



Tapped Out



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Having settled a health care fraud case against TAP Pharmaceuticals for the better part of \$1 billion, the government is now focusing on billing by physicians.

On September 28, 2001, TAP Pharmaceuticals and the U.S. Department of Justice settled the largest health care fraud case in history. TAP Pharmaceuticals agreed to pay the federal government \$875 million to settle criminal charges and civil liabilities related to the alleged fraudulent marketing and pricing of Lupron, a medication used to treat prostate cancer.

The government's investigation of TAP Pharmaceuticals started in 1997 as a "qui tam" or "whistleblower" suit. "Qui tam" actions allow private individuals to initiate suits alleging fraudulent misuse or appropriation of government funds or resources, and this suit alleging fraudulent billing of the Medicare program is a recent example. If successful, the private individual initiating the suit receives a percentage of the amount recovered.

In the TAP Pharmaceuticals case, two individuals initiated suits against the company. One plaintiff was the company's former Vice President of Sales, who left TAP Pharmaceuticals because of concerns regarding suspected illegal marketing conduct.

The other, a urologist at Tufts Associated Health Maintenance Organization, was allegedly offered \$65,000 in unrestricted educational grants by a TAP representative if he agreed to reverse the decision by the HMO to use what the Medicare program views as a less expensive alternative medication, Zoladex.

The litigation record indicates that during the 1990s, TAP engaged in numerous marketing programs to encourage physicians to use Lupron, including offering physicians free gifts, expense-paid trips to resorts and other expensive locales, free mediations and unrestricted educational grants.

However, the main issues that triggered the criminal and civil charges of kickbacks and fraud were (1) TAP's alleged collusion in billing Medicare and other government health care programs (e.g., Medicaid and CHAMPUS) for quantities of Lupron that TAP had earlier provided as "free samples" to the treating physician, and (2) TAP's reporting a higher price to the government, which served to elevate the price of Lupron paid by government programs.

Generally, the Medicare program does not pay for outpatient medications. However, Medicare will pay for medications that must be administered by a physician, such as intramuscularly administered Lupron. Until approximately 1997, Medicare paid the lower of the physician's actual acquisition cost or the average wholesale price (AWP) of a medication.

Pharmaceutical companies were responsible for reporting the AWP. In 1997, Medicare

changed its reimbursement procedures and started paying no more than the price for what it viewed as the least costly alternative medication. A physician who prescribed a more expensive medication would be paid only the amount of the least expensive alternative medication available.

As with most pharmaceutical companies, TAP Pharmaceuticals distributed free medication samples to physicians. However, TAP also allegedly encouraged physicians to bill Medicare and other government health care programs for these samples, thereby allegedly violating the "Prescription Drug Marketing Act." The Act prohibits physicians and other individuals from charging a fee for medication samples, and states, "No person may sell, purchase, or trade or offer to sell, purchase, or trade any drug sample...The term "drug sample" means a unit of a drug...which is not intended to be sold and is intended to promote the sale of the drug."

Unfortunately, some physicians did apparently bill for the free samples. As a result, TAP Pharmaceuticals and certain physicians billing for free samples were charged with conspiracy to commit Medicare fraud, and conspiracy to violate the Prescription Drug Marketing Act.

In addition, TAP Pharmaceuticals reported an AWP to the government that was allegedly greater than its actual figure. Furthermore, TAP Pharmaceuticals gave physicians a "good deal" on the price of Lupron — much lower than the AWP. TAP encouraged physicians to report the AWP when billing Medicare, lest the physicians be reimbursed at the lower acquisition cost.

The False Claims Act prohibits physicians or other individuals from submitting or causing to be submitted false or fraudulent claims to the Federal or state government. For every false or fraudulent claim submitted, the government may recover (1) a penalty of up to \$10,000, and (2) an assessment of three times the amount of the false or fraudulent claim.

In addition, the individual may be excluded from participating in the Medicare program and/or any other government health care program. In this case, it appears that some physicians did bill Lupron at the average wholesale price instead of their actual cost of acquisition. Again, TAP Pharmaceuticals and the physicians billing Lupron at the AWP were charged with conspiracy to commit Medicare fraud.

In settlement, TAP Pharmaceuticals agreed to (1) plead guilty to criminal conspiracy to violate the Prescription Drug Marketing Act and pay a fine of \$290 million (2) pay \$559.4 million in civil damages to the federal government for fraudulent billing and marketing affecting Medicare and CHAMPUS, and (3) pay \$25.5 million in civil damages to the state governments for fraudulent billing and marketing affecting Medicaid. TAP also had to abide by a "corporate compliance program" requiring it supervise its marketing and sales employees, and report the true average sales price for medications reimbursed by government healthcare programs.

In addition, as part of the settlement agreement, TAP Pharmaceuticals also agreed to cooperate fully with the ongoing investigation of other individuals, including TAP's officers, employees, and physician clients and customers. This cooperation has included making its documents and records available to the government and taking reasonable measures to ensure that its officers and employees cooperate with the government.

The "next wave" of investigations and charges has already begun. Physicians are now being investigated and charged with Medicare fraud for billing for samples of Lupron, and for billing at the AWP, as opposed to the acquisition cost of the medication. Physicians may be required to pay a penalty of up to \$10,000 per false claim submitted, as well as triple the cost of the damages for each false or fraudulent claim submitted.

Even more devastating, physicians can be excluded from Medicare. Often this is a career-ending punishment, because an excluded physician cannot work with any physician who accepts Medicare, and most physicians accept Medicare.

So there are many morals to this story.

- First, do not rely upon your pharmacy representative for authoritative guidance regarding Medicare reimbursement standards.
- Second, if a deal seems too good to be true, it probably is.
- Third, the Medicare program must generally benefit from any discount you receive. If it does not benefit, you are probably not billing correctly.
- Fourth, errors in the application of Medicare laws can be perilous.

One final note: the "whistleblowers" in this case received approximately \$95 million dollars.

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