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The New and Expanding Claims of Third-Party Payors Against Pharmaceutical Manufacturers

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INTRODUCTION

Traditionally, plaintiffs who bring suit against pharmaceutical companies in United States courts have been individuals, or classes of individuals, who allege that they have been physically injured by a drug's side effects. Recently, a new type of plaintiff has emerged, seeking financial damages as a result of alleged illegal marketing, antitrust violations, and fraud. These third-party payors do not claim that the drugs are unsafe in any way, but instead assert that pharmaceutical companies were unjustly enriched by stifling competition and by creating a market of users who derive no medical benefit from the drugs. Third-party payors have been increasingly successful on both an individual and class-wide basis in convincing United States courts and juries that they have been economically injured by pharmaceutical companies, and many of these cases have resulted in settlements or decisions costing pharmaceutical companies hundreds of millions of dollars. If this trend continues, these claims will move to the forefront of pharmaceutical litigation in the United States.

II. PLAINTIFFS

A. Who are the Third-Party Payors?

As one United States court has observed, [third-party payors] include:

1.) traditional insurance companies,

2.) health maintenance organizations ('HMOs'),

3.) other forms of ERISA plans,

4.) self-insured employers, and

5.) union benefit funds.

In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. 61, 71 (D.Mass 2005).

In order to understand the basis of these parties' claims of economic injury, it is first necessary to understand the general United States payment model for prescription drugs. Typically, a pharmacy or other retailer purchases drugs from a wholesaler or a manufacturer. Id. When a patient presents his or her prescription to the pharmacy, the pharmacist checks to see whether the prescribed drug is on the "formulary" for that patient's insurance company. Id. A formulary is the insurance company's listing of approved and covered medications. If the drug is on the formulary, the patient pays a fixed co-pay or a percentage of the drug's average wholesale price. Id. The remainder of the cost for that drug is then typically borne by one of the third-party payors listed above, or a Pharmacy Benefit Manager on behalf of the third-party payor. Id. at 71.

B. Pharmacy Benefit Managers

Pharmacy Benefit Managers have acted as the middlemen in these benefits transactions in the United States since the mid-1990s. Initially, they merely handled claims transactions. Over time, however, they began handling more aspects of the United States pharmaceutical reimbursement process including "pharmacy network administration, formulary design and management, manufacturer rebate negotiation, drug utilization review (to determine whether a patient's prescriptions may interact), physician communication and education (including formulary compliance incentives), mail-order pharmacy services, generic substitution plans, and assumption of risk." AWP Litigation 230 F.R.D. at 71 According to published estimates, over 95% of Americans with health benefits receive drug coverage through a Pharmacy Benefit Manager. Because such a large percentage of Americans is covered by these managers, the commercial success of a drug in the United States depends in large measure on the manufacturer's success in getting its drug on as many formularies as possible.

When a pharmaceutical manufacturer is alleged to have acted improperly with respect to its marketing or promotion of a particular drug, this opens the door for affected third-party payors to allege that those improper efforts resulted in that drug being improperly included on their formularies. In turn, the third-party payors claim they were required to pay for covered prescriptions that they should and would not otherwise have had to incur.

II. CAUSES OF ACTION

A. Product Liability Withdrawal from the Market

Subsequent to withdrawal of a drug from the market, third-party payors may recover for the costs associated with the withdrawal. For example, the anti-cholesterol statin Baycol was withdrawn from the market on August 8, 2001. See Center for Drug Evaluation and Research, Baycol Information, http://www.fda.gov/cder/drug/infopage/baycol/default.htm Bayer, the drug's manufacturer, refused to refund third-party payors for their unused drugs or for the costs of switching patients to new medicines. See In re Pa. Baycol Third-Party Payor Litig., 2005 Phila. Ct. Com. Pl. LEXIS 129, at *1-2 (Pa. Phila. Ct. Com. Pl. 2005). Plaintiffs filed a class action suit in the Philadelphia Court of Common Pleas asserting claims of breach of warranty and unjust enrichment on behalf of the third-party payors "who have purchased Baycol, or reimbursed their beneficiaries/insureds for their purchases of Baycol, that is unusable and/or have incurred additional expenses associated with Baycol's withdrawal." Id. After the court certified the class, Bayer subsequently settled, agreeing to pay the third-party payors up to 150% of their actual costs. In re Pa. Baycol Third-Party Payor Litig., Settlement, No. 001874, dated September Term, 2001.

B. Hatch-Waxman Amendment Causes of Action

The Hatch-Waxman Amendments[1] were enacted in 1984 to permit an abbreviated application for approval of generic drugs. In re Cardizem CD Antitrust Litigation, 332 F.3d 896, 901 (6th Cir. 2003) Instead of having to submit new efficacy and safety studies, the generic drug manufacturers are permitted to submit an Abbreviated New Drug Application ("ANDA"), relying on the studies of the "pioneer" drug that is the bioequivalent of the generic. Id. If the "pioneer" drug manufacturer believes that the generic entry violates a patent, it can file suit and automatically stay the approval of the generic drug for thirty months. Id. In order to compensate for this thirty-month protective period and to encourage entry of generic drugs on the market, the first company to file an ANDA receives a 180-day exclusivity period following approval. Id.

Once a generic is released on the market, the demand for the brand-name drug is reduced, and the prices are lowered accordingly. As more and more generic equivalents are released, the prices of both the brand-name and the earlier generics drop even further. While the Hatch-Waxman Amendments were intended to increase the availability of generic equivalents on the market, pharmaceutical companies are alleged to have taken advantage of its provisions to create a non-competitive market, thus allowing them to keep selling their drugs at premium prices.[2]

For example, Abbott Laboratories sued Geneva, a generic manufacturer, claiming that it infringed upon one of the patents on terazosin hydrochloride. In re Terazosin Hydrochloride Antitrust Litig., 164 F.Supp.2d 1340 (S.D. Fla. 2000) During the litigation, Abbott and Geneva entered into an agreement in which Geneva agreed not to enter the generic market with terazosin

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[1] Drug Price Competition & Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984), to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301-399.

[2] Community Catalyst, K-Dur 20, http://www.prescriptionaccess.org/index.php?doc_id=586 ("The first generic version of a brand name drug to hit the market usually costs 30 to 40 percent less than the brand name drug. Then, as more generic versions become available, prices generally drop by as much as 70 to 80 percent of the brand name price. As a result of these lower prices, brand name manufacturers generally lose as much as two-thirds of their

hydrochloride until an appellate ruling on the patent litigation in exchange for a monthly fee. Id. The Southern District of Florida found this agreement *per se* illegal and affirmed this ruling on remand from the Eleventh Circuit. Id.

Each time a patent is filed for a new formulation, the filer receives an additional period of exclusivity. SmithKline Beecham Corp. d/b/a GlaxoSmithKline plc ("GSK") is the manufacturer of Augmentin, an antibiotic.[3] A class of consumers and third-party payors filed suit in the Eastern District of Virginia claiming that GSK misled the patent office into issuing patents to extend GSK's exclusivity and, as a result of this fraud, the class was required to pay higher prices for Augmentin than for generic equivalents. GSK settled the matter and on January 11, 2005, the court approved the settlement of $29 million, 55% of which would be placed in a fund for consumers with the remaining 45% available for the third-party payors.[4]

The 180-day exclusivity period also can give rise to alleged anti-competitive behavior by generic drug manufacturers. Biovail and Elan Corporation were manufacturers of a generic version of Bayer AG's Adalat, which is used for the treatment of hypertension. In re Nifedipine Antitrust Litig., 335 F. Supp. 2d 6, 8-9 (D.D.C. 2004) Plaintiffs alleged that although both Biovail and Elan were approved to sell 30 mg and 60 mg generic nifedipine, Biovail produced only the 60mg product and Elan produced the 30 mg product. Plaintiffs argued that the end result of this agreement between the two companies was to force the plaintiffs to pay higher amounts for both generic dosages by in effect extending the 180-day exclusivity period. Plaintiffs brought suit requesting injunctive relief, damages under various state consumer fraud, antitrust, and unjust enrichment laws. Nifedipine, 335 F. Supp. 2d at 2-3 The court found that there was no threat of ongoing harm and

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market share to lower priced generic versions within the two years.").

[3] Augmentin Antitrust Litigation, Consumer and Third Party Payor Settlement Information, http://www.augmentinlitigation.com

[4] Class counsel was awarded $7.25M. House v. GlaxoSmithKline PLC, 2005 U.S. Dist. LEXIS 33711, at *15.

that the plaintiffs lacked standing and accordingly dismissed plaintiffs' injunctive relief claims for lack of jurisdiction. Because the court dismissed the federal claim, it declined to entertain jurisdiction over the pendant state claims, and dismissed the case in its entirety. Nonetheless, it appears that courts could entertain future actions that allege that companies conspired to minimize competition, thereby causing third-party payors to pay anti-competitive prices.

C. Suppressing Generic Entry

One of the more common causes of action against "pioneer" drug manufacturers is the suppression of generic bioequivalent drugs from entering the market. Based on market studies that have proven that less competition results in higher prices, third-party payors who have paid anti-competitive prices for drugs as a result of alleged monopolistic conduct have been successful at recovering their losses.

An example of this is the K-Dur 20 Multi-District litigation currently pending in the United States District Court in the District of New Jersey. In that litigation, a group of consumers and third-party payors sued Schering-Plough, the manufacturer of the pioneer drug, and two generic drug manufacturers, Upsher-Smith and American Home Products Corporation. In re K-Dur Antitrust Litigation, Settlement Agreement, Civil Action No. 09-1652 (JAG, Jr.), MDL Docket No. 1419.[5] The complaint alleged that Schering-Plough initiated sham litigation against the generic companies for patent infringement and then settled with the companies in exchange for their agreement not to enter the generic market for a specified period. Id. Because no generics were able to enter the market, plaintiffs claimed Schering-Plough could retain a monopoly and charge the plaintiffs higher-than-competitive prices. Id. In support of their claims, plaintiffs cited Schering-Plough estimate that sales would decrease by $30 million in the first year if generics were released onto the market. Id.

As the K-Dur 20 litigation is still pending, plaintiffs' ultimate success on their claims has not

been determined. Moreover, in addition to the K-Dur 20 litigation, there is ongoing litigation concerning suppression of generic entry of several other drugs, including Neurontin, OxyContin, and Wellbutrin. Depending upon the success of plaintiffs in these cases, the prevelance of such claims in United States courts could increase.

D. Anti-Competitive Monopolization of Active Pharmaceutical Ingredients

A related basis for some third-party payor claims relates to alleged anti-competitive conduct to monopolize a drugs' pharmaceutical ingredients. For example, after a $35 million (USD) settlement between many end-payors and Mylan Laboratories, four plaintiff third-party payors who opted out of the settlement filed suit against Mylan, the manufacturer of the anti-anxiety medications Lorazepam and Clorazepate, alleging restraint of trade, conspiracy to monopolize the generic markets, monopolization of the generic markets, attempted monopolization of the generic markets, and price fixing." In re Lorazepam & Clorazepate Antitrust Litig., 202 F.R.D. 12, 15 (D.D.C. 2001) According to plaintiffs, Mylan entered into exclusive contracts with certain specialty chemical manufacturers to supply the so-called "Active Pharmaceutical Ingredient" ("API") for these drugs. In return for this exclusive supply, Mylan allegedly shared a percentage of its gross profits with these API suppliers. By exclusively controlling the supply market and excluding competition, Mylan was allegedly able to sell its drugs at an increase of 6500%, despite facing no significant increase to its costs. Id. at 17. At approximately the same time, one of Mylan's API suppliers raised its own price for the API by approximately 1900% for sales to a Mylan competitor, which in turn raised the price of its generic to approximately the same price as Mylan was charging. Id. Plaintiffs' claims went to trial, with the jury finding that the defendants had acted willfully and ultimately awarding the four opt-out third-party payors $12 million. In re Lorazepam & Clorazepate Antitrust Litig., Jury Form, MDL Docket 1290, dated June 1, 2005.

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[5] Community Catylsy, K-Dur 20, http://www.prescriptionaccess.org/index.php?doc_id=586.

E. Deceptive and Off-Label Advertising

Last but not least, third-party payors have successfully sought damages for alleged deceptive and off-label promotion by drug manufacturers. Under the U.S. Food, Drug, and Cosmetics Act, 21 U.S.C. §§301-97, new drugs must be demonstrated to be safe and effective for certain uses before they can be sold, and once approved, a drug can only be marketed for those specific uses. United States ex rel. Franklin v. Parke-Davis, 147 F. Supp. 2d 39, 44 (D. Mass. 2001) While these approved indications limit the marketing of a drug, doctors still can prescribe any approved drug for any other use. Id. The FDA permits this "off-label" use of approved drugs because it intends to regulate the pharmaceutical industry without interfering with the practice of medicine. Id. If a pharmaceutical company wants to promote a drug for these "off-label" indications, however, it must resubmit the drug for additional safety and efficacy testing before the drug can start the FDA approval process for those indications. Id. Moreover, Medicaid will only reimburse out-patient prescriptions for drugs that are being used for their FDA approved use or for another use in a specified compendia of drugs. Id. at 44.

Such off-label promotion can and does lead to claims by third-party payors. For example, Serona manufactured and sold Serostim, a drug used to treat AIDS wasting.[6] At approximately the same time as the launch of Serostim, protease inhibitor drugs used in an "AIDS cocktail" began to reduce the prevalence of AIDS wasting and, therefore, reduced the potential market for Serostim. Id.

Serona then allegedly promoted the use of Serostim to treat lipodystrophy, an off-label indication. Id. Serona was also accused of creating a new market for Serostim by redefining AIDS wasting using a new computer software package to diagnose that condition and providing training to doctors for this off-label use. Id. Following a whistleblower action and subsequent government

[6] Department of Justice, Serono to Pay $704 Million for the Illegal Marketing of Aids Drug, http://www.usdoj.gov/opa/pr/2005/October/05_civ_545.html.

investigation, Serona and its affiliates pleaded guilty to both civil and criminal charges, including conspiracy to defraud and to offer illegal remuneration to doctors, leading to a $704 million (USD) payment. Id. Of this sum, $567 million (USD) was distributed to Medicaid to recoup damages it incurred as a third-party payor as a result of Serona's illegal activities.[7]

Another example of this kind of claim involves Warner-Lambert (now owned by Pfizer), the manufacturer of Neurontin. Following a whistleblower action filed by a former employee, the United States government initiated an investigation into allegations of off-label promotion of Neurontin and illegal kickbacks. The government alleged that Warner-Lambert conducted an "extensive and far-reaching campaign to use false statements to promote increased prescriptions of Neurontin. . . for off-label uses." Serostim, 147 F. Supp. 2d at 39, 45. Ultimately, Pfizer/Warner-Lambert pled guilty to two criminal violations and settled civil charges for $430 million (USD).

Not every third-party payor action for deceptive advertising has been successful, however. Recently, in the United States District Court for the District of Delaware, third-party payor plaintiffs alleged that before the expiration of its Prilosec patent, AstraZeneca received FDA approval for a new proton pump inhibitor, Nexium, and then subsequently advertised and promoted Nexium as superior to Prilosec. Penn. Employee Benefit Trust Fund v. Zeneca Inc., 2005 WL 2993937 at *5 (D.Del. Nov. 8, 2005) Plaintiffs further alleged that Nexium was no more effective than Prilosec, and that the advertising campaign caused "billions of dollars of unnecessary drug expenditures by third-party payors" who purchased Nexium instead of the newly available generic version of Prilosec. Id. The court examined the defendant's advertising claims and compared them to the FDA-approved labeling. Id. The court found that AstraZeneca's claims of safety and efficacy were consistent with the FDA-approved labeling, and that its Nexium advertising was thus not false or misleading under the Delaware Consumer Fraud Act. 6 Del.C. § 2513. The court further found that

[7] J. Cinquegrana & D. Lloyd, Pharmaceutical Executive, Off Label Promotion, January 2006

plaintiffs' claims were not actionable under state consumer fraud laws because they were preempted by U.S. federal law. Zeneca, 2005 WL 2993937, at *4.

F. Reimbursement for Medical Treatment Costs.

In the United States tobacco litigation, third-party payors have been unsuccessful in their attempts to convince courts that they should be able to recover from tobacco companies whose products allegedly adversely affected the health of their participants. SEIU Health & Welfare Fund v. Philip Morris Inc., 249 F.3d 1068, 1072 (D.C. Cir. 2001). Generally, courts have found that these plaintiffs lacked antitrust standing because the alleged damages were too remote. See, e.g., Lorazepam II, 295 F. Supp. 2d at 38. Courts have also held that the damages sought by these plaintiffs were too speculative and that the apportionment of those damages would be too complex. Id. In addition, at least one court has opined that third-party payors suffered no real financial harm because they could raise premiums to recover their losses. Id.

Pharmaceutical companies, however, have had mixed results in asserting these defenses. For example, as one United States court explained

> [T]he tobacco companies' alleged tort directly harmed only the smokers, who suffered both a health injury (smoking-related illness) and an economic injury (the purchase price of the fraudulently marketed cigarettes). The smoker's health injuries, in turn, caused economic losses to the insurance companies, who had to reimburse patients for the cost of their smoking related illnesses. That case was clearly one in which the Plaintiffs' damages were entirely derivative of the injuries to the insured. . . . In the instant case, instead, Plaintiffs allege an injury directly to themselves . . . . Thus the damages—excess money Plaintiffs paid Defendants for the [diabetes treatment drug] Rezulin that they claim they would not have purchased "but for" Defendants' fraud—were in no way 'derivative of damage to a third party.' Id.

Thus, indirect purchasers, such as third-party payors, could claim antitrust standing in actions against pharmaceutical manufacturers and marketers because those indirect purchasers were directly harmed

by the defendants' alleged fraud.

On the other hand, Rezulin was prescribed to diabetics who took insulin to help control their sugar levels.[8] Because of the possibility of severe liver damage, the FDA requested that its manufacturer, Parke-Davis/Warner-Lambert, withdraw the drug from the market.[9] Following withdrawal, the manufacturer recommended that patients who had taken the medicine receive certain diagnostic tests to monitor their liver function levels. Rezulin, 171 F. Supp. 2d 299, 299-300 (S.D.N.Y. 2001) The third-party payors that paid for these diagnostic tests sued the manufacturer to recover the costs for these tests. Id. The court rejected the third-party payor's efforts finding that the injuries were derivative, rather than direct and because they were derivative the apportionment of damages would be prohibitively complex. Id. Finally, the Court noted that the injured victims in this case could sue for themselves. Id.

G. The Success of Third-Party Payors in the Vioxx Litigation

A very recent and high profile third-party payor class action decision that illustrates some of the concepts discussed above was released by the New Jersey Appellate Division earlier this year. The decision upheld the certification of a nationwide consumer fraud class action against Merck filed by plaintiff third-party payors arising out of Merck's marketing and promotion of Vioxx. International Union of Operating Engineers Local #68 Welfare Fund v. Merck & Co., Inc., 384 N. J. Super 275 (N.J. Sup. Ct. App. Div. 2006)

Plaintiff, a joint union-employer Taft-Hartley trust fund, organized and operating in New Jersey, sought certification of a nationwide class of third-party payors who, as a result of Merck's alleged fraudulent conduct in the marketing and promotion of Vioxx, paid to cover prescription costs for Vioxx. Judge Carol Higbee, the New Jersey Superior Court trial judge assigned to handle all

[8] FDA News Release, March 21, 2000, Rezulin to be Withdrawn from the Market, http://www.fda.gov/bbs/topics/NEWS/NEW00721.html (last visited Sept. 25, 2006).

Vioxx-related litigation in the New Jersey state courts, certified such a class and ruled that the New Jersey Consumer Fraud Act ("CFA") N.J.S.A. 56:8-1 would apply to all class members' claims.

In upholding Judge Higbee, the court first noted that New Jersey's Consumer Fraud Act, which was intended to be one of the strongest consumer protection laws in the nation, was also intended to be applied liberally to achieve its three main purposes: to compensate victims; to punish wrongdoers through awards of treble damages; and to attract competent counsel to counteract fraud. Next, with respect to ascertainable loss, which is a prerequisite to bringing a claim under the CFA, the court held that plaintiff need not prove that the third-party payor class members actually relied on the alleged fraud committed by Merck, but must instead establish that it (and they) suffered an ascertainable loss "attributable to conduct made unlawful by the [CFA]." Moreover, Merck's conduct need not be the sole cause of the loss, but must simply be a cause. Plaintiff argued that most of the third-party payor class members relied on the services of prescription benefit managers ("PBMs"), who in turn relied on pharmacy and therapeutics committees ("P&T Committees") to develop and maintain formularies of approved drugs. As articulated by the panel, plaintiff's causation theory was that "Merck's fraud induced P&T Committees to place Vioxx on healthcare plans' formularies, thereby encouraging physicians to prescribe the medication for patients, which resulted eventually in the ultimate payment for the prescribed drug by plaintiff third-party payors." Although it acknowledged that "the causal chain appears somewhat elongated," the court held that it could not find "that the alleged fraud was not a cause of the third-party payors' loss."

This matter is now on appeal before the New Jersey Supreme Court and unless this decision is reversed, this class action against Merck will proceed with plaintiff representing the claims of a nationwide class of third-party payors, which obviously will present significant issues for Merck and its insurers, not to mention the rest of the pharmaceutical industry.

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[9] *Id.*

CONCLUSION

In sum, the claims of third-party payors are expanding into many new legal areas and are becoming a significant part of litigation against pharmaceutical companies in the United States. These claims are having enough success that when litigation ensues over any pharmaceutical product, the company and the company's insurers must immediately be aware of the likelihood of a third-party payor claim for reimbursement.