



Assigned Reading for Susan Moyer's Students

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The New York Times

June 27, 2004 Sunday
Late Edition - Final

SECTION: Section 1; Column 1; National Desk; MEDICAL MARKETING --
Treatment by Incentive; Pg. 1

LENGTH: 1975 words

HEADLINE: As **Doctor Writes** Prescription, Drug Company Writes a Check

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BODY:

The check for \$10,000 arrived in the mail unsolicited. The doctor who received it from the drug maker Schering-Plough said it was made out to him personally in exchange for an attached "consulting" agreement that required nothing other than his commitment to prescribe the company's medicines. Two other physicians said in separate interviews that they, too, received checks unbidden from Schering-Plough, one of the world's biggest drug companies.

"I threw mine away," said the first doctor, who spoke on the condition of anonymity because of concern about being drawn into a federal inquiry into the matter.

Those checks and others, some of them said to be for six-figure sums, are under investigation by federal prosecutors in Boston as part of a broad government crackdown on the drug industry's marketing tactics. Just about every big global drug company -- including Johnson & Johnson, Wyeth and Bristol-Myers Squibb -- has disclosed in securities filings that it has received a federal subpoena, and most are juggling subpoenas stemming from several investigations.

The details of the Schering-Plough tactics, gleaned from interviews with 20 doctors, as well as industry executives and people close to the investigation, shed light on the shadowy system of financial lures that pharmaceutical companies have used to persuade

physicians to favor their drugs.

Schering-Plough's tactics, these people said, included paying doctors large sums to prescribe its drug for hepatitis C and to take part in company-sponsored clinical trials that were little more than thinly disguised marketing efforts that required little effort on the doctors' part. Doctors who demonstrated disloyalty by testing other company's drugs, or even talking favorably about them, risked being barred from the Schering-Plough money stream.

Schering-Plough says that the activities under investigation occurred before its new chief executive, Fred Hassan, arrived in April 2003, and that it has overhauled its marketing to eliminate inducements.

At the heart of the various investigations into drug industry marketing is the question of whether drug companies are persuading doctors -- often through payoffs -- to prescribe drugs that patients do not need or should not use or for which there may be cheaper alternatives. Investigators are also seeking to determine whether the companies are manipulating prices to cheat the federal Medicaid and Medicare health programs. Most of the big drug companies, meanwhile, are also grappling with a welter of suits filed by state attorneys general, industry whistle-blowers and patient-rights groups over similar accusations.

In many ways, the investigations are a response to the evolution of the pharmaceutical business, which has grown in the last quarter-century from a small group of companies peddling a few antibiotics and antianxiety remedies to a \$400 billion behemoth that is among the most profitable industries on earth.

Offering treatments for almost any affliction and facing competition in which each percentage point of market share can represent tens of millions of dollars, most drug makers now spend twice as much marketing medicines as they do researching them. Their sales teams have changed from a scattering of semiretired pharmacists to armies of young women and men who shower physicians with attention, food and -- until the drug industry recently agreed to end the practice -- expensive gifts, just to get two to three minutes to pitch their wares. A code of conduct adopted in 1990 by the American Medical Association suggests that doctors should not accept any gift worth more than \$100, but the guidelines are widely ignored.

A quarter-century ago, the Food and Drug Administration was the lone cop on the drug industry beat. But the F.D.A.'s enforcement powers over drug marketing have been severely curbed since 1976 by a series of court rulings based mainly on the companies' free-speech rights. That left a vacuum that many companies decided to exploit, said William Vodra, a former F.D.A. lawyer.

"A lot of people decided there was no check on what they were allowed to do," Mr. Vodra said. Using fraud, kickback and antitrust statutes, federal prosecutors, state attorneys general and plaintiffs lawyers stepped into the void, asserting that the

companies' sales pitches have cost the government billions of dollars in payments for drug benefits.

This legal scrutiny can be expected to intensify. Once the new Medicare drug benefit takes full effect in 2006, the government will pay for almost half of all medicines sold in the nation. So the marketing programs will cost the government even more money and, if they are uncovered and determined to be illegal, will probably result in even larger fines.

Last month, Pfizer agreed to pay \$430 million and pleaded guilty to criminal charges involving the marketing of the pain drug Nuerontin by the company's Warner-Lambert unit. AstraZeneca paid \$355 million last year and TAP Pharmaceuticals paid \$875 million in 2001; each pleaded guilty to criminal charges of fraud for inducing physicians to bill the government for some drugs that the company gave the doctors free.

Over the last two years, Schering-Plough, which had sales of \$8.33 billion last year, has set aside a total of \$500 million to cover its legal problems -- mainly for expected fines from the Boston investigation and from a separate inquiry by federal prosecutors in Philadelphia who are investigating whether Schering-Plough overcharged Medicaid.

Besides looking into whether Schering-Plough paid doctors large sums to prescribe the company's drug for hepatitis C, prosecutors are investigating whether many company-sponsored clinical trials for the drug were simply another way to funnel money to doctors.

Dr. Chris Pappas, director of clinical research for St. Luke's Texas Liver Institute in Houston, said that Schering-Plough "flooded the market with pseudo-trials."

Dr. Pappas and eight other liver specialists who were interviewed say the system worked like this: Schering-Plough paid physicians \$1,000 to \$1,500 per patient for prescribing Intron A, the company's hepatitis C treatment. In conventional clinical trials, participants are given drugs free, but the doctors said that in these cases the patients or insurers paid for their medication. Because patients usually undergo Intron A treatment for nearly a year and the therapy costs thousands of dollars, Schering-Plough's payments to physicians left plenty of room for the company to profit handsomely, the doctors said.

In return for the fees, physicians were supposed to collect data on their patients' progress and pass it along to Schering-Plough, the doctors said. But many physicians were not diligent about their recordkeeping, and the company did little to insist on accurate data, according to Dr. Pappas and the others.

One of the nation's most prominent liver disease specialists, who spoke on condition of anonymity for fear of angering big drug makers, called the trials "purely marketing gimmicks."

"Science and marketing should not be mixed like that," the doctor said.

Schering-Plough did more than encourage physicians to place patients on Intron A, many

of the physicians said. They said the company would remove any doctor from its clinical program -- and shut off the money spigot -- if he or she wrote prescriptions for competing drugs, participated in clinical trials of alternatives to Intron A or even spoke favorably about treatments besides Intron A.

The main competitor to Intron A, which Schering-Plough now sells as Peg-Intron, is Roche's comparably priced drug Pegasys.

Dr. Donald Jensen, the hepatology director at Rush University Medical Center in Chicago, said he wanted to perform clinical trials using drugs from both Schering-Plough and Roche. "I was told by Schering-Plough that I couldn't do both -- that I had to sign an exclusive agreement with them," Dr. Jensen said. "That was the juncture when Schering and I parted ways."

Six specialists in liver disease said Schering-Plough also paid what it called consulting fees to doctors to keep them loyal to the company's products. The letter accompanying a check for \$10,000 explained that the money was for consulting services that were detailed on an accompanying "Schedule A," said a doctor who insisted on anonymity. But when the doctor turned to the attached sheet, he said, "Schedule A" were the only words printed on an otherwise blank sheet of paper.

Dr. Pappas, who in the past has consulted for Schering-Plough and worked for Roche, said that stories about the enormous sums that Schering-Plough paid its consultants were common among liver specialists. "These were very high-value consulting agreements with selected opinion leaders that looked like payments of money with no clear agreements on what was supposed to be executed," Dr. Pappas said.

In an interview, Mr. Hassan and other top executives declined to discuss past marketing practices. Richard Kogan, the company's previous chairman and chief executive, declined to be interviewed.

Schering-Plough's current management says that much has changed at the company since Mr. Hassan took over. The company no longer allows sales representatives or marketing executives to have any say over its clinical trials, physician education or medical consulting, they said. And in all clinical trials begun in the last year, they said, drugs have been provided free to the enrolled patients, rather than being billed to them or their insurers.

"The temptation to give clinical grants to high prescribers and consulting agreements to high prescribers is why we pulled those decisions out of the hands of the sales representatives," said Brent Saunders, who was named senior vice president for compliance and business practices last year. "Sales representatives had an input into that process before, which I think is still fairly normal in the industry."

In the separate Philadelphia investigation, Schering-Plough is expected to plead guilty soon to charges that it failed to provide Medicaid with its lowest drug prices, as is

required by law, and to pay a fine. Investigators are examining whether Schering-Plough, to gain sales with some private insurers, offered premiums, such as free patient consulting arrangements, with its drugs. Prosecutors are arguing that such incentives had a market value and meant that Schering-Plough was offering drugs to private payers at prices well below those offered to Medicaid. Many other drug companies are the targets of similar inquiries.

The Boston inquiry into suspected kickbacks and improper marketing by Schering-Plough could take months more to resolve, people close to the investigation say. Schering-Plough may also be charged with obstruction of justice and document destruction as part of the Boston inquiry, according to the company's filings with securities regulators.

Industry experts say the federal inquiries into Schering-Plough and the other drug giants have led some companies to adopt significant changes in the way they peddle drugs to doctors. Other companies have been slower to react. "These investigations came out of left field, and no one saw them coming," said Peter Barton Hutt, a former F.D.A. general counsel who now advises drug companies. "The industry has since had to reshape entirely what they are doing, but it was too late to redo what they'd been doing for years."

Tony Farino, leader of the pharmaceutical consulting service at PricewaterhouseCoopers, said that as a result of the investigations many companies in the drug industry were hiring executives to police marketing and sales practices.

"Reputational risk is something they're all trying to manage," Mr. Farino said, "because the damages from failure can be significant."

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