

Class Actions Over Off-Label Prescriptions

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The problems with class actions against pharmaceutical companies over off-label prescriptions stem largely from the problems with class actions in general. As a number of critics have noted, some judges have permitted the procedural convenience of the class action to trump the substantive rights of defendants.¹ Such improper certifications of class actions, by creating aggregate litigation in which individualized issues predominate, often prevent defendants from adequately defending themselves, and create settlement pressure on defendants where none would otherwise exist.² Because of the inordinate sums at issue, the expense of defending cases, and the fact that lengthy civil trials over complex issues cannot be said to be 100% accurate, trial lawyers can usually induce settlement of all but the most meritless cases so long as they are willing to settle for pennies on the dollar of the ostensible damages claims. With billions of dollars at stake in some cases, it is often economically rational to agree to settle for tens of millions of dollars even if a defendant believes that it is in the right and is likely to be vindicated at trial.

This leads to an *ex ante* issue where the incentive of plaintiffs' attorneys bringing class actions is less to find meritorious cases, but to find cases (and jurisdictions)³ where there will be class certification and a survival of a summary judgment motion. To the extent such strike suits serve the public good, it is purely a function of serendipity, rather than incentives that are other than perverse.

This serendipity is entirely absent when it comes to class actions alleging consumer harm from technical violations of Food & Drug Administration off-label marketing regulations. If the marketing is fraudulent, then it should make no difference to the defendant's culpability whether the end-use was on-label or off-label.⁴ If the marketing is truthful, then plaintiffs

¹ See, e.g., Richard A. Epstein, *Class Actions: Aggregation, Amplification, and Distortion*, 2003 U. CHI. LEGAL F. 475, 477–78 (2003). Accord Theodore H. Frank, *A Taxonomy of Obesity Litigation*, 28 U. ARK. LITTLE ROCK L. REV. 427, 439 (2006) (“[S]ome judges let the tail wag the dog; class actions are regularly certified when the individualized issues predominate, simply by structuring a trial plan in which the individualized issues are not tried at all.”); Mark Moller, *Controlling Unconstitutional Class Actions: A Blueprint for Future Lawsuit Reform*, POL’Y ANALYSIS, June 27, 2005, at 2, available at http://www.cato.org/pub_display.php?pub_id=3827 (“[A] second look at the class action procedure underscores that judges who manage those actions often change the law, arbitrarily, for the benefit of plaintiffs.”).

² See, e.g., Epstein, *supra* note 1; *In re Bridgestone/Firestone, Inc.*, 288 F.3d 1012, 1015–16 (7th Cir. 2002); Szabo v. Bridgeport Machines, Inc., 249 F.3d 672, 675 (7th Cir. 2001); *In re Rhone-Poulenc Rorer Inc.*, 51 F.3d 1293, 1299–1300 (7th Cir. 1995); HENRY J. FRIENDLY, FEDERAL JURISDICTION: A GENERAL VIEW 119–20 (1973); Frank, *supra* note 1 at 440. See also Milton Handler, *The Shift from Substantive to Procedural Innovations in Antitrust Suits—the Twenty-Third Annual Antitrust Review*, 71 COLUM. L. REV. 1, 8–9 (1971) (“Any device which is workable only because it utilizes the threat of unmanageable and expensive litigation to compel settlement is not a rule of procedure—it is a form of legalized blackmail.”).

³ Linda S. Mullenix, *Abandoning the Federal Class Action Ship: Is There Smoother Sailing for Class Actions in Gulf Waters?*, 74 TUL. L. REV. 1709, 1715 (2000); Ted Frank, *The Class Action Fairness Act Two Years Later*, LIABILITY OUTLOOK, Mar. 2007.

⁴ Of course, a class action over fraudulent marketing may have entirely different problems of its own. MICHAEL S. GREVE, HARM-LESS LAWSUITS?: WHAT’S WRONG WITH CONSUMER CLASS ACTIONS (2005); Victor E. Schwartz & Cary Silverman, *Common-Sense Construction of Consumer Protection Acts*, 70 KANS. L. REV. 1 (2006).

can establish harm only through attenuated theories of causation or damages, and the lawsuits raise First Amendment problems. Private class actions based on technical violations of off-label marketing regulations thus present particular concern about the abuse of the class action mechanism.

Prohias v. Pfizer, a suit brought by Hagens Berman and other plaintiffs' firms, would have been an especially problematic complaint if fully honored by the federal district court.⁵ Pfizer's ads for its cholesterol-regulating statin Lipitor mentioned that cholesterol was a risk factor for heart disease. Plaintiffs sought to certify two classes of all elderly patients and all women who had been prescribed Lipitor for cholesterol regulation, but did not have preexisting heart disease or diabetes. Their allegation, mirroring a petition to the federal National Cholesterol Education Program by the advocacy group Center for Science in the Public Interest,⁶ was not that Lipitor did not lower their cholesterol, nor that they suffered any personal injury from Lipitor use, but that "there is no proven health benefit to lowering cholesterol" for class members, and that they were entitled to their money back. Plaintiffs—who originally filed in Massachusetts and Pennsylvania before re-filing in Florida—alleged three causes of action: violation of consumer protection statutes in 46 jurisdictions; unjust enrichment; and negligent misrepresentation. Because of procedural shenanigans by the plaintiffs in voluntarily dismissing and amending complaints, Pfizer was forced to file four separate motions to dismiss before it could have one heard by the court.

Prohias is especially interesting because the FDA approved a label change in July 2004 for Lipitor for the prevention of cardiovascular disease "[i]n adult patients without clinically evident coronary heart disease but with multiple risk factors," to "[r]educe the risk of myocardial infarction," and "[r]educe the risk for revascularization procedures and angina." The off-label uses were now approved on-label uses because Pfizer had taken the trouble to go through the approval process, yet they were still being sued, with plaintiffs even seeking an injunction against promoting the new on-label use. Can litigants successfully require the courts to find liability for a use complying with an FDA-approved label? The Vermont Supreme Court said as much in *Levine v. Wyeth*, a product liability case currently pending before the U.S. Supreme Court for argument this October where the manufacturer was held liable for a known side effect from an approved use because of the failure to modify the label to instruct doctors not to engage in the approved use. Such second-guessing that would "frustrate the accomplishment of a federal objective" seems especially appropriate for federal preemption.⁷ The way to object to FDA decision-making is through a Citizen Petition⁸ and then on appeal through the Administrative Procedure Act,⁹ not through a

⁵ *Prohias v. Pfizer, Inc.*, 490 F. Supp. 2d 1298 (S.D. Fla. 2007); *Prohias v. Pfizer, Inc.*, 495 F. Supp. 2d 1329 (S.D. Fla. 2007). See James Beck and Mark Herrmann, *Striking Back at Strike Suits*, <http://druganddevicelaw.blogspot.com/2007/06/striking-back-at-strike-suits.html> (Jun. 27, 2007) (last accessed ____, 2008).

⁶ The government rejected the petition. Letter from Barbara Alving to Merrill Goozner, October 22, 2004, available at <http://www.nhlbi.nih.gov/guidelines/cholesterol/response.htm> (last accessed ____, 2008).

⁷ *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 873 (2000). See also *Dohwal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1, 14 (Cal. 2004).

⁸ 21 C.F.R. § 10.30.

collateral attack on the manufacturer that complies with the rulings. The *Probias* court held preempted the claims made after the label change, but permitted the false advertising claims from before the label change was made.¹⁰

Even beyond the underlying motion to dismiss, there is a causation problem. Pfizer's ads also included the caveat that the drug "has not been shown to prevent heart disease or heart attacks." At least some plaintiffs—and their learned intermediary doctors—must have known that, but decided to take Lipitor anyway. They cannot be said to have been misled, but that causation determination is inherently individualized. Indeed, of the named plaintiffs, one of the third-party payors continued to offer Lipitor to its members and two of the end-users continued to take Lipitor, showing that they did continue to believe there was health benefits to regulating cholesterol even after their attorneys had brought suit. These plaintiffs were dismissed from the case, but their absence of a cause of action means that class certification is inappropriate.

The learned intermediary doctrine should also block most consumer fraud claims involving revelation of scientific data. Prescription drugs are only available to the public after doctors have decided that they are appropriate for the treatment of particular patients. "When the purchase of the product is recommended or prescribed by an intermediary who is a professional, the adequacy of the instructions must be judged in relationship to that professional."¹¹ This further attenuates any alleged injury: the advertising allegedly caused a physician to choose to prescribe a drug that the patient then purchased. When third-party payers are plaintiffs, seeking recovery for drugs they purchased for their beneficiaries, there is yet another intermediate stage. Each prescribing decision is individualized, preventing common proof of claims under a class action. If proximate cause is to be honored, courts must reject liability.

That leaves the question how plaintiffs could possibly have been damaged when they allege no personal injury or failure of the drug to work as prescribed. One *Probias* theory of damages was especially attenuated, alleging a sort of "fraud on the market" theory that the advertising inflated demand for Lipitor, increasing the costs to the plaintiffs—and, conveniently for the plaintiffs, side-stepping many issues of individualized proof. Obviously, however, the prescription drug market is not akin to the securities market; there is no Prescription Drug Exchange where traders and speculators hedge forward contracts on deliveries of medications, and the price of the drug fluctuates upon the release of new information.¹² (For example, Lipitor's price did not go up when the label changed in July 2004.) For this reason, most courts, including *Probias*,¹³ reject price inflation theories.¹⁴ The

⁹ 5 U.S.C. §§ 701-706.

¹⁰ 490 F. Supp. 2d at 1232-35.

¹¹ *Mampe v. Ayerst Labs.*, 548 A.2d 798, 802 n.6 (D.C. 1988); *In re Meridia Products Liability Litigation*, 328 F. Supp. 2d 791, 811 (N.D. Ohio 2004) ("The underlying premise of this doctrine is that patients rely on their doctors' expert judgment—not any materials included on the label or in the drug packaging—when deciding which drugs to use and how to use them.").

¹² *Cf. Heindel v. Pfizer, Inc.*, 381 F.Supp.2d 364, 380 (D.N.J.2004).

¹³ 485 F. Supp. 2d at 1337-39.

Probias court dismissed most of the claims, though defendants had to file several sets of briefs to get to that stage. The rest of the case will likely be dismissed on summary judgment, after expensive discovery; plaintiffs have filed a Rule 56(f) motion for still more discovery as the summary judgment motion is pending. And all this is for a drug where not even the federal government alleges wrongdoing.

Where the federal government does step in and win settlements, private attorneys invariably piggyback, often attracted by the information in a plea agreement. After such a \$435 million agreement by Schering-Plough with the government in August 2006, trial lawyers hit Schering-Plough with several lawsuits over Intron A and Temodar.¹⁵ Plaintiffs sue under RICO, consumer fraud laws, negligent misrepresentation, common law fraud, and unjust enrichment; again, the theory of the case is that truthful scientific information that was allegedly technically illegally disseminated inflated sales or prices of drugs, entitling plaintiffs to refunds, without any evidence that the drugs were not efficacious, that the marketing affecting the individual plaintiffs' doctors' prescription decisions, or that the plaintiffs were injured in any way.¹⁶ The court has yet to rule on the motion to dismiss.

While the *Probias* court eventually cut down the claims against Pfizer, the business model of the entrepreneurial plaintiffs' bar is one of relentlessness, recognizing that it will not win every case, but that it will eventually find outlier courts who support implausible claims. Other courts have adopted a similarly irrational "benefit-of-the-bargain" theory for prescription drug pricing in consumer fraud claims;¹⁷ in *Clark v. Pfizer, Inc.*¹⁸ one Pennsylvania state court even held that a pharmaceutical manufacturer could be liable for sales of generic versions of Neurontin sold by other manufacturers because of its own off-label marketing.

Clark, aside from adopting an unprecedented theory of liability,¹⁹ demonstrates the problem of forum-shopping in class actions. Plaintiffs' firms, including Lief Cabraser and Hagens

¹⁴ Heindel, *supra*; N.J. Citizen Action v. Schering-Plough Corp., 842 A.2d 174, 178 (N.J. Super. A.D. 2003); *see also* Beck and Herrmann, *supra* note 5 (citing state cases).

¹⁵ Charles Toutant, *Schering-Plough Defends Suits Over Marketing of 'Off-Label' Drug Uses*, N.J.L.J., Aug. 31, 2007.

¹⁶ Consolidated Amended Complaint, *In Re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-5774 (D.N.J.).

¹⁷ *In re Zyprexa Prod. Liab. Lit.*, 493 F. Supp. 2d 571 (E.D.N.Y. 2007) (Weinstein, J.) (denying summary judgment); *In re Bextra and Celebrex Marketing, Sales Practices and Prod. Liab. Lit.*, No. MDL 05-1699 CRB, 2007 WL 2028408 (N.D.Cal. Jul. 10, 2007); *International Union of Operating Engineers Local # 68 Welfare Fund v. Merck & Co., Inc.*, 384 N.J. Super. 275, 894 A.2d 1136 (N.J. Super. A.D. 2006), *rev'd*, 192 N.J. 372, 929 A.2d 1076 (2007); *cf.* *Price v. Philip Morris, Inc.* No. 00-L-112, 2003 WL 22597608 (Ill. Cir. 2003) (tobacco), *rev'd*, 848 N.E.2d 1 (Ill. 2005); *Small v Lorillard Tobacco Co.*, 94 N.Y.2d 43, 56 (1999) (*dicta*).

¹⁸ *Clark v. Pfizer, Inc.*, No. 1819, slip op. (Phila. Ct. C.P. Mar. 12, 2008); *see* Amaris Elliot-Engel, *Drug Companies on the Hook for Off-Label Use of Generic*, LEG. INTELLIGENCER, Mar. 24, 2008.

¹⁹ *But see* *Foster v. American Home Products Corp.*, 29 F.3d 165, 168 (4th Cir. 1994) (rejecting theory of liability for generic sales); *Colacicco v. Apotex*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) ("every state and federal district court which has confronted the issue of innovator drug-manufacturer liability has either adopted the *Foster* reasoning or cited *Foster* with approval"); *accord* *Goldych v. Eli Lilly*, No. 5:04-CV-1477, 2006 WL 2038436 (N.D.N.Y. July 19, 2006); Mark Herrmann, *A Tactical Thought About Clark*, <http://druganddevicelaw.blogspot.com/2008/04/tactical-thought-about-clark.html> (Apr. 2, 2008) (last accessed ____, 2008).

Berman, brought a similar class action in the federal Neurontin MDL, making claims under the federal RICO statute and the New Jersey Consumer Fraud Act, and of unjust enrichment.

In 1993, the FDA approved Neurontin for use in the treatment of partial seizures in adults with epilepsy. Parke-Davis engaged in research on the effectiveness of Neurontin for other uses, such as depression and pain, and disseminated the resulting scientific literature, but internal marketing documents show the company chose, because of the short patent life remaining on the drug, not to seek FDA approval for these other uses. Parke-Davis's successor, Warner Lambert, eventually paid \$240 million in fines (and \$190 million in Medicare reimbursements) as part of a plea agreement when the U.S. Attorney's Office of the District of Massachusetts found the company's sponsorship of educational promotions and payments to opinion leader physicians problematic.²⁰

The federal court refused to certify a class, holding that, while it might be possible for an expert to determine the degree of classwide damages, the individualized prescription decisions were not susceptible to classwide proof, given that it was impossible to define a class that did not include some members who had suffered no injury.²¹ The court refused to endorse a theory of "fluid recovery."²² A New York court similarly rejected a statewide class action over Neurontin on the grounds that the plaintiff had not demonstrated actual harm.²³

In Pennsylvania, however, a state court, hearing the same theories for the same class with the same expert witness on damages, certified a statewide class²⁴ and denied summary judgment,²⁵ in each instance giving at most cursory evaluation of the precedent and public policy arguments against such rulings. In future litigation, the Class Action Fairness Act will largely prevent such forum-shopping by moving most such class actions into federal court and consolidating them,²⁶ but cases such as *Clark* demonstrate why the Class Action Fairness Act was needed in the first place.

State consumer fraud statutes can sometimes be especially challenging in the class action context because they often omit a reliance requirement. Plaintiffs can be found claiming that they are entitled to disgorgement or punitive damages for a false statement regardless of the

²⁰ Ironically, a couple of years later, a class action successfully challenged the state of Florida's refusal to use Medicaid funds to pay for off-label prescriptions of Neurontin, and a court ordered the state to provide coverage for such prescriptions. *Edmonds v. Levine*, 417 F.Supp.2d 1323 (S.D. Fla. 2006).

²¹ *In re Neurontin Marketing and Sale Practices Litigation*, 244 F.R.D. 89, 109-15 (D. Mass. 2007).

²² *Id.* See also *Schwab v. Philip Morris USA, Inc.*, 449 F.Supp.2d 992 (E.D.N.Y. 2006) (Weinstein, J.) (endorsing fluid recovery in class actions), *rev'd*, *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008) (thoroughly rejecting fluid recovery as a violation of due process and the Rules Enabling Act).

²³ *Baron v. Pfizer, Inc.*, 42 A.D.3d 627 (N.Y.A.D. 2007).

²⁴ *Clark v. Pfizer, Inc.*, No. 1819, slip op. (Phila. Ct. C.P. June 29, 2007).

²⁵ *Clark*, *supra* note 18.

²⁶ Frank, *supra* note 3. See also, e.g., *In re Epogen and Aranesp Off-Label Marketing and Sales Practices Lit.*, ___ F.Supp.2d ___, 2008 WL 1393694 (U.S.Jud.Pan.Mult.Lit., Apr. 8, 2008) (consolidating five class actions over objection of defendant).

existence of damages.²⁷ Alaska, in its litigation over Zyprexa, argued that it was entitled to \$1,000 to \$25,000 a prescription under the Unfair Trade Practice Consumer Protection Act, which plainly had a large effect in inducing Eli Lilly to settle for \$15 million, a tiny fraction of the billions hypothetically at stake—precisely the sort of *in terrorem* settlement that critics of the class action process criticize. Courts are largely rejecting such interpretations, requiring a showing of causation of injury even when there is no reliance requirement in the statute,²⁸ but this is a dangerous game for pharmaceutical defendants, given the lottery awards available to the trial lawyer who finds an outlier court.

Conclusion

The problem of overdeterrence in the class-action context is multiplied when it comes to class actions over off-label uses. As other essays in this volume show, off-label use is already overregulated and overlitigated to the detriment of health outcomes. Such problems are only exacerbated by the private class-action bar. To date, the problems of overenforcement of off-label regulations and the overdeterrence in class actions have yet to be fully realized, in part because courts have largely been sensible in addressing aggressive claims of the trial bar. Where federal district courts have overreached, appellate courts have so far done their duty to set matters correct. But the fiscal health of pharmaceutical companies should not be dependent on the happenstance of the assignments of the Judicial Panel on Multi-District Litigation.

Between the incentives of federal prosecutors, state attorneys general, and *qui tam* relators to suss out wrongdoing, there is absolutely no evidence that illegitimate off-label marketing by pharmaceutical companies is going unpunished. Indeed, as the other essays in this volume show, the problem is not false negatives, but false positives: over-enforcement and overdeterrence, often of legitimate activity that is being held with hindsight to be on the wrong side of an ambiguous line.

Adding private class actions to the mix accomplishes nothing useful. At best, the trial lawyers will be rent-seeking by piling onto an existing investigation in search of attorneys' fees. If current levels of federal fines are somehow insufficient deterrence, there are surely better means to ensure appropriate levels of disgorgement than paying substantial commissions to trial lawyers. If, on the other hand, federal penalties are at the optimal level (or, as theorized by other papers here, too high), then the added expense of paying off the plaintiffs' bar is detrimental.

²⁷ MICHAEL S. GREVE, HARM-LESS LAWSUITS?: WHAT'S WRONG WITH CONSUMER CLASS ACTIONS (2005); Victor E. Schwartz & Cary Silverman, *Common-Sense Construction of Consumer Protection Acts*, 70 KANS. L. REV. 1 (2006).

²⁸ *E.g.*, Baron, *supra* (New York); *In re* St. Jude Medical, Inc., Silzone Heart Valve Prods. Liab. Litig., 522 F.3d 836 (8th Cir. 2008) (Minnesota); *Williams v. Purdue Pharma Co.*, 297 F. Supp. 2d 171 (D.D.C. 2003) (D.C.). *See generally* Schwartz & Silverman, *supra* note 4; McLaughlin, *supra*, 522 F.3d at ___ (requiring individualized proof for any showing of reliance on misrepresentation).

More often, plaintiffs' attorneys will be seeking to characterize appropriate behavior as wrongful, and thus adding illegitimate expense to legitimate actions, an unalloyed deadweight loss to society at large.

Given the high costs, inefficiencies, and risks of error of private class actions over drug marketing; given the existing incentives for federal prosecutors and regulators to scrutinize pharmaceutical marketing practices; and given the lack of evidence that private enforcement outside of the *qui tam* process provides any marginal benefit to product safety, it would seem best to have federal regulators occupy the field through preemption of private rights of action.²⁹

²⁹ Cf. Richard Epstein, *Why the FDA Must Preempt Tort Litigation: A Critique of Chevron Deference and a Response to Richard Nagareda*, 1 J. TORT LAW art. 5 (2006).