IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

STEVEN RATTAY, and SHARON RATTAY, his wife

Plaintiffs,

v. **CIVIL ACTION NO. 5:05-cv-177**
(Judge Keeley)

MEDTRONIC, INC., individually and t/d/b/a MEDTRONIC NEUROLOGICAL; and MEDTRONIC USA.,INC., individually and t/d/b/a MEDTRONIC NEUROLOGICAL

Defendants.

CORRECTED MEMORANDUM OPINION AND ORDER

The Synchromed Infusion System is a medical product made by the defendant, Medtronic, Inc. It consists of a refillable, programable pump and an attached catheter that are implanted into a patient to deliver doses of a drug internally on a set schedule. Plaintiff Steven Rattay received a Synchromed pump and catheter to deliver morphine to his back. Unfortunately, the catheter later ruptured, leaving a fragment close to his spine that cannot be removed. In 2005, Rattay and his wife, plaintiff Sharon Rattay, filed this multi-claim product liability suit against Medtronic. Pending is Medtronic's motion for summary judgment, which asserts that most of the Rattays' claims are preempted by the United States Food and Drug Administration's ("FDA's") premarket approval ("PMA") of the Synchromed catheter, and that the remaining claims are factually or legally unsupported. In considering these issues,

the Court has been mindful that there is no controlling case law in the Fourth Circuit on the central question of the preemptive effect of the FDA's premarket approval of a medical device after that device has been subject to the PMA process.

I. Factual and Procedural Background

In January, 1986, Medtronic submitted an application to the FDA for approval to sell an internal drug delivery pump in the United States under the brand name Synchromed. The FDA evaluated the Synchromed pump under the PMA process. The PMA process imposed (and still imposes) formidable requirements on a company seeking approval of a medical device. Accordingly, Medtronic's application included detailed information on the Synchromed pump's design, components, manufacturing process, and other characteristics, along with data from laboratory, animal, and human testing and samples of all written materials, including labeling and instructions for doctors, that would accompany the pump. In all, Medtronic's submission exceeded 1,700 pages. After the FDA reviewed these materials, it sent a letter to Medtronic on March, 14, 1986, informing the company that its pump had been approved for sale in the U.S.

In its approval letter, the FDA reminded Medtronic that, before it could make changes to the device or the documentation

related to the SynchroMed pump's safety or effectiveness, it would need to file an application for a so-called PMA supplement and obtain the agency's approval. Indeed, Medtronic has applied for many such supplements in the years since it received initial approval of the SynchroMed pump. In November, 1997, for example, Medtronic's application for the 39th PMA supplement for the pump sought approval to use the "InDura 1P One Piece Intrathecal Catheter" in concert with the SynchroMed pump to deliver drugs into a patient's spinal cavity. The FDA approved that supplement in May of the next year. Thereafter, in February, 1999, Medtronic applied for a PMA supplement to offer a changed version of the Synchromed pump itself. This supplement, the 42nd, proposed various design improvements to the pump, with the improved version to be marketed under a slightly different brand name: the SynchroMed EL. On March 18, 1999, the FDA approved the PMA supplement for the SynchroMed EL.

During an operation at West Virginia University Hospitals in Morgantown, West Virginia on January 16, 2002, Rattay received a SynchroMed EL pump and attached InDura intrathecal catheter for the purpose of delivering morphine to his back. Apparently, the SynchroMed system worked as indicated until the fall of the next year and Rattay was able to return to work as a truck driver. A CT

scan conducted on October 31, 2003, however, showed that the catheter had broken. Although surgeons operated on Rattay on November 7, 2003 to remove the catheter, they were unable to extract a fragment resting close to his third lumbar vertebrae.

Rattay and his wife then sued Medtronic on October 25, 2005. Their complaint alleges claims of 1) strict liability, 2) negligence in designing, manufacturing, and/or marketing of the Indura catheter, 3) failure to warn Rattay of the risk of catheter breakage, 4) breach of express and/or implied warranty, and, on behalf of Mrs. Rattay, 5) loss of consortium.[1] The Rattays seek damages for medical expenses, pain and suffering, lost wages and Rattay's "permanent scarring and disfigurement."

On December 12, 2005, Medtronic answered the complaint, asserting, *inter alia*, the affirmative defense that some or all of the Rattays' claims are preempted by the provisions of the Medical Device Amendments to the federal Food Drug and Cosmetics Act. 21 U.S.C. §§ 301, *et. seq*. Subsequently, on May 16, 2006, Medtronic filed a motion for summary judgment under Federal Rule of Civil Procedure 56, contending that most of the Rattays' claims are

[1] Rattay's strict liability, negligence, and failure to warn claims are all brought in Count I of the complaint under the general heading, "Tort". Rattay's breach of warranty claims and Mrs. Rattay's loss of consortium claim make up Counts II and III of the complaint, respectively.

preempted, and that the remainder do not raise triable issues of fact. This Court then suspended discovery in the case while it analyzed the supporting materials and arguments filed by the parties in conjunction with the motion for summary judgment.

II. Procedural Standards for Decision

A motion for summary judgment should be granted when the record reveals that there is "no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Rule 56(c). To win summary judgment, the moving party bears the initial burden of asserting, with specificity, why no triable issue of fact exists and it is entitled to judgment under the law. Celotex Corp. v. Catrett, 477 U.S. 317, 325(1986). Once the movant has done so, the non-moving party, at the least, must show the existence of a genuine issue on the claims on which it has the burden of proof by setting forth specific material facts that would be admissible as evidence at trial. Id. at 322-323; Rule 56(e). Material facts are those necessary to establish the elements of a party's cause of action. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986).

The purpose of a summary judgment inquiry is not to weigh the factual evidence and determine the outcome of a case in lieu of a jury trial. Id. at 249 (1986). Indeed, a court must view the

facts presented in the light most favorable to the non-moving party and must draw all reasonable inferences in the non-movant's favor. Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587-588 (1986). The non-moving party, however, must offer more than a mere “scintilla” of evidence to establish a genuine issue of fact, Anderson, 477 U.S. at 252; it must provide “concrete evidence from which a reasonable juror could return a verdict in [its] favor." Id. at 256.

Importantly, this analysis applies when a summary judgment motion is brought after both parties have had adequate opportunity to marshal evidence for their positions, a point that usually occurs after the completion of discovery. See Celotex, 477 U.S. at 322 (“Rule 56(c) mandates the entry of summary judgment, *after adequate time for discovery* and upon motion, against a party who fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial.”)(emphasis added). Indeed, if the non-moving party has not had an opportunity to make full discovery, Rule 56(f) gives the district court the discretion to deny a summary judgment motion or grant a continuance. Id. at 326.

III. Discussion

Medtronic's motion and associated briefs assert that it is entitled to summary judgment on each claim alleged by the Rattays. The majority of its arguments center on the asserted preemption of the Rattays' state law claims, although Medtronic concludes that Rattay's negligence claims are not preempted to the extent they assert the company failed to comply with applicable FDA regulations. The remainder of Medtronic's arguments focus on Rattay's non-preempted negligence claims and assert that he cannot produce enough factual support for those claims to show the existence of a genuine issue for trial. Finally, Medtronic argues that Mrs. Rattay's derivative loss of consortium claim must fail if the Court grants its motion for summary judgment.

The heart of the controversy now before this Court is obviously the question of preemption. The product involved, Medtronic's allegedly defective catheter, was approved for sale and use in the United States through the FDA's rigorous PMA process. Medtronic posits that this process creates federal requirements for the catheter that, under the FDCA, can preempt certain state law requirements, and that most of the claims brought by Rattay would, if successful, impose such state requirements on a federally regulated device. The Rattays reject both contentions.

While there is no shortage of case law on preemption and the PMA process nationwide, the Fourth Circuit has not yet addressed the preemptive implications of the FDA's PMA process. To resolve the preemption issues raised by Medtronic's motion, therefore, this Court must look to the Supreme Court's treatment of similar, although not identical issues, and also examine the views expressed by the circuit courts that have decided PMA process preemption cases. The Court also must address whether Rattay's non-preempted claims and Mrs. Rattay's loss of consortium claim may proceed.

To put these issues in the proper context, the Court's analysis begins with a brief discussion of the structure of medical device regulation under the FDCA and the status of modern preemption law.

a. Medical Device Amendments and the PMA Process

Prior to 1976, regulation of the introduction of new medical devices was a field left almost entirely to the States. In that year, however, the federal government took a major step into the arena by enacting the Medical Device Amendments ("MDA"), 90 Stat. 539, to the FDCA. "Congress enacted the MDA in the midst of rising concern regarding the safety and effectiveness of the growing number of medical devices being introduced into the marketplace." Duvall v. Bristol-Myers-Squibb Company, 103 F.3d 324, 327 (4th Cir.

1996). Those amendments established a multi-tiered system of federal regulation which "provide[s] for the safety and effectiveness of medical devices by classifying them according to the amount of risk they present to the public and imposing appropriate controls." Id. (citing Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996))(internal quotation marks omitted).

As outlined by the Fourth Circuit in Duvall:

> Class I devices, such as tongue depressors, do not present an unreasonable risk of illness or injury and are subject only to general controls. 21 U.S.C.A. § 360c(a)(1)(A); 21 C.F.R. § 880.6230 (1996). Class II devices, such as bone-conduction hearing aids, for which 'general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device,' are subject to special controls. 21 U.S.C.A. § 360c(a)(1)(B); 21 C.F.R. § 874.3300 (1996). Class III devices are those devices: (1) for which there is insufficient information to determine that the controls applicable to Class I and II devices are alone enough to provide reasonable assurance of the safety and effectiveness of the device; and (2)(a) that are to be used for 'supporting or sustaining human life' or that are 'of substantial importance in preventing impairment of human health' or (2)(b) that 'present[] a potential unreasonable risk of illness or injury.' 21 U.S.C.A. § 360c(a)(1)(C).

104 F.3d at 327. Here, there is no dispute that Medtronic's SynchroMed EL Infusion System, including the InDura 1P One Piece Intrathecal Catheter is a Class III medical device.

Unlike Class I and II devices, Class III devices must conform to the mandates of 21 U.S.C. § 360e. See 21 U.S.C. § 360c(a)(1)(C).

Under § 360e, unless it qualifies for an exception, a Class III medical device must be subjected to PMA scrutiny before it can be marketed and sold in the United States. When applying for PMA, a device maker must submit a wide range of detailed data to the FDA regarding safety and effectiveness. This includes information on a device's design, component materials, manufacturing process, and results of required experimental testing, as well as samples of all labeling and marketing materials associated with the device. 21 U.S.C. § 360e.

Once the device maker's submission is complete, the agency performs a thorough review of the application for PMA, utilizing experts in relevant, specific medical fields. If the FDA determines that the product is reasonably safe and effective for its intended medical use, the agency then grants permission to market the device. Once a device is approved for marketing, a PMA supplement must generally be filed with the FDA before a maker may market a version of the device that has undergone changes affecting its safety or effectiveness.

As noted above, there are exceptions to the requirement that Class III medical devices must pass PMA scrutiny before they can be sold. First, devices marketed before passage of the MDA in 1976 need not be withdrawn while the FDA completes a PMA review. 21

U.S.C. § 360e(b)(1)(A). Secondly, new devices that are "substantially equivalent" to devices already on the market do not have to go through the PMA process. 21 U.S.C. § 360e(b)(1)(B). Rather, if the FDA finds a new device substantially equivalent to one already in use, its maker is only required to comply with the general controls applicable to all medical devices. Finally, a special Investigational Device Exemption ("IDE") allows device makers to distribute a device for the limited purpose of testing its safety and effectiveness. See 21 § U.S.C. § 360j(a); 21 C.F.R. § 812-813.

In addition to outlining a scheme for the federal regulation of medical devices, the FDCA also contains a provision that provides for the preemption of certain state and local device regulations. That provision, found at Section 360k, states in pertinent part:

> (a) General rule. 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–
> (1) which is different from, or in addition to, any requirement applicable under this Chapter to the device, and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Chapter.

21 U.S.C. § 360k(a). The preemption issues in the present case turn on the interpretation of this language.

b. Preemption Jurisprudence

Article VI of the U.S. Constitution contains the Supremacy Clause:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land; and the Judges in every State shall be bound thereby, any thing in the Constitution or Laws of any State to the Contrary notwithstanding.

The power, indeed the duty, of courts to ignore provisions of state law when they are inconsistent with federal law - to find the contrary state law preempted, in other words - stems from this constitutional provision. Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516 (1992).

There are several variations of preemption. Express preemption occurs when Congress explicitly states its intent to invalidate state authority over a subject in the language of a statute. Id. Preemption can also be implied from a federal statute in a given circumstance if state law actually conflicts with that statute or if the text evinces that Congress intended to fully occupy a field of regulation, leaving no room for the states.

Id. Given the clear text of 21 U.S.C. § 360k(a), this case involves express preemption.

In the past fifteen years, the Supreme Court has decided three major cases that required it to interpret the scope of express preemption statutory provisions. Those cases provide the necessary foundation for determining the validity of Medtronic's preemption defense here.

I. Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992).

In 1992, the Supreme Court's decision in Cipollone v. Liggett Group, Inc., 505 U.S. 504 (1992), announced major new developments to the doctrine of preemption. Cipollone had sued the major tobacco companies in a product liability suit that focused mainly on alleged wrongdoing in the companies' labeling and advertising practices. The cigarette manufacturers argued that Cipollone's claims were preempted by two federal statutes enacted in 1965 and 1969, respectively, that prescribed certain warnings for cigarettes and contained explicit preemption provisions to nullify other state requirements. In a fractured outcome in which no single opinion carried the support of five justices, the Supreme Court held that some, but not all, of Cipollone's claims were preempted. Writing for a four-justice plurality, Justice Stevens concluded that the 1965 statute, which preempted warning "statements" required by

state law, applied only to positive enactments of a legislature or state agency and thus did not preempt state tort claims. Cipollone, 505 U.S. at 519. The plurality opinion also examined another provision, a 1969 amendment that replaced the 1965 provision, that preempted any state law "requirements or prohibitions" on advertising. Id. at 521. Justice Stevens found that this language "plainly reaches beyond" positive enactments to "easily encompass obligations that take the form of common-law rules."[2] Id.

Although the phrase "requirements or prohibitions" was not limited to positive enactments, in the plurality's view neither did it automatically preempt all or "any familiar subdivision" of common law claims; Justice Stevens therefore examined each claim individually to assess "whether the legal duty that is the predicate of the common-law damages action constitute[d] a 'requirement or prohibition' . . ." Id. at 524.

The plurality concluded that the plaintiff's claims for failure-to-warn were preempted insofar as they alleged that

[2] The plurality defended this position by noting that "state regulation can be as effectively exerted through an award of damages as through some form of preventative relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." Cipollone, 505 U.S. at 521 (quoting San Diego Building Trades Council v. Garmon, 359 U.S. 236, 247 (1959)).

cigarette manufacturers had a duty to put more or better warnings about the dangers of smoking on their cigarette packs. Additionally, it concluded that Cipollone's claim that the companies had fraudulently misrepresented the health hazards of smoking by essentially trying to nullify the effect of the cigarette warnings through their advertisements was preempted as it would have imposed a prohibition on advertising beyond that required by the federal statute. Id. at 527.

The plurality, however, concluded that a claim for breach of express warranty was not preempted because it was based on a more general legal obligation that did not directly relate to "smoking and health" – namely, the general duty not to breach contractual warranties. Id. at 526. Likewise, it concluded that Cipollone's claims that the cigarette companies fraudulently misrepresented and conspired to misrepresent the health hazards of smoking were not preempted because those claims were based on the general duty not to make false statements on which others will rely. Id. at 528-529.

Justice Scalia, joined by Justice Thomas, concurred in plurality's decision regarding the preempted claims, but, writing separately, urged the Court to find that all of the plaintiff's claims subject to the 1969 amendment were preempted. Id. at 544

(Scalia, J., concurring in part and dissenting in part). Justices Blackmun, Kennedy and Souter, on the other hand, concluded that Congress had not expressed a clear purpose to preempt state tort claims in the 1969 language and, therefore, found that none of the plaintiff's claims were preempted. Id. at 531 (Blackmun, J., concurring in part and dissenting in part).

Despite the fact that no particular opinion in Cipollone secured the support of five justices, because six justices clearly found that a statutory provision expressly preempting state law "requirements" reached at least some state law civil claims, id. at 521 (four justice plurality); and id. at 548 (Justices Scalia and Thomas), following Cipollone, product makers began to assert the defense of preemption with much greater frequency and success.[3]

ii. Medtronic v. Lohr, 518 U.S. 470 (1996).

In 1996, the Supreme Court considered the preemption of medical device liability claims under 21 U.S.C. § 360k. Although Medtronic, Inc. v. Lohr, 518 U.S. 470 (1996), dealt with the same preemption provision at issue here, the medical device at the

[3] See Bates v. Dow Agrosciences LLC., 544 U.S. 431, 441 (2005)("It was only after 1992 when we held in Cipollone[] that the term 'requirement or prohibition' in the Public Health Cigarette Smoking Act of 1969 included common-law duties, and therefore pre-empted certain tort claims against cigarette companies, that a groundswell of federal and state decisions emerged holding that [the relevant statute] pre-empted claims like those advanced in this litigation.")

center of that case, a pacemaker, had not been approved for use through the PMA process. Instead, its manufacturer had submitted the device to the FDA as one "substantially equivalent" to devices already on the market. As such, the pacemaker was only subject to the requirements of § 510k, which outlines general "Good Manufacturing" controls that are applicable to all medical devices. The question before the Supreme Court, therefore, was whether those general requirements triggered § 360k preemption of the plaintiff's state law product liability tort claims.

The Court's answer to that question came in a decision even more fractured than its decision in Cipollone. Justice Stevens wrote a seven-part opinion that commanded the full support of just three other justices. Justice Breyer, writing separately, concurred in five parts of the opinion while Justice O'Connor, joined by three other justices, concurred in part and dissented in part from the opinion.

All nine justices agreed that the plaintiff's claim that the pacemaker was negligently designed was not preempted, and that the FDA's general controls place no restrictions on the design (rather than the manufacture) of a device. Moreover, from the portions of Justice Stevens' opinion joined by Justice Breyer, it is clear that a majority of the Court adopted certain procedural guidelines to be

applied in preemption analysis. For example, where Congress has enacted an express preemption provision in a statute, a court should turn directly to the scope of that provision's preemptive effect; no inquiry into implied preemption is needed or possible. Lohr, 518 U.S. at 484 (citing Cipollone, 505 U.S. at 517). Furthermore, although the purpose of Congress is the "ultimate touchstone" in a preemption inquiry, there is a presumption against finding preemption in cases involving the historic police powers of the states. Id. at 485 (citations omitted). Congressional purpose to preempt in such cases must be "clear and manifest." Id.

The portions of Justice Stevens' opinion joined by Justice Breyer also decided several substantive issues regarding the scope of § 360k(a) preemption. Most importantly, the five justices concluded that the general controls contained in § 510k of the Act did not constitute federal requirements that could have preemptive effect. Id. at 494. Their analysis on the issue was "substantially informed" by the FDA regulations implementing § 360k(a). Id. at 495-96. Specifically focusing on 21 C.F.R. § 808.1(d)(1), the justices concluded that state regulations are preempted "only when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.'" Id. at 498 (quoting 21 C.F.R.

§ 808.1(d)(1995)). They then held that the requirements in § 510k were not specific requirements applicable to a particular device:

> The generality of [the § 510k] requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.

Id. at 501. In sum, Lohr held that the general controls in § 510k did not require a device "to take any particular form for any particular reason." Id. at 493.

Despite the conclusion of a majority of the Court that the mandates of § 510k were not federal requirements within the scope of § 360k(a), and that the plaintiff's claims were not preempted, Justice Stevens, without the concurrence of Justice Breyer, went on to discuss whether state law civil suits impose "requirements" under § 360k(a), and found that they generally do not. He distinguished Cipollone, finding that Congress had written the preemption provision at issue in that case with a much different purpose than the preemption provisions in § 360k(a). Id. at 488-491. Further, he stated that "few, if any, common-law duties have been pre-empted" by § 360k(a) and predicted that instances of preemption of state law claims under the section would be "rare indeed." Id. at 502.

Joined by Chief Justice Rehnquist and Justices Scalia and Thomas, Justice O'Connor argued that, given the express language of the preemption provision at issue, the Court's reliance on FDA regulations, such as 21 C.F.R. § 808.1(d), to inform its decision on the preemptive scope of § 360k(a) was misplaced. Id. at 511-12 (stating that "[t]he Court errs when it employs an agency's narrowing construction of a statute where no such deference is warranted"). Thus, she strongly disagreed with the plurality's conclusion that, to have preemptive effect, federal requirements need to be device-specific under § 360k(a). Id. She also disagreed that Cipollone was inapposite to the case before the Court. See id. at 510-11 (contending that the four justices who adopted that view had "fail[ed] to refute the applicability of the reasoning" of Cipollone and that the case's rationale was "equally applicable in the [§ 360k(a)] context").

In his concurring opinion, Justice Breyer expressed a mixed view between the competing four-justice blocks. In accord with Justice Steven's view, he expanded on the need to look to the FDA regulations regarding § 360k(a) and how that step supported the position that federal requirements had to be "specific requirements applicable to a particular device" to trigger § 360k(a) preemption. Id. at 505-08. On the issue of whether state law product liability

claims could be preemptable state requirements, however, he stated his basic agreement with Justice O'Connor on the point and noted that Cipollone's rationale seemed applicable to the circumstances facing the Court. Id. at 504. Indeed, he asserted that a holding to the contrary would have "anomalous consequences." Id.

iii. Bates v. Dow Agrosciences, 544 U.S. 431 (2005).

Although the Supreme Court has not revisited the preemptive scope of § 360k(a) addressed in Lohr, it recently discussed the meaning of similar preemption language. In Bates v. Dow Agrosciences, 544 U.S. 431 (2005), the Court dealt with the preemptive effects of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA requires pesticide makers to register a pesticide with the Environmental Protection Agency ("EPA") before putting it on the market in the United States. Before the EPA can accept the registration for a pesticide and permit its sale, the agency must determine that it is efficacious, that it will not cause unreasonable harm to humans and the environment, and that its label is not false or misleading. See 7 U.S.C. § 136a(c); Bates, 544 U.S. at 438. Significantly, at 7 U.S.C. § 136v(b), FIFRA also contains a provision that bars states from imposing or continuing "any requirements for labeling or

packaging in addition to or different from those required under [FIFRA]."

In Bates, a group of Texas peanut farmers alleged that a Dow pesticide that had been labeled for use "in all areas where peanuts are grown" had, in fact, devastated their peanut crops. The farmers brought claims for strict liability, negligence, fraud, breach of warranty and violation of a Texas consumer protection statute. 544 U.S. at 435-436. Lower courts had concluded that all of the farmers' claims either failed under Texas state law or were preempted by § 136v(b). In a 7-2 decision, however, the Supreme Court held that most of the farmer's claims were not preempted and remanded other claims to the circuit court for further consideration.

Justice Stevens authored the majority opinion in Bates and, in accord with his reasoning in Cipollone, concluded that the term "requirements" in § 136v(b) embraces state common law and statutory duties. Id. at 444. The Court also pointed out, however, that, under § 136v(b), a state law requirement must be a requirement "for labeling" or "packaging" and must be "in addition to or different from" federal requirements under FIFRA. Id. at 447.

This latter condition, although absent from the preemption provision in Cipollone, closely mirrors the text of the preemption

provision involved in Lohr. See § 360k(a)(only requirements that are "different from, or in addition to" federal requirements are preempted). Indeed, in Bates the majority relied on Lohr for the proposition that "equivalent" and "fully consistent" state law requirements are not "in addition to or different from" those federal requirements and thus are not preempted by that statutory language. See Bates, 544 U.S. at 447-448 (citing Lohr, 518 U.S. at 495; Id. at 513 (O'Connor, J., concurring in part and dissenting in part)). In adopting this "parallel requirements" rule, Bates clarified that, when determining whether a state law cause of action creates an inconsistent "requirement" subject to preemption, a court must focus on the duty underlying the claim and not the potential for damages resulting from a successful claim.[4] Id. at 447-448.

[4] In so finding, the Bates majority looked to Justice O'Connor's dissenting opinion in Lohr, and stated:

As Justice O'Connor explained . . . a state cause of action that seeks to enforce a federal requirement "does not impose a requirement that is 'different from, or in addition to,' requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*."

Bates, 544 U.S. at 447-448 (emphasis in original)(quoting Lohr, 518 U.S. at 513 (O'Connor, J., concurring in part and dissenting in part)).

IV. Preemption Analysis

Having examined the holdings in Cipollone, Lohr, and Bates, the Court now turns to the task of interpreting the scope of the preemption language contained in § 360k(a) and its application to the Rattays' claims. The overarching preemption issue here breaks down into three essential questions. First, does the PMA process create federal requirements that have preemptive force within the meaning of § 360k(a)? If so, do state law product liability claims constitute state law requirements within the ambit of that provision? Finally, if the answer to both of these questions is "yes", are those state requirements related to safety and effectiveness and non-equivalent to those federal FDA requirements? The Court will now take up each of these questions in turn.

a. The PMA Process Creates Federal Requirements that have Preemptive Force Within the Meaning of § 360k(a).

Medtronic does not contend that there are any relevant positive enactments by the FDA that could constitute federal requirements under § 360k(a). Rather, it contends that this case directly implicates a question unaddressed in Lohr – whether FDA approval resulting from the PMA process creates federal requirements under 360k(a) that preempt state law. Since neither the Supreme Court nor the Fourth Circuit has answered this

question, this Court must look to the reasoning in Lohr and also examine the views of circuit courts that have directly addressed this issue.

As noted, a majority of the justices in Lohr agreed that general good manufacturing controls associated with § 510k's premarket notification process are not sufficient to trigger preemption under § 360k. As also noted, however, the Supreme Court took pains to distinguish the § 510k process from the PMA process and stated explicitly that the processes are "by no means comparable." Lohr, 518 U.S. at 478-79. Specifically, the § 510k process is a limited form of review focused on a device's equivalence to an already approved device, while the PMA process involves a rigorous review of the safety and effectiveness of a device.[5] Id. at 479.

Although Lohr did not involve a device that had undergone PMA review, it provides the standard that courts must apply when determining whether the PMA process gives rise to § 360k(a) federal requirements. Lohr's discussion of the governing statutory and regulatory language clarifies that federal requirements must be

[5] Perhaps nowhere is the striking difference in the two processes more clearly stated than in congressional hearing testimony cited by the Court: "in contrast to the 1,200 hours necessary to complete a PMA review, the § 510k review is completed in an average of only 20 hours." Lohr, 518 U.S. at 479.

"specific requirements applicable to a particular device" in order to preempt state law device regulations under § 360k(a). Lohr, 518 U.S. at 498 (quoting 21 C.F.R. § 808.1(d)). These elements can be reduced to a single test: Is a requirement is "device-specific."

Of the circuit courts that have addressed the issue, all save one have concluded that the PMA process does indeed create device-specific requirements. See Riegel v. Medtronic, Inc., 451 F.3d 104, (2nd Cir. 2006); Horn v. Thoratec Corp., 376 F.3d 163 (3d Cir.2004); Martin v. Medtronic, 254 F.3d 573 (5th Cir. 2001); Brooks v. Howmedica, Inc., 273 F.3d 785 (8th Cir. 2001); Kemp v. Medtronic, Inc., 231 F.3d 216 (6th Cir. 2000); Mitchell v. Collagen Corp., 126 F.3d 902 (7th Cir. 1997) . Only the Eleventh Circuit has rejected this conclusion. See Goodlin v. Medtronic, Inc., 167 F.3d 1367 (11th Cir. 1999).[6] Of course, the fact that a majority of circuits that have addressed the issue have held that the PMA process creates federal requirements is far from dispositive. Nevertheless, after careful consideration, this Court believes that the majority position is also the substantively better position.

Unlike the § 510k process considered in Lohr, the PMA process gives rise to requirements that force a device to "take [a]

[6] State appellate courts appear to be much more divided on the question. See Riegel, 451 F.3d at 117 (collecting a number of state cases on both sides of the issue).

particular form for [a] particular reason." The particular form required is that approved by the FDA at the conclusion of PMA review. Moreover, a device maker may not change this approved form in any way affecting the device's safety or effectiveness without first seeking the FDA's permission by filing a PMA supplement. 21 C.F.R. § 814.39. The reason for requiring a device maker to adhere to that particular form is clear: The FDA has found the device's approved form to be reasonably safe and effective. See 21 U.S.C. §§ 360c(a)(1)(C) & 360e.

While there is strong support in logic and case law for the position that the PMA process creates federal requirements that can preempt state law under § 360k, this Court cannot ignore that the Eleventh Circuit reached the opposite conclusion in Goodlin. There, the court confronted a product liability suit related to an allegedly defective pacemaker approved through the PMA process. The district court found those claims preempted by requirements arising from a PMA, but the Eleventh Circuit reversed, rejecting the defendant's argument that the PMA process imposes § 360k(a) federal requirements. While acknowledging that the PMA process was significantly different from the § 510k process that the Supreme Court had analyzed in Lohr, and that Lohr, therefore, was not controlling on the PMA issue before it, Goodlin, 167 F.3d at 1374,

the court concluded that the FDA's approval of a PMA submission "neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement . . ." Id. at 1376.

Despite the reasoning in Goodlin, this Court finds no mandate in the Act or its implementing regulations suggesting that FDA rules must be "prerequisite" to a device's approval in order to constitute federal requirements within the scope of § 360k(a). Having once gone through the PMA process and received approval to sell a device, a device maker cannot then deviate from or modify the specifications approved by the FDA without first seeking the agency's permission. The manufacturer must produce and market its device in conformity with those specifications, or not at all. Simply put, those approved specifications are device-specific requirements under §360k(a).

The record in this case establishes that Medtronic's catheter was approved through a PMA supplement instead of an original PMA submission. That distinction, however, is irrelevant to the questions at hand, see Kemp v. Medtronic, 231 F.3d 216, 227 (6th Cir. 2000) (approval of changes set forth in a PMA supplement has the same preemption implications as approval of an original PMA submission), because Medtronic was not allowed to distribute its

catheter except in accordance with the FDA preapproved specifications. Accordingly, the Court concludes that the FDA's approval of the PMA supplement for Medtronic's Indura catheter created federal requirements governing the catheter under the § 360k(a) preemption provision.

b. State Law Product Liability Claims Constitute State Law Requirements Within the Ambit of §360k(a).

The Court turns next to whether there are any state law requirements applicable to Medtronic's catheter under § 360k(a). This issue turns, particularly, on the Supreme Court's treatment of the issue in Lohr.

In Cipollone and Bates the Supreme Court interpreted preemption provisions containing language similar to § 360k(a) and concluded that the scope of potentially preempted state law "requirements" includes state law civil claims. Unlike the interpretation of the preemption provisions at issue in those cases, however, 21 C.F.R. § 808.1(d) "substantially inform[s]" the interpretation of § 360k(a), Lohr, 518 U.S. at 495, the preemption provision at issue here.

That federal regulation provides examples of state and local requirements that the FDA does not believe are preempted because

they are not "applicable to a device." The first such exemption states:

> Section [360k(a)] does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e. g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

21 C.F.R. § 808.1(d)(1).

This regulation did not go unnoticed by Justice Stevens in Lohr. In a portion of his opinion (part V) joined by Justice Breyer, Justice Stevens addressed the relevance of 21 C.F.R. § 808.1(d)(1) to a preemption analysis after finding that all of the plaintiffs's claims were grounded in general common law duties:

> These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a work force. These state requirements therefore escape pre-emption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be "with respect to" specific devices such as pacemakers. As a result, none of the Lohrs' claims based on allegedly defective manufacturing or labeling are pre-empted by the [FDCA].

Lohr, 518 U.S. at 501-02. Taken alone, this statement - adopted by five justices - would resolve the issue and bind lower courts to the conclusion that civil claims based on general duties of care

cannot constitute § 360k state law requirements. Indeed, in their briefs the Rattays urge this reading of Lohr.

Justice Stevens' statement cannot be taken alone, however, but must be assessed in light of Justice Breyer's general agreement with Justice O'Connor's contrary view regarding the state law requirement issue, and the opinion expressed in his concurrence that Lohr is analogous to Cipollone. Additionally, Justice Breyer used a hypothetical example to demonstrate why preempting state positive enactments, but not requirements imposed by jury verdicts, would have "anomalous consequences."[7] Id. at 504. Following that example, Justice Breyer flatly stated: "I believe that ordinarily, insofar as the [FDCA] pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action."

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[7] Justice Breyer offered the following to illustrate his point:

> Imagine that, in respect to a particular hearing aid component, a federal [FDCA] regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" [FDCA] regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)? The effects of the state agency regulation and the state tort suit are identical. To distinguish between them for pre-emption purposes would grant greater power (to set state standards "different from, or in addition to," federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes.

Id. at 504-505. Indeed, Justice Breyer never mentioned 21 C.F.R. § 808.1(d)(1) at all; rather, he concluded that the actual statutory language of § 360k(a), read literally, supports the conclusion that the provision can preempt state law tort claims. Id. at 503.

That Justice Breyer formally joined the part of Justice Stevens' opinion concluding that general tort claims can rarely, if ever, be preempted by § 360k(a) cannot be ignored, especially given the general presumption against finding preemption in the context of health-related regulations. Nevertheless, the views expressed in his concurrence cause this Court to conclude that he disagreed with Justice Stevens about whether state law civil claims could constitute state law requirements. As the Ninth Circuit has aptly noted:

> [I]t makes little sense to argue that Justice Breyer would write separately to make clear his position that duties arising under state common law can constitute state law "requirements" which can be preempted by the [FDCA], and then agree that because tort law consists of generally applicable principles, it is always preempted, even in the face of specific federal requirements.

Papike v. Tambrands, Inc., 107 F.3d 737, 742 (9th Cir. 1997). Justice Breyer's fundamental agreement with Justice O'Connor on this point suggests that a majority of the Court in Lohr actually supported the proposition that state law civil duties, including

the relatively general duties of care that underlie product liability claims, are state law requirements under § 360k(a).

Accordingly, this Court concludes that Rattay's state law product liability claims would, if successful, impose state requirements that could be preempted by § 360k(a). The only remaining question, then, is whether any of Rattay's state law claims actually are preempted.

c. Certain of Rattay's Claims Relate to Safety and Effectiveness and are Non-Equivalent to Federal Requirements.

Although this Court has concluded that state common law and statutory claims premised on general duties of care are state requirements within the meaning of § 360k(a) and that Medtronic's catheter was governed by federal requirements arising from the PMA process, those conclusions, standing alone, do not resolve the preemption dispute in this case. As the Supreme Court explained in Bates, the mere fact that federal requirements can "pre-empt judge-made rules, as well as statutes and regulations, says nothing about the *scope* of that pre-emption." 544 U.S. at 443-44 (emphasis in original). Thus, the final piece of the preemption analysis in this case must focus on the range of state law requirements that are preempted under § 360k(a) and which, if any, of Rattay's claims come within that range.

Section 360k(a) imposes two limitations on the range of state law requirements that are preempted by its reach. To be preempted, a state law requirement must, first, be "different from, or in addition to" the federal requirements that are applicable to a given device, § 360k(a)(1), and, second, relate to "the safety or effectiveness of the device" or to some other matter covered by the federal requirements. § 360k(a)(2). Moreover, when applying the "parallel requirements" rule to an analysis of the first condition, a court must focus on either the common law or the statutory elements that provide the foundation for the claims in issue. Bates, 544 at 445; see also Cipollone, 505 U.S. at 523 (plurality opinion). Thus, this Court must look to the duties underlying Rattay's claims to determine whether those claims satisfy the conditions in § 360k(a)(1) and (2).

1. Strict Liability and Negligence

Rattay's strict liability claim alleges that Medtronic breached its duty to produce a catheter that was "reasonably safe" for his use. Likewise, his negligence claims allege that Medtronic failed to use reasonable care in designing, manufacturing and marketing the Indura catheter. These claims clearly relate to the safety and effectiveness of Medtronic's product. Cf. Bates, 544 U.S. at 444 (strict liability and negligence claims were not

preempted because they did not relate to "labeling and packaging"). Moreover, to the extent these claims would, if successful, impose liability on Medtronic for producing its catheter in accordance with the specifications approved by the FDA through the PMA process, they constitute state law requirements different from or in addition to the federal requirements established by the FDA for the catheter.

As one of his claims, Rattay asserts that Medtronic negligently failed to manufacture the Indura catheter to the specifications approved by the FDA. While Medtronic argues that it is entitled to summary judgment on this claim on its factual merits, it does not dispute that, as a matter of law, the claim is not preempted by § 360k(a). Accordingly, to the extent Rattay's negligence claims allege that Medtronic's InDura catheter was not produced in accord with, or otherwise failed to adhere to, the applicable federal regulations established by the PMA process, those claims are not preempted. By contrast, however, the remainder of Rattay's negligence claims and his strict liability claims are preempted by § 360k(a). Thus, Medtronic is entitled to summary judgment on the latter claims.

2. Failure-to-Warn

In his complaint, Rattay asserts that Medtronic's failure to include certain information regarding product use and the possibility of catheter breakage in its patient information materials constitutes a state civil law violation for failure-to-warn. Like his strict liability and negligence claims, the failure-to-warn claim clearly relates to the safety of Medtronic's catheter. Rattay, however, contends that the duty at the heart of his claim - the general duty of a manufacturer to warn consumers of a dangerous condition associated with its product - is not in addition to or different from a federally imposed requirement for the catheter. He points out that, under 21 C.F.R. § 814.39, a device maker is allowed to make temporary additions to a device's labeling and marketing materials to improve the safety of the device while a PMA supplement to make those changes on a permanent basis is pending with the FDA.

According to Rattay, this flexibilty prevents the state law requirements established by a successful failure to warn claim from being different from or in addition to federal requirements that are susceptible to such temporary changes. Several circuits, however, have concluded that this additional flexibility does not change the preemption status of the regulation. See McMullen v. Medtronic, Inc., 421 F.3d 482, 488 (7th Cir. 2005); and Brooks v.

Howmedica, Inc., 273 F.3d 785, 796 (8th Cir. 2001) (en banc). The Court agrees, and finds that because the PMA process established federal regulations for the labeling and marketing of Medtronic's catheter Rattay's failure to warn claim is also preempted.

3. Breach of Express Warranty

Rattay alleges, without great specificity, that Medtronic made express warranties regarding its catheter and then breached those express warranties in this case. The Synchromed system labeling and informational materials submitted by Medtronic in support of its motion do contain some language that apparently is intended to address what Medtronic will and will not warrant. The parties, however, have not addressed this language or any statements of warranty regarding this claim. Rather, Medtronic argues that this claim is preempted while the Rattays assert that it is not.

There is support for Medtronic's argument in Fourth Circuit case law. In Duvall v. Bristol-Meyers-Squibb Co., 103 F.3d 324 (4th Cir. 1996), the court dealt with a case the Supreme Court had summarily remanded for reconsideration in the wake of Lohr. Prior to the decision in Lohr, the Fourth Circuit had concluded that an express warranty claim was preempted by the FDA's § 510k substantial equivalency process. Duvall, 103 F.3d at 331-332. On

remand, the court reversed this holding, but noted that nothing in Lohr affected its previous reasoning that

> § 360k(a) preempts an express warranty claim to the extent that the claim is based on FDA-mandated labeling, packaging, or advertising. Indeed, the essence of the holding in [Lohr] – that § 360k(a) gives rise to preemption when the FDA has imposed specific requirements on a particular device – lends credence to our previous conclusion that when the FDA requires the manufacturer of a device to employ certain words to convey information about its product, § 360k(a) operates to preempt differing or additional state law requirements.

Id. at 332.

Later, in Bates, the Supreme Court addressed the issue of whether, under FIFRA's preemption provision, a claim for breach of an express warranty was preempted by language similar to § 360k(a). In finding that it was not, the Supreme Court focused on the common law duty underlying the cause of action and concluded that

> a cause of action on an express warranty asks only that a manufacturer make good on the contractual commitment that it voluntarily undertook by placing that warranty on its product. Because this common-law rule does not require the manufacturer to make an express warranty, or in the event that the manufacturer elects to do so, to say anything in particular in that warranty, the rule does not impose a requirement "for labeling or packaging."

544 U.S. at 444-445. Although the Supreme Court decided this point in the context of section 136v(b) of FIFRA, its reasoning is based on the nature of express warranty claims and, therefore, necessarily would apply to § 360k(a).

That analysis, however, does not extend to the scenario the Fourth Circuit discussed in *dicta* in DuVall – namely, that when a device maker must warrant its product to conform with device-specific FDA regulations established by the PMA process, that warranty does not result from a contractual commitment "voluntarily" undertaken. Since Bates, at least one other circuit court has echoed the reasoning of the Fourth Circuit in DuVall. See Gomez v. St. Jude Medical Daig Division, Inc., 442 F.3d 919, 932 (5th Cir. 2006)(finding that because a device maker's representations about a device "were approved by the FDA through the PMA process," and because the duties underlying the plaintiff's breach of express warranty claim were potentially inconsistent with federal regulation, the claim was preempted).

This Court concludes that the scope of the duty at issue when a cause of action on an express warranty is raised depends on whether that warranty is required to comport with federal regulations established by the PMA process, Duval, 103 F.3d at 332, or whether it is a mutually agreed to contractual term voluntarily entered into by the device maker, Bates, 544 U.S. at 444-445. Because it is unclear what language or statements Rattay relies on to bring his breach of express warranty claim in this case, the Court cannot decide whether that claim is preempted. Accordingly,

it denies Medtronic's motion for summary judgment on this ground subject to renewal on preemption and any other appropriate ground following the completion of discovery in this case.

4. Breach of Implied Warranty

The Rattays' complaint also contains a statutory claim alleging breach of the implied warranty of fitness contained in W.Va Code § 46-2-316. Again, the parties have argued only the preemption issue, and the Court's decision on that point is controlled by 21 C.F.R. § 808.1(d)(1), which specifically states that a U.C.C. breach of warranty claim is not preempted by § 360k(a). Although the exact import of § 808.1(d)(1) remains uncertain following the fractured treatment of that regulation in Lohr, at the very least it seems clear that the specific exclusion for a U.C.C. warranty of fitness must be upheld if, as the Supreme Court has said, the regulations are to "substantially inform" how § 360k(a) is interpreted. Thus, this court concludes that Rattay's breach of implied warranty claim is not preempted, and it reserves for another day all other issues regarding the claim.

In conclusion, this Court finds that Rattay's strict liability and negligence claims are preempted insofar as they allege liability on any grounds other than violation of FDA regulations, that his claim of failure-to-warn is also preempted, that whether

his claim for breach of express warranty is preempted requires further discovery, and that his claim for breach of implied warranty is not preempted.

V. Remaining Issues

In addition to the questions raised by its preemption defense, Medtronic's motion raises several other issues. Although Medtronic has not argued that Rattay's claims of negligence by violation of FDA regulations are preempted, it does contend that it is entitled to summary judgment on those claims because Rattay cannot demonstrate the existence of a genuine issue of material fact. In response, the Rattays assert that they have been prevented from gathering evidence to support those claims because of the stay on the discovery process that was entered by the magistrate judge pending resolution of the preemption issues in the case. In light of this stay and their inability to undertake discovery, the Rattays argue that, beyond the preemption issues discussed above, Medtronic's motion for summary judgment is not ripe for review.

The Court agrees. Besides the express authorization in Celotex for deferring a summary judgment determination until both sides have had the opportunity to undertake adequate discovery, 477 U.S. at 322, Rule 56(f) also allows a district court to continue summary judgment proceedings. Although the Rattays have not filed

a Rule 56(f) affidavit explaining why they have not had adequate opportunity for discovery, the answer is obvious and stems from the Court's own order staying discovery.[8] The Court, therefore, denies summary judgment on these issues, with leave to Medtronic to refile its motion after adequate discovery has occurred.

The last issue involves Mrs. Rattay's derivative loss of consortium claim. Because there are underlying claims remaining in the case, the Court also denies Medtronic's motion for summary judgment on her claim.

VI. Conclusion

For the reasons discussed, the Court: 1) **GRANTS** Medtronic's motion for summary judgment regarding Rattay's strict liability and failure-to-warn claims; 2) **DENIES** Medtronic's motion for summary judgment regarding Rattay's claims that Medtronic negligently violated FDA regulations in producing or marketing the Indura

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[8] As a prominent commentator on the federal rules reminds:

> Summary judgment procedure is not a catch penny contrivance to take unwary litigants into its toils and deprive them of a trial, it is a liberal measure, liberally designed for arriving at the truth. Its purpose is not to cut litigants off from their right of trial by jury if they really have evidence which they will offer on a trial, it is to carefully test this out, in advance of trial by inquiring and determining whether such evidence exists.

10A Wright & Miller, Federal Practice and Procedure § 2712 (quoting Whitaker v. Coleman, 115 F.2d 305, 307 (5th Cir. 1940).

catheter; 3)**GRANTS** Medtronic's motion for summary judgment regarding all of Rattay's other negligence claims; 4) **DENIES WITH LEAVE TO REFILE** Medtronic's summary judgment motion regarding Rattay's breach of express and implied warranty claims; and 5) **DENIES** Medtronic's motion for summary judgment regarding Mrs. Rattay's derivative loss of consortium claim. Further, the stay on the discovery process is hereby **LIFTED** and this case is again **REFERRED** to Magistrate Judge Kaull for proceedings consistent with this opinion. Finally, the Court will set a date for a scheduling conference in this case by separate order.

It is so **ORDERED**.

The Clerk of the Court is directed to transmit copies of this Memorandum Opinion and Order to counsel of record for the parties.

DATED: April 3, 2007.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE