman* court and thus the plaintiff's negligence *per se* claim must fail.

Further, the vast majority of courts have specifically rejected negligence *per se* claim like that being asserted by the plaintiff here. In *Hackett v. Searle*, the plaintiff brought a negligence *per se* claim against a manufacturer alleging that it violated the Food and Drug Cosmetic Act and various FDA regulations by providing inaccurate information in their warnings, informational materials and package inserts. 246

F.Supp.2d 591, 594 (W.D.Tex. 2002). The court pointed out that the Fifth Circuit had not ruled on this "novel theory of liability" and "decline[d] to create a new cause of action," holding that the FDCA and FDA regulations "do not give rise to a negligence *per se* cause of action." *Id*.; *see also, Vanderwerf v. SmithKlineBeecham Corp*., 414 F. Supp.2d 1023, 1027 (D. Kan. 2006).

In fact, numerous courts have rejected negligence *per se* claims based on alleged violations of FDA regulations as contrary to Congressional intent. *See e.g.*, *Martin v. Ortho Pharmaceutical Corp*., 661 N.E.2d 352, 355-56 (Ill. 1996). Accord, *e.g., In re Orthopedic Bone Screw Products Liability Litigation*, 193 F.3d 781, 789-90 (3rd Cir. 1999); *Bish v. Smith & Nephew Richards, Inc*., 2000 WL 1294324, at *3 (Tenn. App. Aug. 23, 2000); *Osburn v. Danek Medical, Inc*., 520 S.E.2d 88, 93 (N.C. App. 1999), aff'd, 542 S.E.2d 215 (N.C. 2000); *Friedlander v. HMS-PEP Products, Inc.*, 485 S.E.2d 240, 242 (Ga. App. 1997); *Scott v. CIBA Vision Corp*., 44 Cal. Rptr. 2d 902, 912 (Cal. App. 1995); *Alexander v. Smith & Nephew, P.L.C.*, 98 F. Supp. 2d 1299, 1308 (N.D. Okla. 2000); *Blinn v. Smith & Nephew Richards, Inc*., 55 F. Supp. 2d 1353, 1361 (M.D. Fla. 1999); *Cali v. Danek Medical, Inc*., 24 F.Supp.2d 941, 954 (W.D. Wis. 1998).

Even in the minority of jurisdictions that have allowed negligence *per se* claims based on violations of federal regulations, they have only been allowed in cases of substantive violations, not administrative violations. *See King v. Danek Medical., Inc*., 37 S.W.3d 429 (Tenn. App. 2000). In *King*, the court held that the administrative requirement that a device be approved by the FDA before being marketed, as opposed to the substantive requirement that the device be safe and effective, was merely a tool to facilitate administration of the underlying regulatory scheme. *Id*. at 457 (citing to

regulations contained in the MDA). The court explained that since such administrative requirements lack independent substantive content, they do not impose a standard of care, the breach of which could form the basis of a negligence per se claim. *Id.* The defendant contends likewise, i.e., that the reporting regulations contained in the MDA which the plaintiff maintains were not properly met in this case are the type of administrative tools used by the FDA to facilitate the administration of its underlying regulatory scheme and are, thus, administrative, and not substantive, federal regulations. This court agrees.

It is interesting that the case law cited by the plaintiff actually supports BSC's argument that her state law claims are preempted. In *Mattingly v. Medtronic, Inc.*, a case which pre-dates *Riegel*, the court did allow the plaintiff's negligence *per se* claim because it could parallel similar federal requirements. 486 F.Supp.2d 964, 969 (E.D.Mo. 2007) (holding that "such a common law claim could parallel similar federal requirements such that the claim could survive a preemption challenge")(citing *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001)) (this case actually did not even deal with an assertion of "parallel" claims, but included the sentence cited by the plaintiff).

However, what the plaintiff ignores is that the *Mattingly* court specifically preempted all of the plaintiff's state law causes of action. *Id.* at 968. The *Mattingly* plaintiffs' design and manufacturing defect claims, as well as their warning claim, were preempted regardless of any alleged failure of the defendant to meet FDA regulations. *Id.* The court stated: "a finding by the fact finder in this case that the device was defective would necessarily impose requirements on the device that are 'different from, or in addition to,' the requirements of the FDA." *Id*. Thus, while *Mattingly* is the one

court that seemingly supported the plaintiff's negligence *per se* theory, it also unequivocally finds that preemption protection bars every other claim brought by the plaintiff. *Id*.

In *Bausch v. Stryker*, decided on August 31, 2009, the Northern District of Illinois addressed the issue of negligence *per se* based on failure to comply with FDA regulations that is similar to the one currently before this court. *See Bausch v. Stryker Corp*., 2009 WL 2827954, *4 (N.D.Ill. Aug. 31, 2009). The *Bausch* plaintiff attempted to file an amended complaint on the eve of dismissal of her traditional product liability claims under the preemption clause of the MDA. 2009 WL 2827954 at *4. Just as in the instant case, in her amended complaint the *Bausch* plaintiff recast her claims as claims premised on the defendants' alleged conduct in non-compliance with federal regulations rather than mere product liability claims. *Id*.

The *Bausch* court found that under the *Riegel* analysis, even when the plaintiff's claims have been pled in terms of violations of federal regulations, i.e., negligence *per se*, state law tort principles inevitably invade such a cause of action. Thus, negligence *per se* claims have requirements that are "different from, or in addition to" federal regulations, and are pre-empted under *Riegel*.

The court explained its holding, stating that there is more to a negligence *per se* claim (under applicable state law) than a simple *prima facie* showing that a statute or regulation has not been followed. *Id.* In other words, the violation in and of itself does not constitute negligence *per se. Id.* Rather, the defendant may still prevail by showing that he or she acted reasonably under the circumstances. *Id*. As such, common law tort principles of the reasonableness of the defendant's actions invade the cause of

action. Once a state's tort law becomes ingrained with the cause of action, it runs afoul of *Riegel*. *Id.* The court appropriately noted that "[d]espite the changes to her claims, *Bausch* is still left holding a square peg for the round hole that is the parallel claims exception under *Riegel.*" *Id.*

Similarly, in this case, the plaintiff's negligence *per se* claims are not parallel claims that fall within the *Riegel* exception because they are ingrained with questions of state law. Under Mississippi law (like Illinois law analyzed by the *Bausch* court), a violation of a law or regulation is not conclusive on the question of negligence, but is only *prima facie* evidence thereof. *Alabama Great Southern Railroad Co. v. Lee*, 826 So.2d 1232, 1236 (Miss. 2002); *Ripley v. Wilson*, 140 Miss. 845, 105 So. 476 (1925). The alleged violator is permitted to show circumstances excusing the statutory or regulatory violation and rebutting the presumption of negligence *per se. Lee*, 826 So.2d at 1237; *Ripley*, 105 So. at 476. As such, common law tort principles will necessarily be imposed on BSC as it attempts to rebut a presumption of negligence. This imposes a requirement that is "different from, or in addition to" the requirements set forth in the federal regulations. The court concludes that the plaintiff's negligence *per se* claim in this case, like those in *Bausch*, do not fit within the narrow exception set forth by *Riegel* and are accordingly preempted by the MDA.

This court elects to follow the well reasoned and majority rule rejecting negligence *per se* claims arising out of violations of FDA regulations. Further, the court finds that the attempt by the plaintiff to enlarge or expand the reach of *Riegel* by claiming that misrepresentation of, or failure to report correct data, to the FDA amounts to a manufacturing defect, while a novel theory, is not warranted under existing law.

Thus, the court concludes that the plaintiff has failed to offer proof sufficient to create a genuine issue of fact on her manufacturing defect claim (that BSC failed to manufacture the HTA in conformity with the PMA application), her warning/labeling claims (that BSC failed to provide proper warnings and/or labeling in light of its alleged failure to properly report failures or malfunctions of the HTA to the FDA), or any of her other claims.

As a final matter, the plaintiff makes much of the fact that BSC initiated a voluntary recall of the HydroTherm Ablator ("HTA") Procedure Set on July 31, 2009. *See* Notice of Recall, attached to Sur-Reply as Exhibit "A." According to the defendant, the voluntary recall stems from the FDA's May 14, 2009 approval of a change in the design of the procedure set (called ProCerva™). *See* PMA Supplement No. 13, attached to Sur-Reply as Exhibit "B." The defendant contends that the design change further assists the physician in gaining and maintaining a cervical seal which in turn may reduce the risk of a fluid leak and, possibly, a burn. The practical effect of the recall was to replace old design procedure sets with the new ProCerva™ design. Thus, the defendant argues that, if anything, this recall only further serves to prove that regulation of Class III medical devices such as the HTA is the exclusive province of he FDA. BSC asserts that regardless of the recall, the plaintiff's state tort claims remain preempted by *Riegel v. Medtronic, Inc.,* 128 S.Ct. 999, 1003 (2008), which holds that it is only for the FDA, and not a Mississippi jury applying Mississippi law, to regulate the HTA. The court agrees and so finds.

Further, the defendant asserts that the voluntary recall is irrelevant and inadmissible. Federal Rule of Evidence 407 provides in relevant part:

When, after an injury or harm allegedly caused by an event, measure are taken

> that, if taken previously, would have made the injury or harm less likely to occur, evidence of the subsequent measures is not admissible to prove negligence, culpable conduct, a defect in a product, a defect in a product's design, or a need for a warning or instruction.

F.R.E. 407. Under this rule, evidence of subsequent remedial measures is only admissible to prove ownership or control, feasibility of precautionary measures, or for impeachment. *Id*. Indeed, the plaintiff argues that she intends to offer it as feasability of a necessary precautionary measure which could have been implemented earlier if BSC had properly reported the allegedly under-reported incidences of malfunction of the HTA.

The Southern District of Mississippi recently held that a post-incident recall notice was inadmissible under FRE 407 in a products liability action. *Rutledge v. Harley-Davidson Motor Co.*, 2009 WL 1635762 (S.D.Miss. 2009) (plaintiff alleged negligence, breach of implied warranty and strict liability theories). In that case, the plaintiff relied exclusively on the recall notices pertaining to the product in question to prove that the defendant breached its duties. *Id*. at *2. The court explained that Rule 407, "as applied to products liability actions, prevents evidence of subsequent remedial measures from being used as a defendant's admission that a design was defective." *Id*. (citing *Mills v. Beech Aircraft Corp., Inc*., 886 F.2d 758, 763 (5th Cir. 1989)).

Additionally, evidence of subsequent remedial measures is inadmissible to prove negligence, demonstrate culpable conduct in a breach of warranty claim, or establish product defect. *Id*. at *3. Specifically, the court stated: "[rule 407] is based on sound and time honored public policy – the threat of litigation should not discourage manufacturers from taking steps designed to enhance safety and protect the public.

Defendant's voluntary recall is the sort of behavior that Rule 407 is intended to encourage." *Id*. Thus, the recall notices were inadmissible to prove a defect. *Id*. The court made clear that in the absence of evidence of a defect, the plaintiff could not recover "merely because there was an accident and [s]he was injured." *Id*. Thus, any evidence of the voluntary HTA recall is irrelevant to the facts of this case and inadmissible under Rule 407, especially in the face of complete preemption of the plaintiff's claims.

IT IS THEREFORE ORDERED AND ADJUDGED that the Motion for Summary Judgment **[#79]** filed on behalf of the defendant, Boston Scientific Corporation is granted and the plaintiff's Complaint and Amended Complaint are dismissed with prejudice and that all other motions are denied as moot. A separate judgment shall be entered herein in accordance with Rule 58, Federal Rules of Civil Procedure.

SO ORDERED AND ADJUDGED this the 12th day of November, 2009.

s/Keith Starrett
UNITED STATES DISTRICT JUDGE