Pharmaceutical company to pay $875 million to settle federal case

GAO suggests Medicare payment system is flawed

The Medicare part B payment system for drugs is artificial and susceptible to manipulation, according to Joseph Gerstein, M.D., a urologist with Tufts Health Plan Inc. of Waltham, Massachusetts.

Gerstein, Tufts' pharmacy programs director, tipped federal investigators to a Medicare fraud scheme that resulted in the largest criminal fine ever imposed on a health care company, the U.S. Attorney's Office announced in October.

TAP Pharmaceutical Products Inc. of Abbott Park, Illinois, agreed to pay $875 million to "resolve criminal charges and civil liabilities in connection with its fraudulent drug pricing and marketing conduct" involving its product, Lupron, the U.S. Attorney and other federal authorities said in a statement.

Lupron, or leuprolide acetate, is a treatment for prostate cancer in men and endometriosis in women.

The crime. In 1997, Gerstein reported to law enforcement authorities that he had been offered a $65,000 "educational grant" by TAP if he would reverse his decision for his health plan to cover only Zoladex, or gosereline, a less-expensive product marketed by AstraZeneca Pharmaceuticals LP of Wilmington, Delaware.

Gerstein said that when he was the chairman of Tufts' pharmacy and therapeutics committee in 1997, he reviewed several scientific reports comparing the efficacies of Lupron and Zoladex.

"I found them to be therapeutically the same," he said. "And I was subsequently vindicated by the Agency for Healthcare Research and Quality that came to the same conclusion," referring to an evidence-based evaluation released in 1999.

According to the U.S. Attorney, TAP's sales representatives told Gerstein that he could use the grant for any purpose "whatever." The representatives also offered Tufts discounts on other products.

The government's investigation also included a civil False Claims Act suit filed in 1996 by TAP's former vice president of sales, Douglas Durand.

Durand, according to the federal government, quit his job at TAP out of concerns about the "illegal marketing conduct of some of TAP's employees.”

A federal grand jury returned an indictment charging six TAP managers with offering to give things of value—including free drugs, so-called educational grants, trips to resorts, free consulting services, medical equipment, and forgiveness of debt—to physicians and other customers to obtain their referrals of prescriptions for Lupron to Medicare beneficiaries, violating the antikickback law.

The government said TAP also violated the Prescription Drug Marketing Act (PDMA) of 1987 by giving physicians free samples of Lupron and then helping them get government reimbursements from the Medicare program.

As part of its civil allegations, the government alleged that TAP set its average wholesale price (AWP) for Lupron much higher than the average sales price offered to physicians and other customers and then marketed the spread between the discounted price and Medicare's reimbursement as an inducement to obtain business.

Government prosecutors alleged that TAP concealed from Medicare the true discounted prices paid by physicians for Lupron and that the company advised physicians to report the higher AWP rather than TAP's real discounted price for the drug.

"There's not a physician or a minister out there that doesn't want to buy low and sell high," Gerstein said.
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He said the government needs to restructure its payment system for Medicare part B.

Pricing. William J. Scanlon, director of health care issues for the General Accounting Office (GAO), testifying before Congress in September, described Medicare's method for establishing payments as flawed.

"Medicare pays 95 percent of the average wholesale price, which despite its name, may be neither an average nor what wholesalers charge," he said in written testimony. "It's a price that manufacturers charge using their own criteria; there are no requirements or conventions that AWP reflect the price of any actual sale of drugs by a manufacturer."

Scanlon said that, unlike the market-based fees paid by the Department of Veterans Affairs (VA) and other government agencies, Medicare's fees are based on AWP.

A September GAO report said Medicare's payments for drugs covered by part B, in some cases, are much higher than physicians' and other providers' actual costs.

The report also noted that physicians, specifically oncologists, argue that Medicare's payment to physicians for administering a drug does not adequately reimburse them and that they need drug payments from Medicare in excess of their actual costs to compensate them.

In opposition to that argument, Scanlon testified: "In our view, it should be a principle of Medicare payment policy to pay for each service appropriately and not to rely on overpayments for some services to offset inadequate payments for complementary services."

GAO "strongly" suggested that Medicare revise its drug payment policies.

The Centers for Medicare & Medicaid Services should consider how information on market transactions already available to the Department of Health and Human Services and VA may be used as a benchmark for Medicare payment levels, GAO suggested.

GAO found that Lupron accounted for 15.1% of Medicare drug spending in 1999.

Penalties. TAP agreed to plead guilty to a conspiracy to violate the PDMA and to pay a $290 million criminal fine.

The plea agreement between the government and TAP specifically states that the company's criminal conduct caused Medicare and Medicaid to lose $145 million, according to the U.S. Attorney.

TAP agreed to settle its federal civil False Claims Act liabilities and to pay the government more than $559 million. In addition, TAP agreed to settle its civil liabilities lawsuit for $25.5 million for failing to provide state Medicaid programs with its best prices.

As part of the settlement, TAP must comply with a corporate integrity agreement that says the company must significantly change the manner in which it supervises its marketing and sales staffs to ensure that the company will report true average sales prices for drugs to the government.

TAP President Thomas Watkins, in a statement, said that although his company "fundamentally" disagreed with many of the government's allegations, TAP resolved the matter to "make clear our commitment to proper and ethical business practices and to avoid protracted legal battles and ensure uninterrupted availability of Lupron for many thousands of patients who rely on it."

Watkins said TAP admitted that it provided free samples of Lupron to a number of physicians with knowledge that the physicians would seek and receive reimbursement.

"The billing for free samples is wrong, and it should never have happened," he said. "We have taken strong action so that this inappropriate marketing practice will never happen again."

Donna Young

International pharmacists group convenes in Singapore

More than 3000 people from 85 countries met September 1–6 in Singapore at the annual convention of the International Pharmaceutical Federation (FIP). Coincident with the two-day business meeting of the FIP Council was the World Congress of Pharmacy and Pharmaceutical Sciences 2001. This year’s main theme for the congress was Combining Practice and Science to Extend Horizons.

Policies approved by FIP Council. Delegates representing pharmacist organizations around the world voted to approve professional standards for electronic prescribing and labels on prescription medicine. Approval was also given to statements addressing pharmaceutical research in geriatric people, pharmacists' responsibility and role in teaching children and adolescents about medicines, and the effects of genomics on genetically-based medicine.

The statement of professional standards for electronic prescribing, or "e-prescribing" as it is called by FIP, was submitted by a task force created last year to examine the safety of drug information and products available over the Internet.

To ensure safe drug therapy, the statement says, a country's standards for electronic prescribing over the Internet must call for inclusion in every prescription at least the following information: patient identity, age, and sex; drug substance, strength, dosage, and quantity; directions for use; and prescriber's identity.

The requirement for inclusion of the pa...