Legal Backgrounder

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COURTS REJECT TWO NATIONWIDE CONSUMER-FRAUD CLASS ACTIONS

by

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The plaintiffs' bar has increasingly used nationwide, consumer-fraud class actions to target pharmaceutical companies. Two recent court decisions – one by a federal trial court, another by a state Supreme Court – have rejected ambitious attempts to certify massive class actions based on allegations of improper marketing and promotion of prescription drugs.

Pharmaceutical Companies Are Facing Challenges on Many Fronts. Pharmaceutical companies are increasingly exposed to liability on multiple fronts. Mass-tort product-liability litigation continues unabated, often spurred by reports of newly found risks about which plaintiffs claim drug companies should have warned. The federal government and Congress have become more aggressive in investigating pharmaceutical marketing and promotion. Indeed, federal False Claims Act and Medicare/Medicaid fraud charges have, in recent years, led to settlements requiring pharmaceutical companies to pay huge sums – sometimes hundreds of millions of dollars. And states are increasingly adopting their own false claims acts and pursuing their own investigations of pharmaceutical marketing and promotion.[1]

For instance, the first highly publicized prosecution under the False Claims Act resulted in a $430 million settlement in which Warner-Lambert resolved charges that the company fraudulently and illegally promoted the prescription drug Neurontin for unapproved uses ("off-label").[2] Although FDA approved Neurontin as an adjunctive anti-seizure therapy for epilepsy patients, Warner-Lambert reportedly marketed the drug for several unapproved uses, such as for treatment of bipolar disorder, pain disorders, Lou Gehrig's Disease (ALS),

[1]The Deficit Reduction Act of 2005 provided financial incentives for states to enact laws that mirror key provisions of the federal False Claims Act. *See* 42 U.S.C. § 1396h, as amended; "Publication of OIG's Guidelines for Evaluating State False Claims Acts," 71 Fed. Reg. 48552 (Aug. 21, 2006).

[2]The federal charges included counts of violating the Food, Drug & Cosmetic Act by misbranding Neurontin and violating the federal False Claims Act. The state charges included claims of losses to state Medicaid programs, and other civil liabilities. *See* Department of Justice Press Release, *Warner-Lambert to Pay $430 Million to Resolve Criminal & Civil Health Care Liability Relating to Off-Label Promotion*, May 13, 2004 ("DOJ Press Release"), www.usdoj.gov/opa/pr/2004/May/04_civ_322.htm.

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attention-deficit disorder, migraines, and restless leg syndrome.

With hundreds of millions of dollars in play, it is no surprise that enterprising plaintiffs' lawyers are attempting to develop ways to parlay improper-promotion claims into private recoveries.

The Allure of Consumer-Fraud Class Actions. One vehicle the plaintiffs' bar has embraced is the nationwide class action asserting state-law consumer-fraud claims.[3] These suits do not assert product-liability claims premised on personal-injury allegations. Rather, they seek to recover alleged economic losses predicated on amounts paid for prescription drugs supposedly as a result of improper marketing and promotion.

Consumer-fraud statutes typically impose less stringent burdens of proof than those required for traditional product liability or common law fraud claims, making them attractive vehicles for class-action claims. Consumer-fraud statutes generally authorize multiple damages (*e.g.*, treble damages), attorneys' fees, and costs. Of course, in the context of a nationwide class action, potential damages grow exponentially – making the class-action device all the more tempting to entrepreneurial plaintiffs' attorneys. And plaintiffs' attorneys often attempt to increase the odds of success by filing a consumer-fraud class action in a state with a particularly consumer-friendly statute (*e.g.*, New Jersey), or requesting a court to apply the consumer-friendly law of another state.

In re Neurontin. In August 2007, Warner-Lambert and its parent, Pfizer, defeated a nationwide, consumer-fraud class action filed in federal court in Massachusetts. *See In re Neurontin Mktg. and Sale Practices Litig.*, 2007 U.S. Dist. Lexis 63898 (D. Mass. Aug. 29, 2007). In that case, plaintiffs sought to certify – under, *inter alia,* the New Jersey Consumer Fraud Act (NJCFA) – a nationwide class of all consumers and third-party payors (health insurers, HMOs, *etc*.) who purchased or paid for the prescription drug Neurontin for unapproved uses. Plaintiffs alleged that they suffered economic losses as a result of a "fraudulent scheme to promote and sell the drug Neurontin for 'off-label' conditions."[4]

The *In re Neurontin* court detailed plaintiffs' factual contentions concerning marketing and promotional strategies utilized by Parke-Davis (a division of Warner-Lambert) – the same strategies that led to the $430 million settlement with the Department of Justice.[5] Plaintiffs claimed that, as a result of Parke-Davis' extensive, off-label promotion, "an estimated ninety percent of all Neurontin prescriptions were for off-label uses."[6]

In addressing the proposed consumer subclass, the *In re Neurontin* court appeared more than willing to accept plaintiffs' efforts to meet class certification requirements. Nevertheless, class certification ultimately foundered on plaintiffs' inability to identify which consumer class members suffered a loss caused by defendants' alleged fraud. Plaintiffs intended to present common proofs based on expert testimony relying on an "econometric analysis to distill, at the aggregate level, off-label prescriptions caused by defendants' marketing activities from those that plaintiffs concede would have been written regardless of any promotional activities on defendants' part."[7] But the court rejected this, concluding that plaintiffs would be unable "to identify which prescribing physicians were exposed to defendants' fraudulent statements" – noting that physicians' prescribing

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[3] *See Private Consumer Protection Lawsuit Abuse: When Claims Are Driven By Profit-driven Lawyers And Interest Group Agendas, Not The Benefit Of Consumers*, American Tort Reform Foundation, at 16-19 ((2006), www.atra.org/reports/consumers/consumer_protection.pdf.

[4] *Id*. at *10. An off-label use is one for which FDA has not approved a drug. Although drug companies may not promote a drug for unapproved uses, physicians are free to prescribe drugs off-label – and off-label use "is an accepted and necessary corollary of the FDA's mission to regulate [drugs and medical devices] without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001); *see also Washington Legal Found. v. Henney*, 202 F.3d 331 (D.C. Cir. 2000).

[5] Parke-Davis' promotional strategies were criticized in an *Annals of Internal Medicine* article examining the "structure and methods of pharmaceutical promotion." *See* Steinman, MA, *et al.*, "Narrative Review: The Promotion of Gabepentin: An Analysis of Internal Industry Documents," *Annals of Internal Medicine*, Vol. 145, No. 4 (Aug. 15, 2006).

[6] *In re Neurontin,* 2007 U.S. Dist. Lexis 63898 at *42-43.

[7] *Id*. at *65-66.

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decisions could not possibly have been caused by statements they never heard.[8]

In other words, the court rejected plaintiffs' aggregate model because it could not determine "*which* consumer class members' Neurontin prescriptions were caused by defendants' alleged fraud – and who therefore have a cognizable injury – and which would have occurred even in the absence of the fraud."[9] The court explained:

> While [plaintiffs] may be able to statistically determine on a national basis that the majority of prescriptions were written as a result of fraudulent marketing activity, there is no way of identifying which doctors prescribed Neurontin based on this promotion as opposed to lawful off-label prescribing by a doctor who is exercising his own medical judgment.[10]

Although the court primarily focused its analysis on the proposed consumer subclass, it also commented on proof problems confronting the proposed third-party payor ("TPP") subclass. Plaintiffs' proposed aggregate model would also be problematic in this context "if TPPs are unable to distinguish between payments for on- and off-label prescriptions, or among the [drug's] indications."[11]

In sum, the *In re Neurontin* court denied class certification (without prejudice) in light of plaintiffs' fundamental inability to identify the members of the consumer subclass, and prove what amounts paid by TPPs were a result of fraud.

Operating Engineers. Another recent case in which plaintiffs attempted, unsuccessfully, to prove class-wide claims based on expert testimony using an econometric analysis was *International Union of Operating Engineers Local No. 68 Welfare Fund v. Merck & Co.*, 192 N.J. 372 (2007) (*per curiam*).

In *Operating Engineers*, the New Jersey Supreme Court unanimously rejected a nationwide class action on behalf of TPPs to recover alleged overpayments for Merck's anti-inflammatory drug, Vioxx, under the New Jersey Consumer Fraud Act. The proposed class representative was a union-employer trust fund that provided prescription drug coverage for its members and beneficiaries.[12] The trust fund asserted that Merck's allegedly "wide-ranging fraudulent marketing scheme" induced TPPs to incur costs for Vioxx they would not have otherwise paid.[13] The theory was that, absent the purported "consumer" fraud, TPPs would not have included Vioxx on their formularies of drugs approved for reimbursement under their coverage plans – or would have given Vioxx less favorable formulary status at lower cost to TPPs.

A wide variety of TPPs would have been included in the proposed nationwide class, and each reached its own decisions concerning Vioxx's formulary status. TPPs typically rely on Prescription Benefit Managers that, in turn, utilize specialized committees of health professionals (Pharmacy and Therapeutics Committees) to develop and maintain formularies for coverage plans. TPPs' formulary processes and structures vary greatly; some formularies essentially include all FDA-approved drugs, whereas others are limited to certain drugs and may assign drugs to tiers with different coverage levels.

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[8] *Id*. at *71.

[9] *Id*. at *73.

[10] *Id*. at *78-79. Notably, the court suggested that plaintiffs could try to overcome the flaw in their theory: "If only a *de minimis* number of doctors prescribed Neurontin for an off-label condition, and then off-label prescriptions skyrocketed after a fraudulent campaign for that indication (*i.e*., migraines or bipolar), the Court will consider statistical proof as sufficient to demonstrate that most purchasers in that period were injured. At present, however, the record does not contain such a proffer." *Id*. at *83. It is unclear, however, how establishing that "most" purchasers sustained economic loss as a result of fraudulent promotion would be sufficient.

[11] *Id*. at 83-84.

[12] The trust fund's benefits plan is administered by Horizon Blue Cross/Blue Shield of New Jersey.

[13] *Operating Engineers*, 192 N.J. at 377.

In July 2005, the trial court certified a nationwide class action and concluded that the NJCFA should govern all class members' claims. The court reasoned that no other state had a stronger consumer-protection statute than New Jersey and, therefore, no state had a stronger interest in having its law apply to the dispute. Class certification meant Merck was potentially subject to huge liability for three-times the class members' alleged overpayments for Vioxx, attorneys' fees, and costs of suit. The trial court's ruling – later affirmed by New Jersey's intermediate appellate court – was criticized for resolving complex choice-of-law issues in an overly simplistic manner, and vastly expanding manufacturers' exposure to liability.

The New Jersey Supreme Court reversed, holding that common questions of law or fact did not predominate and that a class action was not superior to other available methods for adjudicating the claims. Interestingly, although the parties and many observers focused primarily on the choice-of-law issues, the Supreme Court's decision did not turn on those questions.

First, the *Operating Engineers* Court rejected the theory that plaintiffs could prove damages on a class-wide basis through expert testimony. To establish a claim under the NJCFA, a plaintiff must prove (i) unlawful conduct, (ii) an "ascertainable loss," and (iii) a causal relationship between the conduct and the loss. Because each TPP "made individualized decisions concerning the benefits that would be available to its members for whom Vioxx was prescribed," ascertainable loss could not be established generally for all class members. As such, the Supreme Court concluded that common questions of fact did *not* predominate.

In analyzing predominance issues, the Court also rebuffed the suggestion that plaintiffs could prove ascertainable loss on a class-wide basis by expert testimony asserting that Merck's improper marketing efforts resulted in TPPs' paying higher prices for Vioxx than they would otherwise have paid.[14] The Court held that the proposed approach amounted to nothing more than an impermissible fraud-on-the-market theory – which the Court has previously rejected as improper (other than in federal securities-fraud litigation).

In short, the New Jersey Supreme Court soundly rejected the argument that ascertainable loss under the NJCFA may be proven statistically. This is all the more significant because many plaintiffs attempt to invoke the NJCFA in cases filed across the country. *See*, *e.g.*, *In re Neurontin*, 2007 U.S. Dist. Lexis 63898 (discussed above).

Second, the *Operating Engineers* Court pointed out that TPPs "are well-organized institutional entities with considerable resources" such that there is "no disparity in bargaining power" between TPPs and drug manufacturers.[15] Moreover, the Court noted that the alleged losses for each member of the proposed class may be large sums of money, thus alleviating any concern that meritorious claims would not be pursued absent class certification. Thus, the Court found no ground on which to conclude that the proposed class action was superior to any other forum for relief (under the superiority test).[16] The New Jersey Supreme Court's unanimous decision in *Operating Engineers* is a key victory in stemming the growing tide of ever-expanding, novel liability theories that drug companies face.

Conclusion. State consumer-fraud statutes remain extremely attractive to the plaintiffs' bar, particularly when a significant number of similar claims can potentially be aggregated and certified as a class action. Thus, despite the recent victories in *In re Neurontin* and *Operating Engineers*, it is highly unlikely that the plaintiffs' bar will abandon consumer-fraud class actions. Rather, we can expect plaintiffs' attorneys will learn from defeat and will hone their strategies for achieving class certification in cases going forward.

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[14] *Id*. at 391-92.

[15] One question the *International Union* Court did not resolve is whether a sophisticated, commercial entity, such as a TPP, could and should be considered a "consumer" that may invoke the protections of the NJCFA in the first place.

[16] *Id*. at 393-94.