



**GOLDBERG SEGALLA<sup>LLP</sup>**

## Medical Device Litigation Update

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We are happy to share this publication with our clients and friends. This publication is free and distributed via e-mail.

As with other firm publications, we continue to provide concise summaries of significant court decisions and issues. *Medical Device Litigation Update* focuses on cases and issues unique to the defense of medical device manufacturers in all areas of civil litigation with a focus on New York, New Jersey, Connecticut and Pennsylvania. It is our goal to make this publication useful and informative. To discuss the cases and issues highlighted below or to make suggestions for future editions please contact:

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### NEW YORK

**Riegel v. Medtronic, Inc., 552 U.S. \_\_\_\_, 128 S.Ct. 999, 169 L. Ed.2d 892 (2008)**  
**Supreme Court of the United States Holds that Manufacturers of Class II PMA**  
**Devices are Immune From State Products Liability Claims**

Plaintiff asserted state law products liability claims challenging the design, manufacturing, and labeling of Medtronic's Evergreen Balloon Catheter, a Class III PMA Device. The District Court for the Northern District of New York granted summary judgment on plaintiff's negligence, strict liability, and implied warranty claims on the grounds that those claims were expressly preempted by the 1976 Medical Device Amendments ("MDA"). The Supreme Court upheld the dismissal and held that a state products liability claim for negligence or strict liability would directly conflict with the MDA. A full analysis can be found at:

[http://www.goldbergsegalla.com/publications/medical/Alert-February\\_22\\_2008.pdf](http://www.goldbergsegalla.com/publications/medical/Alert-February_22_2008.pdf)

## NEW JERSEY

*Phyllis Sinclair v. Merck & Co., Inc.*, 2008 WL 2340280 (N.J. June 04, 2008)

### **No Medical Monitoring absent a “Manifest Injury;” CFA is Subsumed by the PLA in All Product Liability Personal Injury Cases**

Plaintiff sought medical monitoring despite a failure to allege any physical injury. The Supreme Court held the definition of “harm” under the Products Liability Act (“PLA”) does not include the remedy of medical monitoring when no manifest injury is alleged. In addition, plaintiffs’ Consumer Fraud Act (“CFA”) personal injury claims were entirely subsumed by the PLA. A full analysis can be found at:

<http://www.goldbergsegalla.com/publications/medical/Alert-June2008.pdf>

*Parker v. Howmedica Osteonics Corp.*, 2008 WL 141628 (D.N.J. Jan 14, 2008)

(unpublished)

### **Class Action Complaint Dismissed for Failure to State a Claim**

Plaintiffs brought a class action for economic damages for *inter alia* violations of the Consumer Fraud Act (“CFA”), and the Products Liability Act (“PLA”). The putative class consisted of patients requiring total hip replacement who were implanted with the Howmedica Trident Ceramic Acetabular System. The implants allegedly emit “audible clicking, squeaking and/or squealing sounds” but plaintiffs did not suffer any personal injury as a result of their surgeries or the alleged sounds. The defendant moved to dismiss pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. The District Court granted the motion, holding that plaintiffs failed to adequately plead the CFA when they did nothing more than set forth “legal conclusions cloaked in the guise of factual allegations,” and failed to offer any proof of an “ascertainable loss.” Plaintiffs’ claim that they might sustain costs associated with future medical care and services was purely speculative. Plaintiffs also failed to adequately plead any “harm” as defined by the PLA. The District Court stated that medical monitoring has not been applied by the New Jersey Supreme Court as a remedy to any pure products liability action and that “plaintiffs offer nothing in the way of facts to allege how a ‘squeaking’ hip implant has led to any loss of consortium, particularly in light of the fact that they disclaim any personal injury.”

## CONNECTICUT

*Breen v. Synthes-Stratec, Inc.*, 108 Conn.App. 105 (Conn.App. 2008)

### **Rule Governing Unavoidably Unsafe Products and the Learned Intermediary Doctrine**

Plaintiff instituted an action under the Connecticut Product Liability Act alleging that an implanted dynamic condylar screw plate to fix his fractured left femur broke six months after surgery and that a second, replacement plate broke after six months, causing additional injuries. After a jury found in favor of the defendant, plaintiff appealed claiming that the court improperly instructed the jury on comment (k) to § 402A of the Restatement (Second) of Torts (regarding unavoidably unsafe products) claiming that, under Connecticut law, comment (k) applies only to prescription drugs. To support his argument, the plaintiff referred to the language of comment (k), which lists “drugs,” “vaccines” and “experimental drugs” as examples of unavoidably unsafe products. The

appellate court held that the list in the Restatement was illustrative and not exhaustive and that the implantable plate was incapable of being made safe for its intended and ordinary use. Plaintiff also argued the inapplicability of the learned intermediary doctrine to medical devices. The appellate court rejected this argument and affirmed that the doctrine applies to all cases involving prescription implantable medical devices because there is no principled reason to distinguish between a prescription implantable device and a prescription drug.

***Wegryn v. Smith & Nephew, Inc.*, 2008 WL 803405 (Conn.Super. March 5, 2008)  
(unpublished)**

**Motion to Strike Special Defenses of Learned Intermediary Doctrine and State-of-the-Art**

Plaintiff instituted a products liability action for injuries allegedly resulting from a medical device implanted during total knee replacement surgery. Defendant denied liability and presented Special Defenses in its Answer including: 1) the learned intermediary doctrine and section 402A of the Restatement (Second) of Torts; and 2) the state-of-the-art defense. Plaintiff filed a Motion to Strike the Special Defenses arguing that the learned intermediary doctrine and section 402A of the Restatement (Second) of Torts, comment (k) apply only to unavoidably unsafe products, and that if properly made, a knee replacement system cannot be considered an unsafe product. The trial court held that, as with prescription drugs, a knee replacement system is a complex medical device and is available to patients only by prescription. It found no principled reason why the manufacturer of the knee replacement should not be able to rely upon the physician to provide warnings to the patient as long as the warnings to the physician are adequate. Plaintiff also moved to strike the state-of-the-art defense arguing that the defense impermissibly shifts the jury focus from the product to conduct of the manufacturer. The trial court rejected the argument and held that state-of-the-art evidence is relevant and assists the jury in determining whether a product is defective and unreasonably dangerous.

**PENNSYLVANIA**

***In re Avandia Marketing, Sales Practices and Products Liability Litigation*, 2008 WL 2078917 (E.D.Pa. May 14, 2008).**

**Joining Unrelated Plaintiffs in a Single Complaint in Multi-District Litigation**

Plaintiffs' counsel proposed allowing joinder of multiple parties in a single complaint in multi-district litigation for the purpose of saving on filing fees as well as conserving "the resources of the parties, their counsel and the judiciary." The District Court held that, under Federal Rule of Civil Procedure 20(a)(1), which states "[p]ersons may join in one action as plaintiffs if: (A) they assert any right to relief ... with respect to or arising out of the same transaction, occurrence or series of transactions or occurrences; and (B) any question of law or fact common to all plaintiffs will arise in the action," it would "provisionally and for a limited purpose permit joinder" for plaintiffs domiciled in the same federal judicial district. The ruling was made without prejudice so that the issue could be reevaluated to determine whether "joinder proves to be inefficient or prejudicial to any parties."

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