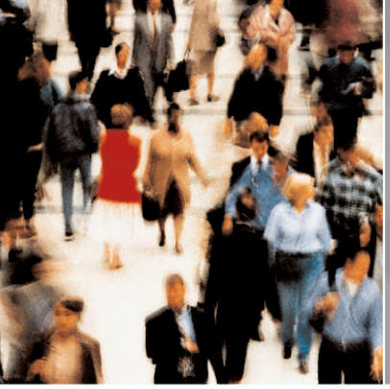

Class Action Alert
Recent developments in class action law

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Federal court denies *Neurontin* class certification

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Adding another weapon to the arsenal of the class action defense bar, a federal judge in Massachusetts refused on May 13 to certify a nationwide class of consumers and third-party payors (TPPs) who paid for prescriptions of the drug Neurontin for treatment of off-label uses, finding that individual differences in the reactions of plaintiffs to the defendants' purported off-label marketing campaigns predominated over other common issues. Judge Patti B. Saris held that plaintiffs' econometric model failed to prove that questions common to the proposed class would predominate over those that would need to be resolved on an individualized basis (in re *Neurontin Marketing, Sales Practices and Products Liability Litigation*, 04-10981 (D. Mass. May 13, 2009)).

Background

The Food and Drug Administration (FDA) approved Neurontin in 1993 for use as an "adjunctive therapy" in treatment of patients with epilepsy. Neurontin was also approved in 2002 for management of pain resulting from certain types of nerve damage. The plaintiffs allege that, in addition to these approved uses, the drug's manufacturers and distributors, Warner-Lambert and Pfizer (which acquired Warner-Lambert after the allegedly wrongful acts occurred), sought to generate additional revenues by marketing Neurontin for the treatment of several "off-label" conditions. Plaintiffs also alleged that these marketing campaigns were conducted despite defendants' awareness that Neurontin was ineffective in treating the off-label conditions. The alleged off-label marketing strategy consisted of multiple elements, but the court's analysis focused primarily on the practice of "detailing," or sending company representatives to doctor's offices to promote various uses of the drug.

Plaintiffs brought claims under the federal RICO statute and the New Jersey Consumer Fraud Act (NJCFA), because Warner-Lambert was based in New Jersey, as well as common-law claims for fraud and unjust enrichment., seeking only economic damages. They initially sought certification of a nationwide class of consumers and TPPs that had purchased Neurontin for off-label uses.

Central to plaintiffs' efforts to obtain certification of a nationwide class was the assertion that, through their off-label marketing activities, defendants had perpetrated a "fraud on the market" that caused physicians to write—and TPPs to approve and pay for—more prescriptions for off-label uses of Neurontin than they otherwise would have. In 2007, the court denied plaintiffs' initial certification motion, holding they had failed to satisfy the commonality, numerosity, typicality, and predominance requirements of Federal Rule of Civil Procedure 23. Plaintiffs submitted a second motion in an effort to address the court's concerns.

Predominance

In their renewed motion, the plaintiffs divided their original nationwide class into several subclasses based upon the different off-label usages that they alleged. Based upon this, Judge Saris found that they had met their burden with respect to Rule 23's commonality, numerosity and typicality requirements. However, she also found that plaintiffs had again failed to establish that questions of law or fact common to class members predominated over any questions affecting only individual members of the class.

Plaintiffs attempted to establish causation through an econometric analysis that supposedly estimated the total number of prescriptions in each subclass likely caused by the allegedly fraudulent off-label marketing. The court noted that, even at face value, this analysis alone satisfied only half of the plaintiffs' burden, because the analysis could not identify which doctors prescribed Neurontin as a result of the allegedly fraudulent marketing activity. The court recognized, based upon the evidence before it, that a significant number of doctors prescribed Neurontin by exercising their own independent medical judgment. Plaintiffs' econometric expert, however, determined that two subclasses consisted almost entirely of prescriptions written as a result of the alleged fraud. Because this meant that individualized inquiries into why each individual prescription in these subclasses was written would not be necessary, it appeared that plaintiffs might have met their burden with respect to these subclasses.

However, the court took issue with the methodology by which plaintiffs' expert reached this conclusion. In particular, Judge Saris focused on the fact that virtually none of the physicians who prescribed Neurontin for off-label use by the named subclass representatives had actually been subjected to the allegedly fraudulent off-label "detailing" that was the principal causative factor analyzed by plaintiffs' expert. In fact, these physicians testified in their depositions that their decisions to prescribe Neurontin to the subclass representatives resulted from a wide array of influences having nothing to do with the alleged fraudulent marketing campaign. This testimony by the prescribing physicians for the subclass representatives was completely contrary to the expert's principal assumption, and showed that the model failed to establish the required nexus between plaintiffs' damages and defendants' acts (i.e., causation). Therefore, plaintiffs could not carry their burden for any of the consumer subclasses. In other words, the model failed to show that it could be reliably substituted for direct evidence of reliance, which is a critical element of any claim based on misrepresentation.

With respect to certification of the subclass of TPPs, Judge Saris observed that there were substantial differences in the approach each TPP adopted to the development and implementation of the "formularies" used to outline which drugs would be covered and how they should be prescribed. Formularies of the TPPs in the proposed class addressed the off-label uses of Neurontin in many different ways. This made it unlikely that each TPP's decisions concerning the drug would have been influenced in the same way by the marketing campaign. The court held that, to establish causation in the face of these differences, the plaintiff TPPs would need to demonstrate that the allegedly fraudulent off-label marketing efforts caused each of them to make different formulary decisions for off-label uses of Neurontin than they otherwise would have. Instead, plaintiffs offered only generalized contentions that the TPPs' formulary decisions were "undoubtedly influenced by the same pervasive disinformation campaign." Accordingly, the court held this form of common proof inadequate to establish that common issues of causation predominated over individual ones, and denied the motion for class certification.

Persuasive case law

In explaining its reasoning, the court highlighted a number of recent decisions that have limited the circumstances under which econometric models like the one at issue may be used as a substitute for direct proof of causation. First, Judge Saris noted that the New Jersey Supreme Court had, in its recent *Vioxx* ruling (*Int'l Union of Operating Eng'rs Local No. 68 Welfare Fund v. Merck & Co., Inc.*, 192 N.J. 372 (2007)), effectively foreclosed establishment of causation for certification of such claims under the NJCFA based on a single expert report. This forced the denial of certification for claims brought under that statute. She also pointed to several federal decisions that supported her reluctance to permit a presumption of reliance/causation unless plaintiffs were able to establish that causation was a certainty for essentially all class members (*McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008); in re *St. Jude Medical Inc. Silzone Heart Valve Products Litigation*, 522 F.3d 836 (8th Cir. 2008); in re *TJX Cos. Retail Security Breach Litigation*, 246 F.R.D. 389 (D. Mass. 2008)). These cases all stand for the proposition that defendants faced with an indirect form of proof, such as the one in this case, cannot be denied the opportunity to present direct evidence that a particular decision-maker was not influenced by a challenged marketing campaign. Where this opportunity is available, it effectively opens the door to individualized inquiries about the circumstances of all class members, rendering certification improper under Rule 23. Furthermore, recent First Circuit case law (in re *New Motor Vehicles Canadian Export Antitrust Litigation*, 522 F.3d 6 (1st Cir. 2008)) required her to engage in a "more searching inquiry" into whether plaintiffs would be able to prove key elements of their theory of causation at trial at all—a level of scrutiny that had previously been postponed until a *Daubert* hearing.

Where, as here, class certification turns on the issue of reliance, a potent defense to the predominance of common issues exists and should be employed. These developments in the case law, including the *Neurontin* decision itself, will likely prove equally persuasive in the future to other federal courts considering certification of proposed plaintiff classes in cases involving allegedly unlawful marketing practices.

Click **here** to view the entire decision.

We welcome your questions and comments. If you need assistance on any matter, please e-mail or call:

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