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United States: This Class Action Lacks Class
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Key Points:

- The "Fraud On The Market" Theory Has Extremely Limited Application.
- Statistical Evidence Cannot Replace Traditional Proofs In A Class Action Claim Involving Misrepresentation.
- A Class Action Can Be Decertified Based On New Evidence Or Changed Circumstances.

In January 2010, the Pennsylvania Superior Court took the relatively bold step of affirming the trial court and decertifying a class action in the case of *Clark v. Pfizer, Inc.,* 2010 PA Super 6 (January 19, 2010). The case involved a class action instituted by a group of patients who had been prescribed the drug Neurontin for "off-label" use.

Neurontin is manufactured by Pfizer, Inc. and Warner-Lambert Company, LLC. These entities obtained FDA approval for use of Neurontin for treatment of partial seizures in adults in 1993. Further approval for treatment of pain associated with herpes zoster rash outbreaks was granted in 2002. These are the ***only*** two FDA approved uses for the drug. Although these are the only two approved uses, federal law does not prohibit doctors from prescribing the drug for any condition they deem appropriate, even though the drug has not been approved for that use. This is known as "off label" prescribing. However, manufacturers are explicitly prohibited from promoting off-label uses for FDA approved medication.

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The plaintiffs in this class alleged that beginning in 1995, the manufacturers impermissibly began to promote Neurontin to physicians for off label uses. The plaintiffs alleged that the manufacturers engaged in a marketing scheme to convince physicians that Neurontin was effective in the treatment of psychiatric disorders, pain syndromes, reflex sympathetic dystrophy, restless leg syndrome, fibromyalgia, anxiety disorder and migraine headaches. Interestingly, the manufacturers pled guilty to two counts of unlawful marketing in violation of the Food, Drug and Cosmetics Act and paid a $240 million fine. However, there is no private cause of action for those violations, and, thus, the plaintiffs brought common law claims of misrepresentation, negligence, negligence *per se* and breach of express warranty.

Class certification was granted in June 2007 based on the requirements, among others, that: (1) there are questions of law or fact common to the class and (2) the claims or defenses of the representative parties are typical of the claims or defenses of the class. The plaintiffs alleged that all of the claims arose out of the unlawful marketing undertaken by the manufacturer and that, but for that marketing, the physicians never would have prescribed Neurontin for off label uses. The plaintiffs' claims were based on a "fraud on the market" theory, entirely supported by the expert testimony of a single physician who had made statistical determinations that physicians had relied on the unlawful marketing by the manufacturers to prescribe Neurontin for off label uses.

Initially, the Pennsylvania Superior Court, much like its counterpart in Massachusetts, found that the fraud on the market theory is an extremely limited doctrine, only applicable to securities cases and price inflation cases. In those types of cases, statistical analysis is commonly used by plaintiffs to meet their burden of proof in class action. This statistical analysis is used to show that plaintiffs would never have purchased securities but for the incorrect information which was made public by the sellers of the securities.

Secondly, the Pennsylvania Superior Court held that the fraud on the market theory has no application to cases such as this one in which the claims were those of common law misrepresentation, negligence and breach of warranty in the prescribing of medication. That being the case, the plaintiffs could no longer rely on the statistical evidence proffered by their medical expert that Neurontin would not have been prescribed for off label uses but for the unlawful activities of the manufacturers. Instead, the plaintiffs would be held to traditional forms of proof for their claims.

Most importantly, the plaintiffs in this case took the position that the claims of the plaintiffs in the class all involved common questions of fact and that the representative plaintiffs' claims were typical of all class members. Enterprising defense counsel undertook discovery of many of the physicians who had prescribed the Neurontin and established that these doctors had not relied on any information from the manufacturers to prescribe the drug for off label uses. Therefore, the claims of the class were not common, and the claims of the representative plaintiffs were not typical of the class, and the class should be decertified. The plaintiffs argued vociferously that it was too late to decertify as substantive rulings had already been made. The Superior Court clearly states in its opinion that if "changed circumstances" arise, it is proper to decertify the class. In this case, thanks to the work of defense counsel, it was proven that many of the plaintiffs' physicians had not relied on unlawful marketing to prescribe Neurontin for off label uses and, therefore, the circumstances had changed from the time of class certification and that it was proper to decertify. Although the class was decertified, the court held that the plaintiffs could still pursue their individual claims of misrepresentation, negligence, negligence *per se* and breach of express contract to the extent they were able.

This is an excellent example of intelligent work by defense counsel to adduce the evidence necessary to decertify the class, thus resulting in far fewer claims, each of which will have to be proven individually, and significantly reducing any potential exposure to the defendants.

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