

Marketing the Spread— What Is It and What Are Payors Doing About It?

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I. INTRODUCTION

The latest reprise of a long-running prescription drug marketing scheme seems to have made another appearance. In May, the U.S. Attorney for the Southern District of Florida and attorneys from the Justice Department's Civil Division announced that the United States had intervened in a False Claims Act lawsuit filed against Abbott Laboratories Inc. (Abbott), alleging that the company had inflated the reported selling price of certain drugs over actual selling prices for those drugs, causing hundreds of millions of dollars of overpayments (*United States ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Laboratories Inc.*, No. 95-1354-CIV-Gold (S.D. Fla.)).

This recent sequel is the latest installment in a line of cases involving allegations of abusive marketing ploys using price inflation tactics to fuel drug sales and drive market share by creating windfall profits to providers at the expense of governmental and private third party payors. For instance in 2001, TAP Pharmaceuticals, a joint venture of Abbott, pleaded guilty to criminal and civil charges and paid \$875 million in penalties arising from inflating the reported selling price of its cancer treatment drug Lupron. Following, the criminal phase of the Lupron case, numerous private claims were filed on behalf of non-governmental victims by consumers and third party payors including insurers, health maintenance organizations (HMOs), and health plans. This article looks at how prescription drug manufacturers profit from inflating the reported selling price, and what the government and private third party payors can do to recover their overpayments.

II. GOVERNMENT'S ALLEGATIONS

The government's complaint filed in May alleges that Abbott reported fraudulent, inflated prices to create windfall reimbursements for providers and drive sales and market share for its products. Specifically, the government contends that Abbott inflated the price of the antibiotic drug Vancomycin, knowing that the amounts of government reimbursements available to providers dispensing Vancomycin to patients enrolled in the Medicare and Medicaid federal healthcare programs are based on reported sale prices.

Like other drugs that do not cross through the stomach lining, Vancomycin must be given intravenously for effective systemic therapy. Intravenous drugs are generally dispensed in a clinical setting with the prescribing physician or one of his or her assistants administering the drug. Accordingly, a physician or clinic will purchase the drug—generally through a wholesaler—and resell it to the patient with the provider receiving reimbursement from a government healthcare program or a private third party payor, such as an insurer.

Although most self-administered prescription drugs were not covered under the Medicare system until the recent enactment of Medicare Part D, most injectable drugs, such as Vancomycin, traditionally have been and continue to be covered under Medicare Part B. Under Part B, Medicare pays providers for up to 80% of the "allowable cost" of physician-injected drugs. The remaining 20% is paid by the Medicare beneficiary as a "co-payment."

“Allowable cost” was defined by regulations until 1998 as the lesser of a drug’s estimated actual acquisition cost or a drug’s average wholesale price (AWP). *See* 42 C.F.R. § 405.517. On January 1, 1998, in response to a directive in the Balanced Budget Act of 1997, the Health Care Financing Administration (now known as the Centers for Medicare and Medicaid Services) amended 42 C.F.R. § 405.517 to redefine the allowable cost as the lower of the actual Medicare billing or 95% of the AWP. Traditionally, AWP is derived from industry sources compiling wholesale drug prices as supplied by manufacturers. No independent verification of the actual AWP was undertaken by Medicare or by the index’s publishers.

Thus, by increasing the reported amount of the drug price in sales transactions, a manufacture could increase the AWP for its drug. An increase in AWP creates an increase in the “allowable cost” and, consequently, the reimbursement rate to providers. Providers continue to pay for the drug at low cost while receiving inflated reimbursements. This increased profit or “spread” is a windfall for the provider and creates tremendous incentive to prescribe and administer products from the manufacturer with the most inflated AWP. Manufacturers, recognizing this market advantage tailor their promotional programs to alert providers to this potential, hence the term “marketing the spread.”

Since most private sources of healthcare funding—third party payors, including insurers, HMOs, and health plans—have reimbursement structures that also rely on benchmark pricing such as AWP, the marketing against the spread scheme is just as effective when marketing to providers reimbursed by private payors as when marketing to providers reimbursed by the government.

In the Vancomycin case, the government’s complaint alleges that beginning on or about January 1, 1991 Abbott reported prices that were more than ten times (or over 1000%) the actual sales prices on many of the drugs it manufactures. The United States alleges that federal healthcare programs, both Medicare and Medicaid, have reimbursed Abbott’s customers in excess of \$175 million for the drugs that are the subject of the complaint. Because reimbursement from the federal Medicare and Medicaid programs was based on the allegedly fraudulently inflated prices, the complaint contends that Abbott caused false and fraudulent claims to be submitted to federal healthcare programs in violation of the False Claims Act.

According to the Department of Justice, the government investigation began after the filing of a civil False Claims Act suit by a local home-infusion company, Ven-A-Care of the Florida Keys Inc., and its principals. The civil False Claims Act allows for private persons to file whistleblower suits to provide the government information about

wrongdoing. Under the statute, if it is established that a person has submitted or caused others to submit false or fraudulent claims to the United States, the government can recover treble damages and \$5,500 to \$11,000 for each false or fraudulent claim filed. If the government is successful in resolving or litigating its claims, the whistleblower who initiated the action can receive a share of between 15% and 25% of the amount recovered.

In the *TAP* case, the published AWP for Lupron ranged from \$418.75 in 1992 to \$623.79 in 2001. Despite the published AWP’s, it was alleged that the actual cost of Lupron to providers declined from \$340 in 1993 to \$207 in 1999. *TAP* also admitted that its sales representatives distributed tens of millions of dollars worth of free Lupron samples to providers knowing that that the recipient providers would seek and receive reimbursement from payors.

III. THIRD PARTY PAYOR RECOVERY OPTIONS

Following resolution of the government’s claims in the Lupron case, *TAP* was swamped with a wave of private actions on behalf of consumers and third party payors. The claims were similar to the government’s allegations that *TAP* had fraudulently reported an inflated sales price to increase the AWP of Lupron and allow the company to market against the spread as an added incentive to increase sales and drive market share. Eventually most of those civil cases were consolidated into a multi-district litigation in the federal court in Boston, where a \$150 million settlement was reached with a class of consumers and third party payors and with several groups of third party payors that opted out of the class action lawsuit. Eventually, plaintiffs in a few state court actions also signed on to the *TAP* settlement, and the settlement funds are currently awaiting distribution.

What happens next in the Vancomycin case will be interesting to watch, given that a large settlement by the Department of Justice is likely to lead to a similar onslaught of private litigation. Without the investigatory powers of the United States or the enforcement powers afforded by the False Claims Act, what options are available to private payors?

A third party payor has choices when deciding how to pursue a prescription drug overcharge recovery. It can file its own lawsuit, wait for a potential class settlement, or join a group of “opt-out” insurers. The right choice depends on both the facts of the underlying case and the circumstances of a particular third party payor. First, you must consider the likelihood of a finding of liability and the amount of the potential recovery. Next, you should consider the economic and other resources that you and your organization would be required to commit to pursuing a recovery.

HEALTH LAW ANALYSIS

Hiring counsel and filing an independent lawsuit is attractive because it affords the greatest control over the course of the recovery effort. But filing an independent lawsuit also requires the greatest commitment of resources including time to identify and retain competent counsel, potential disbursements for attorneys' fees, costs and expenses, as well as a continuing commitment of time and resources to the litigation, such as those needed for the production of documents and witnesses for depositions. Although many cases of this type are brought by attorneys working on a contingent fee basis, some firms request hourly or reduced hourly fees and/or expense payments.

At the other end of the control and risk continuum is waiting to participate as a class member in a potential class recovery. This option requires the least commitment. In exchange, you have no influence over the recovery process other than the opportunity to make a claim (or object) at the end of the claims procedure. Class counsel, sometimes with the assistance of class representatives, evaluates offers and presents class members with a "take it or leave it" settlement in exchange for a fixed percentage of fees, often in excess of 30%.

Opt-out group recoveries often are an appealing middle ground. Typically a number of large insurers, along with groups of small and midsize companies, retain counsel to pursue a recovery either through litigation or negotiation. Generally, because of the stature of the group's largest participants, defendants recognize the group's

credibility and are willing to work with the group toward a resolution separate from any resolution of the class litigation. Sometimes these groups are able to settle their claims with the drug manufacturer without filing suit, by tolling applicable statutes of limitations while a representative suit proceeds to determine disputed factual issues of liability or damages. In the event of settlement, proceeds are quickly distributed, without the administrative and temporal delays required by court approval and appeals common to a class settlement. In addition, fees are negotiated between client and counsel and are ordinarily lower than typical class fees, resulting in a greater and faster recovery for the client. Finally, these opt-out settlements are client-driven, with opportunity for the clients to have input over the structure and amount of the settlement at all stages.

IV. CONCLUSION

While the government and third party payors' responses to prior episodes of marketing the spread schemes did not seem to prevent these most recent allegations or end the practice entirely, a vigorous prosecution of governmental and private claims will likely again result in large recoveries for the payors.

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