



JUNE 30, 2009

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FEDERAL MDL JUDGE REFUSES TO CERTIFY NATIONWIDE RICO CLASSES IN OFF-LABEL PROMOTIONS LITIGATION

In her role as an MDL judge to whom hundreds of putative class actions, third-party-payer and individual product-liability claims have been transferred, Judge Patti Saris has refused to certify any of the plaintiffs' ten proposed nationwide class actions against Pfizer involving claims of allegedly fraudulent off-label promotion of the anti-epileptic medication Neurontin. *In re Neurontin*, 2009 WL 1323835 (D. Mass. May 13, 2009).

Plaintiffs sought nationwide certification of RICO and consumer fraud claims based on allegations that physicians were fraudulently induced to prescribe, and health insurance and other benefit plans were fraudulently induced to reimburse prescriptions of, Neurontin for certain uses other than those for which it was approved by the FDA and for higher and allegedly ineffective doses. In these actions, the consumer and third-party-payer (TPP) plaintiffs seek to recover alleged economic losses for the costs of Neurontin prescriptions and exemplary damages.

Judge Saris refused to certify both the consumer and third-party-payer claims for all of the uses at issue on the ground that common questions would not predominate. She used a "searching inquiry" to closely scrutinize the methodology and conclusions in plaintiffs' proposed expert proof of class-wide impact and found that plaintiffs' proposed statistical analysis could not function as common proof of causation "for millions of disparate and varied human interactions."

Given the variation in whether and to what extent prescribing physicians were detailed, and plaintiffs' failure to account for a wide variety of other influences that may have led doctors to prescribe Neurontin off-label, Judge Saris concluded that individual inquiries would be necessary to determine why each doctor prescribed Neurontin off-label.

Judge Saris likewise concluded that each TPP would have to present individualized evidence about whether and to what extent any alleged fraud may have altered its formulary policies and reimbursement costs with respect to Neurontin, "inevitably result[ing] in a tsunami of individual, complex trials."

DRUG & DEVICE BULLETIN

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Pharmaceutical & Medical Device

Shook, Hardy & Bacon has successfully defended pharmaceutical and medical device manufacturers in products liability and other high-stakes litigation for over 35 years. Today, SHB represents more than 30 pharmaceutical and medical device parent companies and their subsidiaries in products liability, antitrust, employment, environmental, commercial, and intellectual property litigation. With more than 100 attorneys dedicated to the unique needs and challenges of this industry, SHB has cultivated a reputation for dynamic, cost-effective solutions built on decades of experience.

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CONNECTICUT COURT OF APPEALS DISMISSES MEDICAL DEVICE CLAIM AS PREEMPTED UNDER RIEDEL

In April 2008, *Mullin v. Guidant Corp.* became the first case to be dismissed in the wake of the U.S. Supreme Court's preemption decision in *Riegel v. Medtronic, Inc.* On May 6, 2009, the Appellate Court of Connecticut affirmed the trial court's grant of summary judgment in Guidant's favor. *Mullin v. Guidant Corp.*, No. 29829, 2009 WL 1272327 (Conn. App. Ct. May 12, 2009).

The decision is a well-reasoned and straightforward application of *Riegel*, in which the U.S. Supreme Court held that the Medical Device Amendments of 1976 contained an express provision preempting state requirements that are "different from, or in addition to" the requirements imposed by federal law," thereby preempting most state tort claims. The U.S. Supreme Court left open the possibility that state claims would not be preempted to the extent they imposed requirements that were "different from, or in addition to" federal law (that is, parallel claims).

In *Mullin*, the Connecticut court held that the plaintiffs' statutory products liability and warranty claims were preempted by federal law. The court further found that the plaintiffs failed to plead any "parallel claims." As the court observed, "[a] review of the plaintiffs' complaint does not reveal any claim or request for relief that could be construed to allege a violation of FDA regulations. As such, the plaintiffs do not set forth a parallel claim that might entitle them to relief."

The court remanded the case with instructions to dismiss on the merits, reversing the trial court's conclusion that preemption under *Riegel* deprives a state court of subject-matter jurisdiction. The appellate court also clarified that preemption under the Medical Device Amendments presents a choice-of-law question as opposed to a choice between a state or federal forum.

SHB Partner [Andy Carpenter](#) argued the appeal.