

LIFE SCIENCES News Concerning Recent Developments Impacting the Life Sciences Industry



## THE DIFFICULTY IN CERTIFYING A CLASS ACTION AGAINST DRUG COMPANIES

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hree cases decided over the past few months demonstrate the difficulty with certifying class actions by third-party payors (TPPs) against drug companies.

First, in August, the U.S. District Court for the Southern District of Illinois dismissed a class action brought by TPPs against the manufacturers of Yaz, a contraceptive. (In Re: Yasmin and Yaz Marketing, Sales Practices and Products Liability Litigation, 3:09-cv-20071-DRH-PRM, August 5, 2010). Then, in early September, the U.S. Court of Appeals for the Second Circuit reversed a class certification of TTPs who filed suit against the manufacturers of Zyprexa, a drug used to treat schizophrenia and bipolar disorder. (UFCW Local 1776 and Participating Health and Welfare Fund v. Eli Lilly and Company, 2010 WL 3516183 (2d Cir. Sept. 10, 2010)). In both of these cases, the TPPs alleged that they overpaid for the drugs as a result of the defendants' misrepresentations about each drug's safety and effectiveness. Further, both courts refused to certify the class action because of the plaintiffs' inability to prove causation; that is, the TPPs failed to show that the manufacturers of the drug were the cause of their alleged injury.

In a similar case in early September, the U.S. District Court for the Eastern District of Pennsylvania refused to certify a class action brought by individual consumers and TPPs against GlaxoSmithKline. (*Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 2010 U.S. Dist. Lexis 93520 (E.D. Pa. Sept. 8, 2010)). In that case, the court dismissed the action on the basis of the plaintiffs' failure to show common proof to establish their injuries and damages from the manufacturers' sham patent litigation scheme to maintain a monopoly over sales of its drug, Wellbutrin.

The dismissal of these three recent class certifications is indicative of the trend that class actions brought by TPPs against drug companies will continue to fail because of the attenuated link between causation and injury. Federal Rule 23(a) sets forth the requirements for a class action. Once those conditions are satisfied, the rule provides that common issues of law or fact must predominate over individual issues. Specifically with reference to class actions against drug companies, that requirement - that common issues of law or fact predominate over individual issues becomes a tough hurdle for the class to overcome because there are numerous plaintiff-specific variations at the root of the injury.

In the Zyprexa case, the plaintiffs alleged that Eli Lilly engaged in misrepresentations about Zyprexa's off-label use and effectiveness. In 2008, the U.S. District Court for the Eastern District of New York certified a class action of insurance companies and TPPs against Lilly and denied Lilly's motion for summary judgment. On September 10, 2010, however, the 2nd Circuit reversed the certification of the class action, focusing on the plaintiffs' inability to prove that their reliance on the alleged misrepresentations caused their injury. The court also remanded the case for further consideration of the motion for summary judgment.

The 2nd Circuit emphasized that plaintiffs in these types of class actions need to establish the elements of their claims through generalized, not individualized, proof. Specifically, plaintiffs must demonstrate through generalized proof that their injury was caused by physicians relying on Lilly's misrepresentations about Zyprexa and then prescribing that drug for their patients. The plaintiffs were unable to satisfy that requirement because there were too many independent actions that occurred between the cause (alleged misinformation by Eli Lilly) and the injury (overpayment by the TPPs). The court held that the chain of causation "is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof." Because information from Lilly is not the only factor considered by physicians when making prescription decisions, the alleged causal link is too attenuated to sustain a cause of action for misrepresentation.

In the Yaz case, a group of TPPs attempted to certify a class action against the drug manufacturers and marketers claiming overpayment due to fraudulent misrepresentations. Again, the plaintiffs had difficulty overcoming the proximate cause hurdle and the U.S. District Court for the Southern District of Illinois dismissed the class action suit. The court stated, "multiple steps separate the alleged wrongful conduct (the fraudulent advertising campaign and/or the alleged bribery) and the alleged injuries (paying 'too much' for 'too many'Yaz prescriptions), including patient preference, the independent judgment of the prescribing physician, and the reimbursement decision rendered by the third-party payor and its benefits manager." Therefore, the number of independent actions and other variables that occur between the alleged wrongful conduct and the claimed injury prohibits the plaintiffs from achieving a causal connection that implicates the defendants.

In the Wellbutrin case, hundreds of thousands of individual consumers and over 20,000 TPPs alleged that GlaxoSmithKline (GSK) entered into a scheme to maintain higher prices for its drug. Judge Stengel of the U.S. District Court for the Eastern District of Pennsylvania found that the plaintiffs were unable to demonstrate that each member of the class suffered an injury when GSK allegedly delayed the market arrival of its generic form of Wellbutrin. Similar to the Zyprexa and Yaz cases, the court dismissed the class action because the plaintiffs failed to set forth common proof to establish their damages. Thus, this case reflects the problems with class certifications where plaintiffs cannot prove that each member suffered an injury caused by the defendant drug manufacturer.

Although each is slightly different, these three decisions indicate the difficulty of certifying class actions against defendant drug manufacturers because of the proof of reliance and injury, and the causation requirements demanded by the courts. With all the factors bearing on a physician's decision to prescribe a certain drug for a patient, demonstrating that the drug company's alleged misinformation proved to be the deciding factor seems nearly impossible. Further, the courts require every member of the class to suffer an injury caused by the defendant drug manufacturer that can be established through common proof. Plaintiffs can and will keep trying to file class actions against drug companies, but until they can demonstrate a direct causal link between the drug company's actions and the injury suffered, courts will continue to dismiss the cases.

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