Big Pharma Is Big Business

The Reagan administration's “war on drugs” was directed at halting the trafficking of illegal narcotics. During the Obama administration we have a drug problem of a different sort. Americans turn to prescription drugs as a way of medicating the effects of their unhealthy lifestyles. Poor nutrition habits, stress caused by work-family imbalances and personal financial problems, and a lack of physical activity have resulted in an epidemic of obesity, heart disease, diabetes, hypertension, and poor mental health. Rather than eating right, exercising daily, and turning to psychotherapy when necessary, many Americans prefer to medicate and mask their health problems through a plethora of prescription drugs that control cholesterol, acid reflux, heart attacks (antiplatelet agents), high blood pressure, and depression. Not surprisingly, these pharmaceuticals have become staples in the medicine cabinets of many U.S. consumers.

The burgeoning use of prescription drugs is fueled by the aggressive—and sometimes illegal—marketing and pricing tactics of the major pharmaceutical companies. During 2008 total sales for prescription drugs in the United States reached $291.5 billion, a 1.4 percent increase from 2007. And more important, U.S. consumers pay top dollar for their prescription drugs—well above what is paid by consumers in other industrialized countries. In 2008 European drug prices averaged 61 percent of the prices paid by U.S. consumers, and Japanese drug prices averaged 67 percent of the U.S. prices.

It is little wonder that the big pharmaceutical firms are so well-heeled. But every time a member of Big Pharma is accused of a fraudulent practice, the
federal government extracts a huge out-of-court settlement and the costs of the legal fees and the settlement amounts are passed on to the consumer in the form of higher drug prices.

**Read the Labels Carefully**

In its latest round of legal problems, one of the world’s largest pharmaceutical firms, Pfizer, was forced to cough up $2.3 billion to settle criminal and civil cases over the illegal, off-label promotion of four pharmaceuticals—the bipolar and schizophrenic treatment drug Geodon, the pain killer Bextra (withdrawn from the market in 2005), the antiepileptic drug Lyrica, and the infection-treatment drug Zyvox. Pfizer boosted its off-label promotions by wining and dining physicians at posh resorts—complete with golf and massages—all expenses paid. In the decade leading up to the record-breaking settlement, Pfizer paid off on three other settlements, including $430 million in off-label settlements in 2004 and $894 million to settle personal injury suits over Bextra and another pain-killer, Celebrex, which plaintiffs claimed caused cardiovascular damage. These settlements—as large as they are—will not bring down a company that had almost $48.3 billion in revenues and $8.1 billion in profits in 2008.3

The federal government’s second-largest pharmaceutical company settlement is the $1.4 billion dollar settlement imposed on Eli Lilly and Company in January 2009. Lilly agreed to the huge payout after it pleaded guilty to the off-label promotion of Zyprexa, a drug approved only for use by patients suffering from bipolar disorder and schizophrenia. But millions of people, including children in foster care, people having trouble sleeping, and nursing home patients may have also taken the drug. Prosecutors said that Lilly employed thousands of sales representatives in a widespread illegal-marketing campaign. The sales reps were “trained to use the slogan ‘five at five,’ meaning five milligrams at 5 o’clock at night will keep these elderly patients quiet,” said Laurie Magid, acting U.S. Attorney for the Eastern District of Pennsylvania. The drug had also been promoted illegally to treat conditions such as depression, anxiety, irritability, nausea, and gambling addiction. For certain patients, Zyprexa may have severe side effects, something that should have been revealed during the FDA testing and approval process. One patient started taking the drug for bipolar disorder when she was eighteen years old. In a matter of months, she ballooned from 93 pounds to 170 pounds, developed severe diabetes, and endured worsening depression. Although a $1.4 billion forced settlement sounds devastating, Lilly sold about $1.4 billion worth of Zyprexa in the first quarter of 2008 alone.4

As these cases illustrate, large-scale frauds occur in the pricing, marketing, and distribution of prescription drugs. Many of these frauds affect the Medicare
and Medicaid programs. Lewis Morris, chief counsel to the Inspector General, testified before the House Oversight and Government Reform Committee about waste, fraud, and abuse in the pharmaceutical industry.\textsuperscript{5} Between 1995 and 2005, Medicaid expenditures increased more than fourfold—from $8.9 billion to $41 billion. During the same time frame, according to Morris, Medicare drug expenditures increased from $1.4 billion to $10 billion. When Medicare Part D took effect in 2006, it created a spike in Medicare expenditures, temporarily boosting the annual rate of increase to 18.7 percent.\textsuperscript{6}

Fraud in prescription drug pricing sometimes involves the underpayment of Medicaid rebates to the states where the drugs are sold. As noted, the Medicaid program spends billions of dollars a year on outpatient prescription drugs. To control the cost of drugs dispensed through Medicaid, the Medicaid Drug Rebate Program was created by the Omnibus Reconciliation Act of 1990. Pharmaceutical manufacturers—about 550 to date—sign rebate agreements with the Secretary of Health and Human Services to sell drugs through the Medicaid program.

Pharmaceutical companies must pay quarterly rebates to state Medicaid programs based on their drug sales, and these rebates are shared with the federal government. Rebates are calculated for every covered prescription drug based on manufacturer-reported pricing data. The two key prices are the “best price”—the lowest price paid to the drug manufacturer by a specific purchaser—and the “average manufacturer’s price” (AMP)—the average price wholesalers pay manufacturers for drugs that are sold to retail pharmacies. Rebates are paid on both brand-name drugs (15.1% of AMP) and generic drugs (11.1% of AMP), or on the difference between the AMP and the best price per unit, whichever is greater. The drug prices are submitted by the pharmaceutical firms and posted by the Centers for Medicare and Medicaid Services.\textsuperscript{7}

Prices reported to Medicaid must include discounts provided by the manufacturer to health care providers. These discounts, if revealed, lower the actual AMP or best price and increase the amount of rebate that must be paid. Because these rebates amount to millions of dollars per year, pharmaceutical companies may try to avoid payment by concealing or disguising the true prices and rebate amounts. Pharmaceutical companies have disguised discounts to health care providers by structuring them as phony educational grants or as sham data processing fees. Fraud arises when a manufacturer submits an inflated AMP to the CMS that creates a “spread” between the lower purchase price of the drug paid by the provider and the higher amount reimbursed to the provider by the Medicaid program. This inflated, but disguised, spread serves as an effective backdoor marketing tool to encourage physicians to use the dishonest company’s drug. As Lewis Morris noted in the aforementioned congressional testimony, “The objective is always the same—the preferred customer gets a drug at a deep discount and the manufacturer avoids additional rebate obligations to the State Medicaid programs.”\textsuperscript{8}
King Pharmaceuticals was caught manipulating the prices of certain drugs and underpaying its Medicaid rebates to the states. Between 1994 and 2002, the Bristol, Tennessee, company failed to provide accurate reporting of its AMPs and best prices. When an employee expressed his concern to top managers about the company's low-balling of rebates, he was ostracized. Company managers excluded him from meetings and moved his office to a storage room with mold and leaky ceilings. As a result, he turned whistleblower under the False Claims Act. For this fraud, the company paid $124 million plus interest to settle claims with the federal and several state governments.

Fraud in the marketing of drugs may also violate the federal antikickback statute. Physicians often receive free drug samples from pharmaceutical manufacturers. This practice is legal as long as the physician dispenses the samples to patients at no charge. If a physician dispenses the complimentary pharmaceuticals to a patient and then bills Medicare or Medicaid for their cost, an illegal kickback has occurred. The Vaccines for Children program is a joint federal and state effort providing childhood vaccines free of charge to health care providers. Several civil and criminal suits have been settled because providers billed Medicaid for immunizations they had received at no charge. (The provider may, however, recover a small administrative fee for the inoculations.)

Switching drug prescriptions to exploit Medicaid reimbursement rules is another form of pharmaceutical fraud. Drug switching—also known as product conversion—may result in diminishing the efficacy of a patient's treatment or in exposing the patient to undesirable side effects. Omnicare, a nationwide institutional pharmacy serving nursing home patients exclusively, switched from generic Zantac (ranitidine) tablets to generic capsules to avoid both a federal payment upper limit established by the CMS and the “maximum allowable cost” set by state Medicaid programs. This fraud led to a $49.5 million settlement with the OIG. In a similar case, the Walgreen Company agreed to pay $35 million to resolve allegations that it dispensed capsules rather than tablets of generic Zantac and Prozac and brand-name and generic Eldepryl to Medicaid patients without a physician's consent. Forty-six states and Puerto Rico were expected to share the $16.4 million settlement. The federal portion of the settlement was $18.6 million, and the whistle-blower was awarded $5 million.

A pharmaceutical scam of more recent vintage is the growth of Internet pharmaceutical trafficking and abuse. Advances in information technology have made it possible for legitimate health care providers to have prescriptions ordered online, filled, and mailed to patients. Online drug purchases and express delivery are especially useful services for the elderly, the homebound, or those living in rural areas. Information technology has also made it possible for unscrupulous individuals to establish online pharmacies for the illegal distribution of controlled substances. A Minnesota resident was convicted of using the Internet to distribute more than
two million units of Schedule III controlled substances valued at $24 million. Two Iowa doctors who were employed by a corporation that operated Internet pharmacy websites received twenty-month prison sentences for conspiring to dispense Schedule III and Schedule IV controlled substances, primarily pain medications. Although the doctors supposedly reviewed patient questionnaire responses, neither had personally examined any of the patients before prescribing the drugs.

A Texas pharmacist was convicted of being a drug kingpin for his role in conspiring to dispense hydrocodone, a Schedule III controlled substance, through an Internet pharmacy operation. Customers on the websites filled out a medical questionnaire, requested the drug of their choice (usually hydrocodone), and paid a “doctor consultation fee” as well as a fee for the drugs. Three doctors received between forty and a hundred dollars per signed prescription, although they neither examined the patients nor turned down anyone for a prescription. One doctor even admitted he did not review responses to the patient questionnaires. This scheme was linked to the death of a California high school student who overdosed on Vicodin obtained by prescription from the Internet operation.

The federal Drug Enforcement Administration and the FBI, through Operation Cyber Chase, targeted major pharmaceutical traffickers who were selling and shipping controlled substances over the Internet. Using over two hundred known websites, these e-traffickers were selling narcotics, including amphetamines and anabolic steroids, without a physician’s prescription. According to FDA official John Taylor, “The medications may be coming from unknown sources, may not be stored or labeled properly, and may not meet quality assurance standards designed to produce safe and effective products. Many of the safeguards for brick and mortar pharmacies do not exist for Internet Pharmacies and the potential for harmful drug interactions is magnified.”

Eleven individuals were arrested in China and charged with manufacturing counterfeit Viagra, Cialis, and Lipitor. They had 600,000 counterfeit Viagra labels and packaging and 440,000 counterfeit Viagra and Cialis tablets in their possession, as well as 260 kilograms (about 572 pounds) of ingredients used to manufacture counterfeit pharmaceuticals. In addition to the DEA and FBI enforcement actions, Immigration and Customs Enforcement, the U.S. Postal Service, and Customs and Border Protection have become involved in the fight against rogue online drug dealers.

Major Pharmaceutical Frauds: Deep Pockets and Low-Hanging Fruit

Pharmaceutical firms are among the world’s wealthiest corporations. By July 2008, the ten largest pharmaceutical companies in the United States had annual
revenues ranging from $20.2 billion (Bristol-Myers Squibb) to $62.3 billion (Johnson & Johnson) and profit margins from approximately 20 percent (AstraZeneca) to 57 percent (Merck & Company). According to the Congressional Budget Office, the pharmaceutical industry spends more on research and development, relative to sales revenue, than almost any other industry. Estimates vary significantly, but R & D expenditures by major pharmaceutical firms may exceed $40 billion annually, with nearly 20 percent of company revenues being used to support the discovery and testing of new drugs. Bringing a new drug to market may require more than $800 million in R & D costs and over twelve years of developmental work. Once a drug passes FDA scrutiny, it is marketed to health care providers and consumers. Pharmaceutical firms often use aggressive sales campaigns to recoup R & D costs and to extract as much profit as possible from a drug before its patent expires and generic or superior drugs erode its market share.

The pharmaceutical firms discussed here provide examples of how the intense competition associated with the development, manufacturing, and marketing of drugs can create a criminogenic industry environment. Nine of the twenty largest False Claims Act settlements have been directed at pharmaceutical companies—although two of these settlements involved products other than drugs. The federal government has demonstrated a willingness to prosecute and impose tough sanctions on pharmaceutical firms.

**TAP Pharmaceutical Products: “Marketing the Spread,” Bribes, and Kickbacks**

TAP Pharmaceutical Products, originally based in Lake Forest, Illinois, was formed in 1977 as a joint venture between Abbott Laboratories, headquartered in Abbott Park, Illinois, and Takeda Chemical Industries of Osaka, Japan. As of July 2008, TAP became Takeda American Holdings with some 5,500 employees. The merger and restructuring activities during 2008 made Takeda one of the fifteen largest pharmaceutical companies in the United States. TAP was best known for Lupron, a drug used to treat prostate cancer, and Prevacid, a drug used to treat heartburn and related problems.

In October 2001, TAP agreed to pay $875 million to resolve criminal charges and civil liabilities arising from its drug-pricing schemes and marketing practices. TAP pleaded guilty and agreed to pay $290 million to settle charges of conspiracy to violate the Prescription Drug Marketing Act. The company also agreed to pay nearly $559.5 million to settle False Claims Act allegations of filing fraudulent Medicare and Medicaid claims. An additional $25.5 million was assessed against the company to compensate state Medicaid programs for losses caused by TAP’s deceptive drug-pricing and marketing activities. Furthermore,
TAP agreed to comply with a thirty-three-page corporate integrity agreement that changed the way in which TAP supervised its marketing and sales staff. It also required the company to submit reports on the true prices of its drugs to the Medicare and Medicaid programs.

Prior to the enactment of Medicare Part D, the only drugs subject to reimbursement were those that were injected under the supervision of a physician. Back in those days, Medicare paid patients the lower of either 80 percent of the urologist’s charge for Lupron or the average wholesale price of the drug (as set by TAP). Lupron is similar—in terms of its availability and efficacy—to a competing and significantly less expensive prostate cancer drug, Zoladex. Yet, Lupron mysteriously dominated sales and garnered about 80 percent of the market share.

The federal government claimed that TAP and other defendants—using the same deceptive-pricing strategy discussed earlier—concealed the inflated price spread of Lupron. By maximizing the difference between the Medicare reimbursement price and the price charged to physicians—a tactic known as “marketing the spread”—TAP was able to bolster sales by making it extremely profitable for physicians to prescribe the drug. This lucrative deal for physicians, of course, came at the expense of the Medicare program, its beneficiaries, and taxpayers. It also gave companies such as TAP a competitive advantage over pharmaceutical manufacturers that provided truthful pricing information. As noted, the major competing prostate cancer drug was Zoladex, sold by AstraZeneca. Ironically, in 2003, AstraZeneca entered into a $355 million settlement for similar conduct in the marketing and distribution of its prostate cancer drug. One has to wonder—given the timing of the case—whether AstraZeneca was trying to protect its market for Zoladex by fighting fire with fire.

The investigation of TAP began when Douglas Durand, the company’s senior sales officer, resigned after becoming concerned about the distribution of free samples of Lupron to physicians. Durand, who has been described as a “straight arrow,” tried unsuccessfully during his short tenure at TAP to control the flow of free samples from TAP sales representatives to physicians. Not wanting to get mixed up in wrongdoing, Durand resigned in 1995 and filed a whistle-blower suit against the company in 1996. Also in 1996, Dr. Joseph Gerstein, the medical director for pharmacy programs at the Tufts Associated Health Maintenance Organization in Waltham, Massachusetts, reported to the U.S. Attorney’s Office in Boston that he had been offered a generous educational grant if he agreed to include Lupron in the institution’s formulary, even though Zoladex cost each patient about $1,200 less per year than the equivalent dosage of Lupron. Dr. Gerstein began working with the FBI and the OIG, and he agreed to participate in a series of secretly taped meetings with two TAP managers from the Boston area.

The criminal and civil investigation of TAP involved several federal agencies, including the FBI, the OIG, the Food and Drug Administration, the Department of Defense, and the Department of Justice. TAP’s criminal fine of $290 million
was earmarked for the Department of Justice's Crime Victims Fund, which provides services for victims of violent crime. For their roles as whistle-blowers in the case, Durand received $77 million and Gerstein and Tufts shared $17 million.

In a postsettlement statement, Assistant Attorney General Robert D. McCal- lum Jr., noted:

The Medicare and Medicaid drug programs are bulwarks against the financial hardship that can be caused by the need for life-saving medical treatments. These programs cannot afford abuses that enrich doctors or drug companies at the expense of taxpayers and patients. This settlement agreement and the compliance steps that TAP has agreed to take will reinforce the government's long-standing objective of paying Medicare and Medicaid providers for the reasonable costs of the drugs they administer.

According to U.S. Attorney Michael J. Sullivan:

The urologists and the TAP employees who knowingly participated in this broad conspiracy took advantage of older Americans suffering from prostate cancer. The indictment unsealed today alleges that TAP employees sought to influence the doctors' decisions about what drug to prescribe to patients by giving them kickbacks and bribes, from free samples to free consulting services to expensive trips to golf and ski resorts to so-called educational grants. In all instances where the kickbacks worked to ensure the prescription of TAP's product Lupron, the Medicare Program and the elderly Americans suffering from prostate cancer paid more for their care than if the doctor had prescribed the competitor's product. The payment by TAP of nearly $900 million including the highest criminal fine ever imposed on any healthcare company [at that time], and the indictment of the other six TAP employees sends a very strong signal to the pharmaceutical industry that it best police its employees' conduct and deal strongly with those who would gain sales at the expense of the health care programs for the poor and the elderly and the persons insured by those programs.30

Thomas Watkins, president of TAP, had a different perspective on the settlement. He said that even though TAP "fundamentally disagreed" with the allegations, the company decided to settle the case because the federal government had threatened to stop all reimbursements for Lupron. At the time, those reimbursements amounted to about $450 million annually. Watkins added: "We could not afford to have this drug denied to our patients."31

A federal grand jury also returned indictments against a Massachusetts urologist and six TAP managers for conspiring to pay kickbacks to doctors and other customers, conspiring to defraud state Medicaid programs regarding the best
price of their products, and conspiring to violate the Prescription Drug Marketing Act. The latter charge pertained to billing Medicare for drugs supplied free of charge to physicians. Hundreds of Medicare beneficiaries were billed for thousands of free samples of Lupron in violation of the Prescription Drug Marketing Act. Four other physicians, all urologists, had earlier entered guilty pleas in connection with the above practices. The indictment against the seven defendants also claimed TAP offered kickbacks, free drugs, payments disguised as educational grants, vacations at golf and ski resorts, travel expenses to conferences, office Christmas parties, medical equipment, forgiveness of debt, free consulting services, and discounts on Lupron sold to treat endometriosis in women (in addition to its use as a prostate cancer drug).

The trial that began on April 20, 2004, named eleven current and former TAP officials, who were charged individually with defrauding the government by bribing physicians and hospitals to purchase Lupron. Federal prosecutors amassed evidence to show that six hospitals, two health plans, twenty-six group practices, and twenty-five individual doctors were offered or accepted bribes, including cash, free drugs, and tickets to major league baseball games. The Yale-New Haven Hospital was accused of accepting $10,000 from TAP to fund a seminar for urologists and—more to the point—to ensure their continued purchase of Lupron. A urology practice associated with New England Deaconess Hospital in Boston supposedly received 111 free doses of Lupron worth over $44,000. Doctors then billed Medicare for the distribution of these drugs to patients, an arrangement that was essentially a cash kickback from TAP. A TAP district manager who had pleaded guilty earlier to conspiracy to commit fraud oversaw an $11,000 write-off of a physician's debt to the company when he agreed to switch his patients to Lupron. Another doctor had his debt to TAP expunged, and he also received an educational grant, a television, and a VCR player from the company.32

The trial was expected to last six months, but it was completed in less than half that time. A federal jury acquitted eight of the eleven named individuals. Two of the defendants had been acquitted by U.S. District Court Judge Douglas P. Woodlock before the case went to the jury, and charges against a third defendant (who was very ill) were dropped by the government.

TAP's defense lawyers argued that the government's confusing drug-marketing rules made it difficult for the company's sales representatives to know when they were breaking the law. They also said drug firms often feel compelled to settle out of court to avoid being driven out of business. A trial and a guilty verdict against a pharmaceutical firm could result in ruinous criminal and civil payments and banishment from Medicare, Medicaid, and other federal programs. Another attorney suggested that the government—its confidence soaring after the earlier settlement with TAP—overreached in prosecuting individual TAP employees. James Moorman, executive director of Taxpayers Against Fraud, however, called
the verdict a travesty: “The jury has given the big wink to ripping off the old, poor, and sick in this country.” Moorman noted, in referring to the earlier settlement, that “at least we got the money back.” An attorney who represents pharmaceutical firms opined: “In its instructions to the jury, the court distinguished between improper conduct and cultivating a business relationship with a physician in the hope or expectation that prescriptions might occur.” He indicated this verdict could clarify important issues and provide guidance in future cases.

Serono: Extending the Product Life Cycle of an Outmoded Drug

Serono, a Switzerland-based corporation, together with its U.S. subsidiaries agreed to pay $704 million on October 17, 2005, to resolve criminal and civil charges of using illegal methods to promote, market, and sell Serostim, a drug used to treat severe, involuntary weight loss in AIDS victims (a condition known as “AIDS wasting”). The $704 million settlement included a $136.9 million criminal fine and a $567 million payment for civil liabilities. At the time, this case marked the third-largest health care fraud recovery by the U.S. government.

Company officials pleaded guilty to two felony counts—conspiracy to distribute an unapproved and adulterated medical device and conspiracy to pay health care providers to write Serostim prescriptions for Medicaid patients. The civil complaints indicated that Serono sales representatives used a diagnostic test not approved by the FDA and that they manipulated the results of the unapproved test to advance the sales of Serostim. Furthermore, Serono was accused of promoting false and fraudulent claims against Medicaid.

The Serono case was precipitated by the shortened product life cycle of one of its premier drugs, the AIDS-fighting Serostim. Products (and services) follow a life cycle. A product first enters the market and then, if successful, its sales grow. The sales, however, eventually reach a plateau as the market for the product becomes saturated and mature. The demand for the product subsequently declines as its patent expires or as its markets change or as it is rendered obsolete by newer products. A product life cycle may last only a few months—as might be the case for a piece of computer software that quickly becomes outmoded—or it may last for decades—as might be the case with a popular make and model of automobile.

The federal government’s investigation of Serono began in 2000 when employees in Massachusetts, Connecticut, and Maryland filed False Claims Act suits against the company. The investigation focused on the company’s attempt to preserve its market for Serostim after the drug was rendered largely obsolete by the introduction of protease inhibitor drugs. Protease inhibitor drugs curtailed the progress of the AIDS syndrome to the point where severe weight loss was no longer a major cause of death among patients.
Motivated to recapture their investment in a drug that had once commanded a $21,000 price tag for a six-week treatment regime, the company established a joint venture with RJL Sciences to market a “bioelectrical impedance analysis” computer software package. This venture into uncharted territory created two problems. First, the bioelectrical impedance analysis software had not been approved by the FDA. Second, it redefined what constituted AIDS wasting. Instead of measuring changes in a patient’s weight and lean body mass, it defined AIDS wasting based on changes in a patient’s body cell mass.

To further promote Serostim sales to physicians, Serono Labs offered them an all-expense paid trip to Cannes on the French Riviera to attend a medical conference on nutrition and HIV infection. Doctors accepting this offer were expected to write thirty new prescriptions for Serostim, generating revenues of $630,000 from each participating physician (i.e., thirty patients at $21,000 per prescription). Serono pressured the company sales representatives to offer financial incentives to high prescribers of Serostim. Under its 6m–6 Day Plan, the representatives were directed to generate $6 million in Serostim sales within six days. According to U.S. Attorney Michael Sullivan in Boston, 85 percent of Serostim prescriptions were unnecessary. These supposedly needless prescriptions amounted to some $615 million in sales for Serono. Sullivan told reporters the medical testing procedure was “almost voodoolike” and that he suspected some patients may have suffered side effects from the drug.

Serono signed a corporate integrity agreement that focused on the company’s marketing practices and on the training of its sales representatives. Other provisions included oversight, corporate monitoring, and transparency in communications. The latter provision placed special attention on the relationship between the company’s sales representatives and the doctors with whom they did business. Emphasis was also placed on the off-label uses of Serono’s products. For example, Serono was required to document all unsolicited requests for information regarding the off-label use of Serostim. The company also had to examine the geographical distribution of these requests to determine whether patterns of suspicious usage existed. One such pattern linked bodybuilders to the illegal use of Serostim; the drug that helped AIDS patients to regain weight also helped bodybuilders gain muscle mass.

The settlement of this case occurred less than four months before Medicare Part D went into effect. The timing of this settlement probably contributed to the federal government’s later scrutiny of Medicare drug reimbursements. “Americans who need medical care depend on health care companies to have their medical devices and drugs thoroughly evaluated and approved before use,” said then Attorney General Alberto R. Gonzales. He added, “Serono abused the system of testing and approval, and put its desire to sell more drugs above the interest of patients. Today’s settlement will repay with interest the losses to federal
and state Medicaid programs incurred by Serono’s conduct, and would-be wrongdoers are on notice that we will not tolerate attempts to profit at the expense of the ill and needy in our society.”

Assistant Attorney General Peter Keisler of the U.S. Department of Justice Civil Division noted: “This settlement sends the unequivocal message to the health care industry that American taxpayers should not pay for prescriptions induced by unproven medical tests and improper payments to doctors and pharmacies.”

Serono was acquired for more than $13 billion in 2006 by Merck KGaA, a German pharmaceutical and chemical company (not to be confused with the American Merck & Company, which became independent of the German company in 1917). In May 2007, four Serono executives were exonerated by a Boston federal district court jury of charges they bribed doctors to prescribe drugs for AIDS patients. This case was eerily similar to the TAP Pharmaceuticals case that resulted in the acquittal of eleven individuals. Attorneys for the four Serono defendants said the federal government had been leaning too hard on the pharmaceutical industry. “The jury’s verdict once again says this U.S. Attorney’s office has been overreaching on pharmaceutical cases,” said Tracy Miner, an attorney who represented one of the former Serono employees and who had previously defended a TAP executive. “It’s another case where the office has inappropriately charged employees of a pharma company who did nothing more than their jobs,” Miner said. “This is a case that never should have been brought, and the speed of the jury’s verdict confirms it,” said defense attorney Adam Hoffinger.

The Purdue Frederick Company: The Misbranding of OxyContin

The Purdue Frederick Company and Purdue Pharma (known hereafter as Purdue) are part of a worldwide group of pharmaceutical businesses. The company has been an industry leader in developing sustained-release medications to manage pain. Its zealousness in boosting the sales of pain management products, however, led to problems with the FDA and to allegations of fraud.

On May 10, 2007, the U.S. Attorney for the Western District of Virginia announced that Purdue, along with three of the company’s executives, had agreed to pay more than $634.5 million to settle charges that they misbranded Purdue’s OxyContin drug. OxyContin is a Schedule II prescription pain relief medication with the highest potential for abuse. It is prescribed primarily for moderate to severe pain. Because of its euphoric effect, OxyContin has also become a favorite drug of narcotics abusers. The drug has been dubbed variously by street users as “Oxy,” “OC,” “Oxycotton,” “Killer,” and “Hillbilly Heroin.” Its popularity has led to armed robberies of pharmacies, forged prescriptions, and thefts from patients with legal prescriptions for the drug. Abuse of OxyContin has resulted
in hundreds of deaths and countless emergency room visits. Multiple prescriptions of OxyContin have also been obtained by doctor-shopping drug abusers.

Between January 1996 and June 2001, federal prosecutors claimed that Purdue's sales supervisors and employees told health care providers that OxyContin was a safe pain medication, even though they knew it was highly addictive and had a strong potential for abuse by users. Company representatives used misleading graphs to exaggerate the differences between blood plasma levels achieved by OxyContin and blood plasma levels of other pain-relief medications. Although the graphs distorted the “peak and trough” blood-level effects of the drugs, they became part of Purdue’s sales-training programs.

Purdue also sponsored a study on the use of OxyContin in osteoarthritis patients. The results of the research were published in the March 2000 issue of the Archives of Internal Medicine. Eight coauthors contributed to the article: a PhD and seven medical doctors. The PhD was the only contributor, however, who was listed as an employee of Purdue Pharma. The authors noted clearly that oxycodone (the generic form of OxyContin) created side effects in patients: “Common opioid-related side effects were reported during CR [controlled release] oxycodone therapy, several of which decreased in duration as therapy continued. Patients’ ability to function was not compromised during short- and long-term treatment with CR oxycodone.”

Three months after the article was published, the marketing group at Purdue provided each sales representative with a copy along with a “marketing tip” for using its findings to achieve sales success. According to prosecutors, Purdue sales representatives distributed copies of the Archives of Internal Medicine article to health care providers to mislead them into believing that doses smaller than 60 milligrams per day could be terminated abruptly without inducing withdrawal symptoms. Purdue’s position was bolstered by citing two sentences from the article: “There were 2 reports of withdrawal symptoms after patients abruptly stopped taking CR oxycodone at doses of 60 or 70 mg/d. Withdrawal syndrome was not reported as an adverse event during scheduled respites, indicating that CR oxycodone at doses below 60 mg/d can be discontinued without tapering the dose if the patient’s condition so warrants.”

The prosecutors contended that, despite this finding, Purdue representatives knew of other studies that placed OxyContin in a less favorable light. These studies indicated the drug caused patient dependency and withdrawal symptoms. Nevertheless, Purdue decided not to publicize the unfavorable findings. According to the settlement summary issued by the U.S. Department of Justice, Purdue associates “were well aware of the incorrect view held by many physicians that oxycodone was weaker than morphine, they did not want to do anything ‘to make physicians think that oxycodone was stronger to [sic] or equal to morphine’ or to ‘take any steps in the form of promotional materials, symposia, clinical, publications, conventions, or communications with the field force that would affect the unique position that OxyContin had in many physicians’ minds.’”
Purdue also claimed the drug was less susceptible to intravenous abuse by street users because of the difficulty in extracting oxycodone from an OxyContin tablet. This claim was contradicted by Purdue's own study, which found that a drug abuser could extract approximately 68 percent of oxycodone by crushing a 10 mg. OxyContin tablet, stirring it in water, and drawing the solution through cotton into a syringe. By March 2000, Purdue was aware of OxyContin abuse in various communities, but the company reportedly made no effort to change its marketing strategies in response to that threat.52

Purdue and the three executives admitted that the company marketed controlled-release OxyContin by making unsubstantiated claims that it was less euphoric, less addictive, less subject to abuse, and less likely to cause withdrawal symptoms than short-acting opium-based pain medications. Purdue's payments to settle the OxyContin allegations included $276.1 million forfeited to the U.S. government, $160 million paid to the federal and state governments to resolve false claims liabilities against Medicaid and other programs, $130 million allocated to resolve private civil claims, $5.3 million to the Virginia Attorney General's Medicaid fraud control unit to fund further health care fraud investigations, $20 million to fund the Virginia prescription monitoring program, and a criminal fine of $500,000. The three Purdue executives paid a total of $34.5 million, and each was required to pay a $5,000 criminal fine.

"Purdue put its desire to sell OxyContin above the interests of the public," said Assistant Attorney General Peter D. Keisler. "Purdue abused the drug approval process which relies on drug manufacturers to be forthright in reporting clinical data and, instead, misled physicians about the addiction and withdrawal issues involved with OxyContin."

"Purdue's illegal sales and marketing practices concealed information from patients and many health care providers regarding the potency and abuse potential of OxyContin for corporate profit," said Daniel R. Levinson, Inspector General for the U.S. Department of Health and Human Services.53

OxyContin now comes with a black box warning identifying it as a Schedule II substance and cautioning users of its addictive effects. The warning indicates the drug is to be taken only by opioid-tolerant patients. It also contains strict instructions not to break, chew, or crush the tablets. To do so, alters the controlled-release mechanism in the tablets, which could cause a rapid release and potentially fatal absorption of the drug.

**Schering-Plough Corporation: Another Repeat Offender**

Schering-Plough Corporation (Schering-Plough) is a global health-care company manufacturing prescription, consumer, and animal health products as well as advanced drug therapies. The Kennilworth, New Jersey, company had
$12.7 billion in net sales in 2007, with approximately 55,000 employees doing business in more than 140 countries. As is the case with most pharmaceutical firms, Schering-Plough invests heavily in research and development. In 2007 its R & D investments were $2.9 billion (22.8% of net sales) for research in cardiovascular disease, central nervous system disorders, immunology and infectious diseases, oncology, respiratory disease, and women's health. The first decade of the twenty-first century marked a litigious period in the life of Schering-Plough. In 2002 the company agreed to pay $500 million to the government for failing to comply with federal manufacturing guidelines and for failing to address defects in its drug-manufacturing processes. Problems at Schering-Plough facilities in New Jersey and Puerto Rico included the use of outdated equipment and inadequate controls to identify faulty medicines. Some two hundred pharmaceuticals were involved in the substandard-manufacturing processes, including the allergy medicine Claritin and the lung-development drug Celestone used by infants. Two years earlier, Schering-Plough was forced to recall millions of asthma inhalers because of a possible missing ingredient. According to the FDA:

The government's action in this case follows 13 inspections at four New Jersey and Puerto Rico facilities since 1998 during which [the] FDA found significant violations of the CGMP [current good manufacturing practice] regulations related to facilities, manufacturing, quality assurance, equipment, laboratories, and packaging and labeling. The decree requires the companies to pay $471,500 to cover the costs of these inspections. The defendants have had a history of failing to comply with CGMP requirements at these plants, which produce about 90 percent of the firm's drug products. The decree affects about 125 different prescription and over-the-counter drugs produced at the Puerto Rico and New Jersey facilities. As part of the decree, the company has agreed to suspend manufacturing 73 other products.

Schering-Plough reached an almost equally devastating settlement in July 2004 after three former employees of one of the company's subsidiaries filed whistle-blower charges. It agreed to pay $345.5 million ($52.5 million in criminal penalties and almost $293 million in civil penalties) to resolve allegations by the government of manipulating prices to overcharge the Medicaid program. The three employees received over $31.6 million as their share of the settlement.

At the center of the case was Claritin, Schering's top-selling allergy drug during the late 1990s. Schering's major competition was Allegra, a significantly less-expensive allergy medication. The company was being pressured by two of its largest managed-care accounts, Cigna Healthcare and Pacificare Health Systems, to reduce its price for Claritin; otherwise, they threatened to drop Claritin from their formularies in favor of Allegra. Schering-Plough, however, faced a major
dilemma: if it reduced the price of Claritin to Cigna and Pacificare, it would be forced to report a lower best price to Medicaid and to pay a higher rebate to state Medicaid programs.

Schering-Plough devised a strategy to play both ends of the problem. To retain Cigna's business, Schering provided a $1.8 million “data fee,” $3 million worth of deeply discounted Claritin reditabs, below market value health-management services, and prepaid rebates (in essence, an interest-free loan). To retain Pacificare's business, Schering arranged to cover a portion of the managed-care customers' respiratory-drug costs, deep discounts on other Schering products, payment and services for Internet development, and an interest-free loan in the form of prepaid rebates. As noted, a pharmaceutical firm is supposed to include customer discounts when reporting its best price of a drug to Medicaid. By failing to do so, Schering-Plough strengthened its sales of Claritin and short-changed the Medicaid program.

In addition to monetary penalties, Schering-Plough entered into a corporate integrity agreement to monitor its sales and marketing programs. Schering Sales Corporation was also excluded from participation in all federal health care programs for at least five years. A U.S. Attorney described the case as “a very byzantine and complex fraud”; he said the concessions Schering-Plough gave to Cigna amounted to “nothing more than an old-fashioned kickback... a clear payment for nothing.”

Even-numbered years seemed to have been especially harsh for Schering-Plough. In 2006 the company once again had to pay a huge settlement—some $435 million—to settle charges for marketing improprieties and for misreporting its best price for drugs to the federal government. The settlement was the culmination of a lengthy investigation by federal agencies. The Department of Justice alleged that Schering-Plough illegally promoted the off-label use of the drugs Temodar and Intron A. Although the company said that such promotions were isolated incidents, the federal government claimed the Schering sales force was trained and paid to sell drugs to physicians for off-label uses.

In exchange for their commitment to prescribe the company’s medications, physicians were paid for participating in clinical trials and for serving on sham advisory boards. According to the New York Times, one physician received an unsolicited $10,000 check from Schering-Plough and others received remuneration in the six figures. The Times described the practice of paying high-prescribing doctors to conduct clinical trials as little more than a thinly disguised marketing effort. One Texas physician said that Schering-Plough “flooded the market with pseudo trials.”

Clinical trials performed by working physicians instead of by research laboratories may not adhere to rigorous research protocols. Scientifically sound pharmaceutical trials require blind experimental and control (placebo) groups,
proper categorization of patients (e.g., by gender, age, health status, and so forth), correct sampling procedures, regulation of the environment in which the drug is administered, precise measurements of the dosage and the effects of the drug, and meticulous record keeping. Busy—and often overworked—physicians with little or no knowledge of pharmaceutical research are ill-equipped to conduct trials yielding scientifically useful results. As the Texas physician commented, “Science and marketing should not be mixed like that.”

Physicians as Consultants: A Money Trail to Fraud and Corruption?

The conflict of interest cultivated by the relationship between pharmaceutical and medical equipment companies and physicians goes well beyond the Schering-Plough case. The New England Journal of Medicine published an article in April 2007 that provided survey results from 3,167 physicians across six medical specialties about their relationship with pharmaceutical and medical equipment manufacturers. The survey revealed that approximately 94 percent of practicing physicians in the United States had gift-exchange relationships with pharmaceutical and equipment manufacturers, but the extent of those relationships varied significantly. Most doctors accepted food or prescription samples; one-third of the respondents received reimbursements for professional meetings and educational programs; and more than one-fourth received honoraria for consulting, lecturing, or enrolling patients in clinical trials. Astute sales representatives from pharmaceutical and medical equipment companies clearly understood the need to foster ties with physicians—the so-called opinion leaders—who were especially influential among their colleagues and who had the authority to make major purchasing decisions.

The survey also showed major differences in the closeness of the business-physician relationships by medical specialty and by health care arrangement. Cardiologists appeared to have stronger ties to drug and equipment firms than did pediatricians, anesthesiologists, family practitioners, or surgeons. A physician working in a group practice was three times more likely to receive a gift and four times more likely to receive a consulting fee for professional services than was a physician working in a hospital. Compared to earlier studies, the New England Journal of Medicine article suggested that business ties between pharmaceutical companies and physicians were becoming more common.

Another set of ties is the relationship between the pharmaceutical firms and the seven hundred thousand or so physicians practicing in the United States. About 725 accredited providers offer roughly one hundred thousand continuing medical education classes—many of them online—for physicians seeking state-mandated ongoing certification. The key concern, of course, is whether these classes are educational or whether they are a backdoor way of marketing
pharmaceuticals. Courses on smoking cessation, premenstrual syndrome, restless legs syndrome, female hypoactive sexuality, and migraine headaches are among those available through pharmaceutical firms. Not surprisingly, accusations have been made that these companies are concerned primarily with promoting their drugs by emphasizing the positive results and downplaying or ignoring the risks they may present to consumers. And, of course, no mention is usually made of the cost or efficacy of competing pharmaceuticals. The University of Wisconsin–Madison, for example, offered a smoke-cessation course to physicians. The course promoted Pfizer’s Chantix—a drug that has been linked to serious side effects such as depression, agitation, suicidal behavior, and blackouts. In fact, the FAA has banned its use by pilots and air traffic controllers. But none of these problems were mentioned in the Wisconsin course. Pfizer funded the course to the tune of $12.3 million, with $3.5 million going to the university. “Drug companies have essentially hijacked the highest level of medical education we have in this country,” according to Daniel Carlat, an associate clinical professor of psychiatry at Tufts University. Carl Elliott, a professor of bioethics at the University of Minnesota Medical School, said, “American doctors are the best paid doctors in the world. To hear them plead poverty and say they can’t pay for their own education is the height of hypocrisy.”

Although conflicts of interest are inevitable, it is often difficult to distinguish between business relationships that enhance patient care and those that work against the best interests of patients. A Massachusetts anesthesiologist was the subject of a federal investigation in the spring of 2009 for possibly distorting the results of at least twenty-one studies of painkillers involving three major pharmaceutical firms. Medical-device maker Stryker has been targeted by the New Jersey Attorney General regarding compensation the company paid to doctors for participating in the clinical trials. If the allegations are true, the Massachusetts case seems to be a clear case of fraud. But what about paying doctors to perform research that is potentially beneficial? When does the gift-exchange relationship go too far?

One recent controversy involves questionable consulting relationships between medical school faculty—especially psychiatrists—and pharmaceutical manufacturers. Medical school professors and their associates are involved heavily in research, and they frequently have access to state-of-the-art laboratories and multimillion dollar grants from federal funding sources such as the National Institutes of Health. Researchers in all scientific disciplines are expected to adhere to rigorous methodology and to maintain absolute objectivity in analyzing the results of their work. This objectivity cannot be eclipsed by the personal financial interests of those performing the research.

Potential conflicts of interest between the pharmaceutical industry and the academic community have caught the eye of—once again—Iowa Senator Charles
Senator Grassley sent a letter to the American Psychiatric Association questioning its financial links to the pharmaceutical industry and demanding that the APA account for its revenues. According to the New York Times, the APA's revenues in 2006 were $62.5 million, and as much as 30 percent of it may have come from the pharmaceutical industry. The key question, of course, is whether psychiatrists at some of the nation's leading universities have developed unethical consulting relationships with drug companies. According to the Los Angeles Times, "At issue is the safety and efficacy of the stream of new drugs undergoing clinical trials." And the New York Times noted, "Studies have shown that researchers who are paid by a company are more likely to report positive findings when evaluating that company's drugs."

Universities and government agencies providing research grants often require faculty to report income derived from sources outside their institution. But professors at some of the top U.S. medical schools have come under the gun for their failure to disclose payments received from pharmaceutical companies and equipment manufacturers. A University of Minnesota Medical School department head was called on the carpet by Grassley for failing to reveal $1.2 million in consulting fees and honoraria from medical-device maker Medtronic. Grassley aimed another of his mud pies at an Emory University psychiatrist who failed to disclose hundreds of thousands of dollars in payments from pharmaceutical companies. Emory acted decisively and imposed severe sanctions that included removing him from his position as department head, barring him from receiving grants from the National Institutes of Health for two years, and requiring him to report outside income to the school. Grassley said, "Accurate disclosure and transparency are fundamental to the integrity of medical research. Without them, the public trust is violated and public confidence in the system is legitimately shaken."

Concern, for example, has been raised regarding a possible skewing of the clinical trial outcomes of a popular antiseizure drug. But suspecting that something is amiss is one thing, proving it is another. Dr. Steven Nissen, chairman of Cardiovascular Medicine at the Cleveland Foundation, in Ohio, put it this way: "The reality is that a deliberate fraud is extremely difficult to unearth. If scientists and companies agree to report results in a way that wasn't originally intended, unless you have access to original documents, it is extremely difficult to actually figure out what happened and how it happened."

Grassley continued his pursuit of benefactor drug and device makers by sending letters to the American Medical Association (AMA), the American Cancer Society, and thirty-one other medical-advocacy organizations, asking them to provide details on the amount of money they receive from these companies. Earlier, Grassley sent a similar letter to the National Alliance on Mental Illness. The group reported that over two-thirds of its donations came from
the pharmaceutical industry, a revelation that prompted one board member to resign.71

Stanford University School of Medicine leaders have instituted a policy restricting the drug industry's ability to influence its continuing education programs for physicians. Donations by pharmaceutical firms can no longer be used to finance designated courses at Stanford. Instead, the funds are placed in a schoolwide pool of money and applied to whatever classes the faculty deems appropriate—not the classes supported by a specific company. Stanford's policy is similar to those used at several other medical schools, and it shields faculty from potentially biasing commercial influences.72 But actions may ultimately speak louder than words. Stanford accepted a fully disclosed, "no strings attached" $3 million grant from the pharmaceutical giant Pfizer to use for whatever purpose the medical school designated. Not surprisingly, the arrangement produced a great deal of skepticism from outsiders. According to Harvard professor emeritus Arnold S. Relman, for example:

If it is true—a big, big, if—but if it is true that this money is being given without any strings at all and without any obligation on the part of Stanford to please Pfizer, then it's arguable that it's OK. But it's just not a good idea for a profession that says it wants to be independent and trusted, a reliable source of information to the profession and the public about drugs, to take money from the drug company under any conditions.73

Pharmaceutical manufacturers have paid physicians to "write" articles promoting the off-label uses of their products when, in reality, these articles were ghostwritten by the manufacturer. Merck & Co. allegedly used ghostwriters to develop an article about its drug Vioxx, which was published in the highly reputable Journal of the American Medical Association.74 These promotions—if based on bad research—not only circumvent the FDA drug-approval process and provide potentially false or misleading information to physicians, but they also pose a danger to patient health and safety.75 In May 2008, Merck reached a $58 million settlement over allegations that Vioxx advertisements played down the health risks of the drug. As part of the settlement, Merck agreed to stop using ghostwriters to promote the off-label uses of their drugs in medical journals.76 Similarly, between 1998 and 2005, drug maker Wyeth paid ghostwriters to prepare dozens of journal articles on hormone replacement therapy that were published under physicians' names.77

The editors of major medical journals have begun to probe authors' backgrounds to uncover conflicts of interest between writers and corporations. Twelve leading medical journals are requiring authors to complete a disclosure
form that reveals things such as board memberships, employment, consulting and expert witness work, grant applications and funding, honoraria and gifts received, patents and royalties, educational and speaking engagements, stock ownership, and travel paid by others. The form was developed, in part, as a response to a 2004 report by the Center for Science in the Public Interest. The report found that 14 percent of scientific-journal articles included unreported financial conflicts of interest.78

Pressure is likely to continue for the establishment of a national registry where pharmaceutical and other companies must post payments made to physicians. The previously discussed Physician Payments Sunshine Act and its planned registry is a major step in that direction. Prohibitions on the gift-exchange relationship among pharmaceutical firms, equipment manufacturers, and physicians are also on the horizon. The Wisconsin Medical Society's board voted in favor of banning all gifts to preclude conflicts of interest between physicians and outside commercial interests. The ban forbids Wisconsin doctors from serving on a company's speaker bureau and from serving as authors of articles written by health-product companies.79 The Association of American Medical Colleges has issued a report, “In the Interest of Patients: Recommendations for Physician Financial Relationships and Clinical Decision Making.” The thirty nine-page document provides guidance to academic medical centers on navigating through the maze of conflicts of interest that can arise in clinical care settings.80 The Harvard Medical School has revised their conflict-of-interest policy into one that might serve as a model for other medical schools, and the University of Michigan Medical School will no longer take money from pharmaceutical and medical equipment manufacturers for the school's continuing medical education programs.81

Some Examples of Fraud in the Medical Supply and Equipment Industry

As with the multibillion-dollar pharmaceutical industry, medical supply and equipment companies can be extremely aggressive in the way they price and market their products. Some of these companies not only run afoul of the antikickback, false claims, and FDA statutes, but they become entangled in ethical dilemmas with physicians.

Abbott Laboratories, in July 2005, paid $382 million to the federal government and an additional $32 million to the states and Washington, D.C., to settle claims that its Ross Products division defrauded Medicare and Medicaid over a ten-year period. CG Nutritionals, a part of the Ross Products division, pleaded guilty to obstructing a criminal investigation and agreed to pay a $200 million
settlement. The case centered on Ross Products' enteral feeding (infusion) devices used to pump special foods into the digestive tracts of patients who cannot ingest foods in a normal manner.

The government accused the company of providing enteral feeding pumps, primarily to nursing homes, at no charge. In return, the buyers agreed to purchase a specific number of pump set components. Ross Products then showed nursing homes and durable medical equipment suppliers how they could bill Medicare and Medicaid for the free pumps.

This fraud was exposed by the federal government's Operation Headwaters, a joint undercover investigation by the FBI, the U.S. Postal Inspection Service, and the OIG that focused on the illegal activities of DME companies. Federal agents used, as part of the undercover operation, a fictitious medical supplier known as Southern Medical Distributors. Various manufacturers, including Ross Products, offered kickbacks to undercover agents for purchasing the products.

The government also claimed that the company made payments to health care providers to convince them to sign long-term contracts for enteral products. Such payments violate the antikickback statute because these items were then billed to Medicare. CG Nutritionals was permanently banned from participating in Medicare and Medicaid. Abbott Labs also agreed to a five-year corporate integrity agreement, requiring them to reform the sales and marketing practices for their enteral feeding products.

Interventional cardiology and cardiovascular surgery are the cash cows of the American health care delivery system, according to Dr. Nortin M. Hadler, a professor at the University of North Carolina School of Medicine and author of Worried Sick: A Prescription for Health in an Overtreated America. Not surprisingly, then, possible conflicts of interest between the American College of Cardiology and the Cardiovascular Research Foundation have come under scrutiny. Senator Herb Kohl (D-Wisconsin) has expressed concerns over the relationships between member doctors of the American College of Cardiology and the Cardiovascular Research Foundation, which accepts funding from several medical-device manufacturers. In a prepared statement, Senator Kohl said, "This inquiry is part of a much larger effort to examine the tangled financial relationship between America's physicians and these industries." Dr. David Holmes, a cardiologist at the Mayo Clinic, offered a different view. He claimed the "sole mission is to make sure that we put on the very best scientific meeting that we possibly can that explores the art and science of interventional cardiology."

An aging and overweight U.S. population has created a soaring demand for hip and knee replacements. Although innovations in orthopedic surgery and orthopedic appliances are a boon to patients requiring these replacements, a questionable business relationship has arisen between the orthopedic surgeons and the companies that manufacture devices such as artificial joints. Doctors
are being paid as consultants by companies such as Zimmer Holdings, an industry leader in hip and knee products. The question behind these consulting agreements is whether doctors were being paid to conduct training or to assist in product development—both are legal activities—or whether they were being paid kickbacks for using the company's orthopedic products—a violation of the antikickback statute. In September 2007, a criminal investigation put a temporary halt on moonlighting physicians, and the major orthopedic companies paid $311 million and agreed to a monitoring program by the federal government. Payments to doctors, however, have continued as federal authorities try to keep an eye on the new consulting arrangements. Zimmer Holdings, to ensure transparency, posted on their website a list of health care professionals who receive payments from the company as well as a copy of their twenty-three-page deferred prosecution agreement and information on a compliance hotline.

The number of patients with end-stage renal disease is also expected to grow dramatically as U.S. baby boomers age. As the number of kidney dialysis services reimbursed by the federal government grows, so too will their vulnerability to fraud and abuse. Medicare spending for outpatient dialysis was $12 billion in 2000, an amount that was expected to double by 2010.

In December 2004, Gambro Healthcare (Gambro) agreed to pay more than $350 million in criminal fines and civil penalties to settle allegations of health care fraud. The settlement focused on frauds against the Medicare, Medicaid, and TRICARE programs, and it included $25 million in criminal charges and the permanent exclusion of Gambro Supply Corporation from the Medicare program. Gambro Supply was a sham durable medical equipment company owned by Gambro Healthcare. The settlement also required payment of over $310 million to resolve civil liabilities, an additional payment of $15 million for potential state Medicaid program liabilities, and compliance with a comprehensive corporate integrity agreement.

The suit was filed originally in 2001 by Gambro's former chief medical officer, who supervised medical and nursing services at the company's U.S. outpatient dialysis centers. At the time of the case, Gambro was the nation's third-largest owner and operator of renal dialysis clinics. The company used its shell subsidiary, Gambro Supply Corporation, to bill Medicare at the clinical reimbursement rate, which was $500 higher than the home dialysis rate. Gambro Supply, then known as REN Supply Corporation, intentionally left a line blank on Medicare application forms to conceal its connection to the parent company, making it easier to collect the higher reimbursement. Gambro also billed for home dialysis supplies not provided to Medicare beneficiaries. The company used the practice of "hard coding" diagnostic codes to falsify statements and bills submitted for unnecessary services—bone-density studies, nerve-conduction studies,
and electrocardiograms, among others. Gambro also violated the antikickback statute by hiring and paying physicians based on the number of patient referrals they made to company clinics.89

In an earlier brush with the law (2000), Gambro Healthcare Laboratory Services paid over $53 million to settle similar charges of false claims to Medicare, Medicaid, and TRICARE over laboratory services provided to end-stage renal disease patients. Considering the similarities between the earlier and later violations, the corporate integrity agreement signed by Gambro in 2000 appeared to have had little impact on its subsequent business practices. As one legal observer noted:

For whatever it’s worth, if anything, Gambro was required to sign another “integrity agreement” as part of the December 2004 settlement…. The charges above beg the questions of how many patients received unnecessary testing, medications and equipment, and how many patients went without services that were billed for? Also, how much out-of-pocket money did patients lose in co-payments as a result of bogus billings for services not rendered or for services rendered needlessly?90

In 1998 Gambro was also involved in the recall of defective blood tubing after forty patients were hospitalized and four dialysis patients died from hemolysis (the destruction of red blood cells).91 The FDA later became aware of additional serious injuries and deaths connected with Gambro’s Prisma Continuous Renal Replacement Therapy, a system used on critically ill patients. The FDA issued notices in August 2005 and February 2006 regarding safety precautions for renal caregivers.92

Fresenius Medical Care of North America agreed to pay $486 million to settle accusations of fraud against its kidney dialysis subsidiary, National Medical Care (NMC). Fresenius acquired NMC in 1996, inheriting some of the problems that led to the settlement in January 2000. Three NMC subsidiaries also pleaded guilty to separate conspiracies and were fined $101 million. The Fresenius and NMC case centered on blood-testing claims by LifeChem, NMC’s blood-testing laboratory. Kickbacks were allegedly made to dialysis facilities to obtain blood-testing contracts for LifeChem. Furthermore, fraudulent claims were submitted to Medicare for intradialytic parenteral nutrition, a nutritional therapy provided to dialysis patients. Fresenius was required to enter an eight-year corporate integrity agreement.93 In a postsettlement press release, Fresenius indicated that, after acquiring NMC, it worked closely with government officials to resolve the case. The company also emphasized that their legal disputes arose over whether Medicare was billed properly for certain products and services; there was never controversy regarding the quality of patient care delivered by Fresenius or NMC.94
A Few More Words about Antitrust Violations

In the previous chapter, I discussed antitrust issues involving hospitals and networks of health care providers. A number of cases have also arisen in which pharmaceutical and medical equipment firms have become embroiled in litigation about actions that stifle fair competition. Providers of health care services have been accused of perpetuating monopolies as well as agreements not to compete, price collusion, and the obstruction of innovative forms of health care financing and delivery.

Monopoly concerns arise when competing pharmaceutical or equipment firms merge (horizontal mergers), when a merger is thought to discourage innovation, or when a merger involves a company taking control of a supplier or buyer (vertical merger). As noted, monopolistic arrangements threaten to drive up the cost of health care and drive down its quality and accessibility, placing both consumers and competitors at an unfair advantage.

Some pharmaceutical industry antitrust cases involve collusion. “Pay for delay” occurs when a drug manufacturer pays the manufacturer of a generic drug to postpone introducing a competing product. Bristol-Myers Squibb granted Apotex a license to sell a generic version of Plavix, an anti–blood clotting drug that helps to protect patients against heart attacks and strokes. But Bristol-Myers Squibb agreed not to launch its own generic version of the drug during the first six months of the license. This arrangement gave Apotex a valuable—and unfair—advantage during the six-month period that it was allowed to corner the market.95

The FTC charged two generic drug manufacturers, Alpharma and the Perrigo Company, with agreeing to limit competition for over-the-counter children’s liquid ibuprofen. Alpharma and Perrigo were the only two manufacturers having FDA approval to manufacture this drug, and they agreed that Perrigo would be the sole distributor of liquid Motrin for seven years. In exchange, Perrigo would pay Alpharma an initial fee plus a sales royalty. Alpharma and Perrigo estimated that this arrangement would raise the price of the drug by 25 percent. A federal district court in Washington, D.C., ordered the companies to forfeit to harmed consumers over $6 million of the illegal profits from the deal and placed limits on the firms’ ability to compete.96

The Range of Settlements

Between 1990 and 2007, over three hundred health care fraud settlements in the United States resulted in payments of $1 million or more. These settlements yielded almost $15.9 billion to government coffers, including almost $1.8 billion (11% of the total) in criminal fines. Seven settlements were for amounts
over $500 million, and twenty settlements exceeded $250 million. More than 83 percent of the individual settlements (253), however, were in the $1 million to $50 million range with most (174) being less than $10 million.

The pharmaceutical industry led the way with $6.2 billion in settlements, an amount that appears to be increasing at a substantial rate. Hospitals and medical devices occupied the second and third positions with hospitals paying $4 billion and medical-device companies $1.1 billion. Various insurance-related businesses had settlements totaling over $1.1 billion. These included insurers, billing services, carriers, and program-eligibility entities. Other health care industry segments with large cumulative settlement amounts between 1990 and 2007 were: kidney dialysis ($943.6 million), laboratory services ($872.7 million), nursing homes ($518.2 million), home health care ($465.3 million), and rehabilitation services ($341.6 million). Physicians and nursing services had small settlement amounts of $85.4 million and $10.3 million. Durable medical equipment businesses had a surprisingly low settlement amount of $158 million over the almost seventeen-year period. Given the federal government’s growing concern about this industry segment, DME settlements may rise in the future. Retail pharmacies also had a relatively small cumulative settlement of $93.3 million.97

**Prosecuting Health Care Fraud Cases Is a Big Business**

The high-profile cases discussed here and in the previous chapter, along with their large settlement amounts, illustrate several important points. Health care fraud and abuse involve huge sums of money across a wide range of industry segments. When viewed against the vast size of the U.S. health care system, however, these amounts suggest that the problem is serious but not pandemic—at least not yet. During the four-year period from the beginning of 1999 to the end of 2002, health care fraud settlements amounted to $4.6 billion and U.S. health care expenditures were approximately $5.8 trillion. In the four-year period from the beginning of 2003 until the end of 2006, settlements had increased dramatically to $8.2 billion, but U.S. health care expenditures had also risen significantly to $7.7 trillion.98 This eight-year trend suggests that the concurrent rise in U.S. health care fraud settlement amounts is greater than the rise in U.S. health care expenditures. It is difficult to know, however, whether this trend is indicative of more health care fraud, more zealous enforcement efforts by federal and state prosecutors, or some combination of the two.

The nearly $15.9 billion in civil and criminal settlements also distorts the magnitude of the problem because the False Claims Act allows federal prosecutors to seek treble damages and penalties against health care providers. That is to
say, the economic damage caused by most high-profile frauds is not as bad as
the financial settlements suggest. Furthermore, the definition of what constitutes
health care fraud and abuse has expanded, possibly overstating the rate at which
the problem is growing.

The number of health care providers that are touched by investigations or
prosecutions of fraud and abuse is growing. Although only a small number
of health care providers have been the target of an investigation, most have
known—or have known of—someone who has been a target. Victims, of course,
may blow the whistle on those who have defrauded them. Special government
investigations and sting operations also play an integral part in nabbing fraud
perpetrators. But health care fraud is often revealed by insiders—disgruntled
employees, jealous family members, and even former spouses or lovers—who
are motivated both by personal revenge and by the prospect of a big payoff under
the False Claims Act. Accusations of fraud or abuse against health care providers
may also come from consumer advocates, competitors, vendors that have been
treated unfairly, disenchanted shareholders, Medicare fiscal intermediaries and
carriers, inspectors, auditors, fraud investigators, and professional whistle-blow-
ers who seek employment with the intent of digging up dirt on their employer
and, later, filing a lawsuit.

From the 1990s to the present, the federal government has made the prosecu-
tion of health care fraud a priority. Two opposing forces are at work with regard
to major health care fraud and abuse cases. One is the incessant pressure on
health care executives to achieve a strong financial showing. The other is a strong
desire by prosecutors to expose and punish large corporations that cheat federal
health care programs, consumers, and investors. And based on their postsettle-
ment comments, prosecutors and government officials are not bashful when it
comes to bragging about the impact of their legal victories.

Federal prosecutors have followed a strategy of grabbing the low-hanging
fruit. The pharmaceutical industry is far and away the federal government's fa-
vorite target because pharmaceutical firms are financially well heeled. Prosecut-
ing a hospital chain, medical laboratory, or dialysis equipment manufacturer and
obtaining a settlement of several hundred million dollars is a much more effi-
cient use of resources—in terms of the settlement dollars received per the pros-
ecutorial dollar spent—than going after a small group of crooked providers.

The Medicare, Medicaid, and TRICARE programs are similar to a mouse-
trap: they are an enticing target for fraud perpetrators. But once a perpetra-
tor takes the bait, federal agencies, Medicare fiscal intermediaries and carriers,
and state Medicaid agencies have the power to suspend payments temporarily
pending the outcome of a fraud investigation. Temporary suspensions, further-
more, are nearly impossible to contest. Even when such suspensions are later
found to be without merit, they can have devastating consequences on the cash
flow of a hospital, clinic, laboratory, or other provider. For major violators, the HIPAA provides for permanent banishment from the Medicare, Medicaid, or TRICARE programs. And permanent banishment may be the death knell for an outlaw health care organization. For these reasons, hospital chains, pharmaceutical companies, and medical equipment and supply companies often decide to settle on the courthouse steps rather than to risk an adverse verdict in federal court—a verdict that could lead to bankruptcy. The next chapter illustrates the dynamics of prosecuting—and defending—health care fraud and abuse cases.