

**Pharmaceutical Reimbursement: The Sleeping Giant Should Wake Up.
Prescription Costs Grow From Marketing, Not Just Scientific Progress.**
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In 2007, spending on prescription drugs in the United States approached \$300 billion. That number will be larger by the end of 2008 and is expected to grow considerably next year.

Workers' compensation carriers and health care insurers pay the significant portion of these expenses. Traditional third-party subrogation can only recover a small fraction of these costs on a case-by-case basis. Pharmaceutical reimbursement claims offer new strategies to recover these expenses. These strategies can yield significant returns and go hand-in-hand with ongoing programs to manage health care costs and assure safety along with fair marketing of pharmaceuticals.

The volume of sales makes it clear that the sale of drugs is big business. The competition for market share is intense. While scientists work to develop drugs that are effective and safe for treatment, they frequently do so under intense pressure from management and marketing executives. For these companies, the speed of getting a drug from the lab to the market means increased market share and huge financial benefits. Every company is looking for the next "blockbuster" that can attain billion-dollar annual sales, while protected by a patent monopoly. This pressure has been intensifying as numerous successful drugs are coming "off patent," and generic competition will slash sales volume and profit margins.

Furthermore, pharmaceutical industry pricing and marketing strategies are too often aimed at expanding drug usage and shifting prescribing habits toward drugs that cost more but are not necessarily more effective or safer.

Pharmaceutical manufacturers justify the extraordinarily high cost of new medications by pointing to their massive investments in research, but these companies are less likely to brag about their massive promotional budgets. In fact, the top nine U.S. drug companies in 2001 were spending only 11% of sales on research and development (far less than profits) while 27% of sales revenue was going towards "marketing and administration."¹

Last year, the Journal of the American Medical Association reported that 90% of the Pharmaceutical industry's \$21 billion marketing budget is directed at physicians. The industry employs an army of more than 90,000 pharmaceutical representatives – "detailmen" – who visit U.S. physicians, providing free lunches, gifts, marketing paraphernalia and free medication samples.² Physicians' groups are concerned that these enticements are designed to influence doctors to prescribe more drugs and more expensive drugs, and have often become a substitute for objective medical evidence.

Investigations arising from personal injury cases have exposed these tactics. Marketing strategies have seen an increase in direct to consumer marketing, sophisticated detailing of doctors including junkets, samples and other incentives. At the same time, the market is influenced through the publication of articles in peer review journals that reports research touting a drug which, without attribution, was sponsored by the pharmaceutical industry.

The multi-faceted marketing strategy has been effective and has contributed to a rise in cost of prescription drugs that is three times the rate of inflation. "Brand Name" drugs are fueling this surge and

pharmaceutical companies zealously enforce patent rights against the manufacturers of generic versions of the drug. A report by the American Association of Retired Persons found that in 2006, the price of 10 common branded drugs increased up to nine times the rate of inflation. In comparison, the prices for 75 common generics fell by 2%.³

Of course, marketing to managed care, including insurers, health plans and Prescription Benefit Managers represent a large segment of this marketing initiative. Prescription drugs represent 10 to 20% of total medical costs for insurers, exclusive of the cost of drugs administered in hospitals. The cost of drugs is usually tied to “average wholesale price,” although larger insurers may negotiate terms.

Large-Scale Claims Can Recover Excess Costs for Workers’ Compensation Carriers and Other Prescription Payors

The high stakes that have led to the aggressive marketing to consumers and large volume users/insurers have crossed the line on more than one occasion. Overstatements of efficacy, understatement of risk, promoting untested off label uses and other missteps have resulted in an array of cases against pharmaceutical companies.

The novel features of these strategies, commonly known as Third-Party Payor claims, are important to keep in mind in order to distinguish them from traditional case-by-case subrogation.

- First, the Third-Party Payor can be any insurer, self-insured health plan, administrator or health and welfare fund that covers prescription expenses.
- Second, the Payor does not have to wait for, or depend upon, an action by its insured. The Payor can bring a claim directly against the drug manufacturer.
- Third, to make these claims efficient, the Payor can claim damages based on its entire outlay for a particular medication. Because damages arise from the manufacturer’s conduct, rather than the individual facts of a particular patient’s medical condition, a single claim offers the possibility of a large-scale recovery.

These factors have special advantages in the workers’ compensation setting. Recovery of prescription costs is available across the entire book of paid claims, regardless of whether a subrogation file has been opened, regardless of whether any third party is liable for the injury and regardless of whether the claimant has an attorney pursuing a liability claim.

Setting aside legal terminology for a moment, the grounds for these claims can be put into two groups, which can be thought of as “good drug” and “bad drug” cases.

In “good drug” cases, also called pricing cases, the safety or effectiveness of the drug is not an issue. Instead, the drug maker has charged an excessive price for the drug, frequently by means of antitrust violations. Most often, this involves suppressing generic competition by improper patent tactics. Drug makers have also been accused of manipulating the Average Wholesale Price figures or violating “most favored” terms in supply contracts. In these cases, the potential recovery is measured by the excess amount that insurers and other payors have paid for the drug, over and above what it should have cost.

In “bad drug” cases, the manufacturer has promoted a drug without full disclosure of side effects, or over-promoted a drug for inappropriate uses. The drug may or may not have been subject to a recall. The damage claims in these cases take several forms, depending on the circumstances. The claims may include the full cost of the drug or the difference between the drug’s cost and a comparable, safer

generic drug. Claims for the costs of treating side effects can also be made under the category of consequential damages. Here are examples of some pending and completed cases in the two groups.

“Good Drug” Pricing Cases

Paxil:

GlaxoSmithKline has faced several lawsuits for its promotion and pricing practices on the antidepressant Paxil. Accusing of illegally restraining general competitors, it paid \$100 million to settle a class action for direct purchasers (such as drugstore chains and wholesalers) and \$68 million to settle a class action brought by indirect purchasers, including third-party payors like insurers.

Cardizem:

In 2001, 29 states filed an antitrust suit against the maker of Cardizem, now Aventis Pharmaceuticals. They alleged that Aventis had paid the generic pharmaceutical maker, Andrx, \$89 million not to produce a generic version of Aventis’ blockbuster, \$750 million-a-year heart-disease drug Cardizem CD. This allowed Aventis to maintain its monopoly. That action led to a \$29 million settlement for state Medicaid programs and consumers. A similar lawsuit for other payors led to a \$110 million settlement.

Clorazepate and Lorazepam:

Generic manufactures are not exempt from potential liability. Mylan faced antitrust allegations that it unlawfully raised prices for its generic clorazepate and lorazepam tablets, after entering into agreements with suppliers of the drug’s active ingredients that effectively prevented other companies from making competing generic products. Mylan then raised its prices by staggering amounts. Mylan paid approximately \$170 million to settle class actions on behalf of states, consumers and payors.

Remeron:

A class action against the manufacturer of Remeron claimed that it unlawfully filed a patent lawsuit in order to prevent or delay loss of its market share by the introduction of a generic version of the drug. Damage models were based on the difference in price of the name brand versus the generic version. After extensive litigation, an eight-figure national settlement was reached.

“Bad Drug” Cases

Vioxx:

The withdrawal and massive litigation against Merck over the painkiller Vioxx has been widely reported. Several thousand lawsuits by individual patients against Merck and Company are being resolved through a settlement process that will result in the distribution of \$4.5 billion.

In the course of discovery in the Vioxx cases, Merck produced documents regarding several studies purportedly designed to demonstrate the efficacy and safety of the drug. Analysis of the studies suggest that some were intended primarily to fulfill marketing purposes; known as “seeding studies,” these are used, along with interactions between the companies and physicians, to create brand loyalty among prescribing physicians.⁴

Merck's representations about the efficacy of Vioxx and its overstatement of the drug's safety profile were the subject of claims brought on by the Attorney Generals of several states seeking retribution for violation of state consumer protection acts.

Insurers and health funds have brought claims against Merck, seeking damages under State Consumer Protection Acts for purchases made as a result of fraudulent misrepresentations. Those actions remain pending.

Baycol:

In 2006, a national class action on behalf of payor funds was brought and settled against Bayer for reimbursement of the cost of Baycol that was dispensed before it was withdrawn from the market and could not be used.

Paxil:

Paxil has the unusual distinction of falling into both groups. GlaxoSmithKline has settled claims based on overpromotion of Paxil. Several class actions on behalf of payors such as insurers and health funds have recently been settled for \$40 million. These cases recovered costs for Paxil prescribed to adolescents, which was an "off label" use. Although FDA regulations permit doctors to prescribe medication beyond the indications stated in the approved label, a manufacturer is not allowed to promote such use. Plaintiffs claimed that GSK did promote such use to children and adolescents with depression, even though not approved by the FDA.

Cost-Containment And Reimbursement Claims

Effective cost containment or medical management programs go hand-in-hand with pharmaceutical reimbursement claims. Many compensation carriers contract with Pharmacy Benefit Managers to help control prescription costs. These programs may employ formulary lists as well as negotiate favorable pricing and rebate arrangements with manufacturers. The days are long gone when a workers' compensation carrier would pay any and all claims as submitted.

To manage care effectively, especially in the prescription area, carriers must have the ability to combat and challenge abusive practices by drug makers. Where promotional campaigns and misinformation have induced unnecessary prescriptions of expensive new drugs, reimbursement claims provide a tool to recover past outlays when pro-active programs are unable to prevent the outlay in the first instance.

In short, over the past decades, hundreds of millions of dollars have been recovered from manufacturers who engaged in misconduct affecting the pricing or prescribing of their drugs.

In the past, when class actions have led to a broad settlement, workers' compensation carriers could participate, assuming that notice of the class action settlement came to the attention of the right person in the subrogation or recovery department, and the company submitted a timely claim. However, more aggressive, direct action may be needed in the future for successful recovery of drug costs.

This is a result of developments in the Vioxx litigation. The Supreme Court of New Jersey reversed lower courts that had certified a class action for third-party payors. The Court held that insurers and other

funds that paid for Vioxx could only pursue separate, individual lawsuits. Since that ruling, many such separate lawsuits have been filed. But carriers who have not acted will be unable to recover their costs. It remains to be seen whether other courts will follow the New Jersey court and refuse to approve class action treatment of these cases. If that happens, carriers will need to act to protect their rights to recover pharmaceutical expenses.

In large measure, workers' compensation insurers have been sitting on the sideline, rather than taking an active role in seeking remedies for the misconduct of prescription drug manufacturers. If this sleeping giant wakes up, their participation can make a real difference to the cause of drug safety as well as their bottom line.

ENDNOTES

1. Families USA, "Profiting from Pain: Where Prescription Drug Dollars Go," July 2002.
2. A recent survey found that 94% of doctors report some type of relationship with the drug industry: 83% receive food, 78% receive free samples, 35% receive reimbursement for attending professional meetings or trainings, and 28% receive payments for consulting, enrolling patients in trials, or lectures. EG Campbell et al, *A National Survey of Physician-Industry Relationships*, April 26, 2007, NEJM.
3. AARP, *Trends in Manufacturer Prices of Prescription Drugs Used by Older Americans*, Research Report 2006, accessed at <http://www.aarp.org/research/health/drugs/aresearch-import-869-2004-06--IB69.html> .
4. Hill, KP, Ross, JS, The ADVANTAGE Seeding Trial: A Review of Internal Documents, *Ann Intern Med*. 2008; 149:251-258.