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Expert Analysis

Health Care Compliance in 2009 And Going Forward: *Part 1*

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Enforcement in the health care compliance arena exploded in 2009, with more enforcement actions, bigger financial penalties, tougher settlement terms and higher stakes for individuals — including prison sentences. Many of the top companies in the health care industry found themselves in the government's cross hairs last year, with some entering into record-breaking settlements.

But smaller players were hardly immune from scrutiny, with many similarly targeted in 2009. This increased regulatory and prosecutorial emphasis on health care compliance was hardly an anomaly; all signs point to a continuation of this upward trend in 2010 and beyond.

With the current push for reform, health care's significance in the American dialogue increased markedly last year. The multitrillion-dollar question at the center of the current debate is how to provide quality health care to the American public, including the millions of people who lack health insurance, while keeping costs manageable and eliminating waste. A key factor cited in the rising costs is health care fraud, and combating fraud is often depicted as a silver bullet.

Against this backdrop, prosecutors and regulators are focusing with increasing intensity on issues of health care compliance. Tapping into public anger over rising costs and reports of abuse, more and more politicians and public officials look to assign blame for perceived or actual problems in the current system. From conflicts of interest in the use of consultants and creative accounting systems to instances of outright fraud, there is continued pressure to weed out all sources of waste in the system. This is coupled with a formidable populist backlash, as also experienced by other industries, against big corporations allegedly padding their pockets by circumventing the rules and is bolstered by the current focus on key areas of revenue generation for the government.

The result? More than $5 billion in settlements and judgments relating to health care fraud recovered by the federal government in 2009. State governments have collected hundreds of millions more. The U.S. Department of Justice has nearly 1,000 pending civil cases involving health care fraud.[1]

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A key factor cited in rising health care costs is health care fraud, and combating fraud is often depicted as a silver bullet.

Recent settlements serve as concrete examples of the increased exposure of the health care industry. In January 2009 drug company Eli Lilly & Co. agreed to pay $1.4 billion to resolve allegations of off-label promotion of the anti-psychotic Zyprexa. And in August, for alleged off-label promotion of the drugs Bextra, Geodon, Zyvox and Lyrica, Pfizer Inc. and subsidiary Pharmacia & Upjohn agreed to pay $2.3 billion — the largest health care fraud settlement in Justice Department history.

Moreover, health care fraud does not simply result in corporate financial losses. In addition to significant reputational and business implications for companies (such as debarment from participation in Medicare and Medicaid), individual executives and employees are at risk. Individuals can face not only heavy fines, but also criminal conviction and imprisonment.

The concern that companies may view corporate fines — even hefty ones — as simply a cost of doing business has led the government to seek new and creative ways to raise the stakes for the health care industry. As more companies are viewed as "repeat offenders," the government has increasingly focused on combating recidivism. For example, according to Michael Loucks, former U.S. attorney in Massachusetts, referring to Pfizer's $2.3 billion settlement, "[a]mong the factors we considered in calibrating this severe punishment was Pfizer's recidivism."[2]

Government investigations into health care compliance violations are intensifying. In 2009 the DOJ and the Department of Health and Human Services created an interagency group called the Health Care Fraud Prevention and Enforcement Action Team (known as HEAT) specifically tasked with combating fraud. Health care fraud is now a top-five priority at the Justice Department, as well as a key area of focus for the FBI.

In a statement to the Senate Judiciary Committee, Assistant Attorney General Tony West, citing the billions of dollars that are "wasted on fraud and abuse," reiterated that "the Department of Justice, through its civil, criminal, and civil rights divisions, along with U.S. attorneys' offices and the FBI — the entities responsible for enforcing laws against all forms of health care fraud — has prioritized much of our enforcement efforts on protecting the integrity of health care that is provided to patients."[3]

Other players are also taking an interest. With Republican Charles Grassley of Iowa in the lead, several U.S. senators have established themselves as industry watchdogs, spurring new investigations and legislation. States are also taking a closer look at the health care industry, with new laws regulating physician-industry interactions and state attorneys general becoming increasingly active in the field.

HHS has recently taken a tougher stance against health care fraud, with a new approach requiring that many corporate integrity agreements include a provision whereby the company must hire a "compliance expert" similar to the monitors often mandated by the Justice Department in deferred prosecution agreements. If this trend continues, corporate integrity agreements would, as a matter of course, impose some of the same onerous monitoring requirements as DPAs.

On the industry side, players are responding to the heightened scrutiny. Increasingly, companies are strategically adopting stricter policies than the law requires. Several have chosen to voluntarily disclose compensation paid to physicians. These individual corporate initiatives have been matched by the two leading industry professional associations, both of which adopted more stringent ethical codes in 2009.

These recent developments — the national health care debate, the number and magnitude of recent settlements, the increased scrutiny by the government at all levels, and the changes by the industry — mean that companies must vigilantly ensure that health care compliance is, and remains, a priority. Avoiding missteps requires adapting quickly to the changing political and legal environment. Now more than ever, health care compliance must be viewed as a business necessity.

NOTABLE SETTLEMENTS AND JUDGMENTS

This past year saw increased settlement activity, with health care companies paying record amounts to resolve claims of health care compliance violations at both the federal and state levels. 2009 was also marked by significant judgments against companies and individuals alike. The conduct covered by these settlements and judgments ranged from off-label marketing and False Claims Act violations to Medicaid fraud and kickback schemes. The defendants in these cases varied widely as well, from small regional companies to dominant global players like Pfizer, Lilly and AstraZeneca.

Pfizer Inc.

In September Pfizer reached a $2.3 billion settlement with federal prosecutors, which amounted to "the largest health care fraud settlement in the history of the Department of Justice, the largest criminal fine of any kind imposed in the U.S., and the largest ever civil fraud settlement against a pharmaceutical company," according to a DOJ official. The settlement included a $1.2 billion criminal penalty, the highest ever imposed for alleged health care fraud.

According to the DOJ, the "settlement is an example of the department's ongoing and intensive efforts to protect the public and to recover funds for the federal treasury from those who seek to profit from fraud."[4] The case was handled by the U.S. attorney's office in Boston.

Pfizer pleaded guilty to a federal criminal charge of illegally marketing the painkiller Bextra. According to the settlement agreement, subsidiary Pharmacia & Upjohn encouraged doctors to prescribe Bextra "off-label" to treat acute pain, a use not approved by the Food and Drug Administration.

The settlement included a $1 billion fine to resolve related whistle-blower complaints over the alleged off-label promotion of Bextra, along with the anti-psychotic drug Geodon, the antibiotic Zyvox and the painkiller Lyrica. Pfizer also pleaded guilty to marketing Geodon for use by children, which was not approved by the FDA. The settlement also resolved charges that Pfizer treated doctors to meals, paid them for speaking engagements and subsidized their travel to induce them to prescribe 13 drugs off-label. In addition to the fine, Pfizer signed a five-year corporate integrity agreement with HHS, which provides for the appointment of an independent review organization and an outside reviewer.

Eli Lilly & Co.

Just months before the Pfizer settlement, Eli Lilly paid $1.4 billion to settle criminal and civil suits related to its marketing of the anti-psychotic Zyprexa. The drug was approved to treat schizophrenia but Eli Lilly allegedly promoted it to the elderly as a treatment for dementia and Alzheimer's disease, a use not approved by the FDA.

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Eli Lilly agreed to pay $615 million to settle the criminal investigation, which was handled by the U.S. attorney's office in Philadelphia. The company pleaded guilty to a mis-demeanor charge of off-label promotion. It paid $800 million to settle civil Medicaid fraud claims brought by various states. As with Pfizer, Eli Lilly entered into a corporate integrity agreement with HHS.[5]

AstraZeneca

Drugmaker AstraZeneca announced Oct. 29 that it had set aside $520 million as part of a tentative agreement to resolve an investigation by the U.S. attorney's office in Philadelphia into the company's marketing practices. The investigation focused on whether AstraZeneca promoted its anti-psychotic Seroquel, which is approved to treat schizophrenia and bipolar disorder, as a treatment for other illnesses. According to the company, the investigation dealt with separate allegations of the off-label marketing of the drug, as well as allegations regarding physicians who participated in Seroquel's clinical trials. Both sets of allegations were prompted by whistle-blower suits filed under the False Claims Act.

The company said it would not comment on whether it would admit to wrongdoing as part of the settlement, and it did not reveal the terms of the expected deal, except to say that it would include a corporate integrity agreement. AstraZeneca reached the deal with federal prosecutors in September, after a prolonged period of negotiations.[6]

WellCare Health Plans

WellCare pleaded guilty to one count of conspiracy to commit health care fraud against Florida's Medicaid and Healthy Kids programs. The government alleged that WellCare engaged in several fraudulent strategies to avoid returning unspent money to the state programs. WellCare entered into a 36-month deferred prosecution

What They Paid:

Pfizer	$2.3 billion
Eli Lilly	$1.4 billion
AstraZeneca	$520 million
Quest Diagnostics	$302 million
Boston Scientific	$296 million
Mylan Pharmaceuticals, UDL Laboratories, AstraZeneca and Ortho-McNeil	$124 million
Omnicare Inc.	$98 million
WellCare Health Plans	$80 million
IVAX Pharmaceuticals	$14 million
University of Medicine and Dentistry of New Jersey	$8.3 million
Pharmacia Inc.	$4.6 million
Synthes	$230,000

agreement with the DOJ and consented to the appointment of a federal monitor, as well as a fine of $80 million.[7]

Quest Diagnostics

Quest Diagnostics agreed to pay $302 million to settle criminal and civil claims involving alleged misbranding and False Claims Act violations. The DOJ claimed that a subsidiary of Quest Diagnostics had knowingly marketed and sold testing kits that provided unreliable results. The settlement included a $40 million criminal fine to resolve the misbranding charges and a $262 million civil fine to settle the False Claims Act allegations.

The investigation was started by a *qui tam* plaintiff, a whistleblower who reported that the test kits provided consistently incorrect results. The plaintiff received $45 million as part of the settlement.[8]

Mylan, UDL, AstraZeneca and Ortho-McNeil

The DOJ announced Oct. 19 that Mylan Pharmaceuticals, UDL Laboratories, AstraZeneca and Ortho-McNeil Pharmaceutical had entered into settlement agreements totaling $124 million to resolve claims that they violated the False Claims Act by failing to pay appropriate drug rebates to state Medicaid programs. The precise amount of a rebate is determined in part by whether a medication is considered an "innovator" drug or a "non-innovator" drug. The rebate paid for innovator drugs is higher than the rebate for non-innovator drugs. The settlements resolve allegations that each company sold innovator drugs that were manufactured by other companies and had classified those drugs as non-innovator drugs for Medicaid rebate purposes. As a result of the improper classification of these drugs, the companies allegedly underpaid their obligations under the Medicaid rebate program.

States are also taking a closer look at the health care industry, with new laws regulating physician-industry interactions and state attorneys general becoming increasingly active in the field.

Mylan and UDL together agreed to pay $118 million to resolve the allegations that they had underpaid their rebate obligations with respect to several drugs. The federal government will receive $60.1 million, the states will receive $50 million, and $7.3 million will be paid to entities that participated in the U.S. Public Health Service's drug pricing program. Separately, AstraZeneca paid $2.6 million to resolve allegations that it underpaid its rebate obligations with respect to the asthma treatment albuterol. Ortho-McNeil paid $3.4 million to resolve similar allegations with respect to skin ointment Dermatop.

The whistle-blower suit was initiated by a small Florida pharmacy called Ven-A-Care, which will receive $10.8 million as its share of the recovery.[9]

Omnicare Inc.

The Justice Department announced Nov. 3 that Omnicare, a provider of geriatric pharmaceutical services, would pay $98 million to settle charges that it engaged in several kickback schemes with drug companies and nursing homes. In addition, IVAX Pharmaceuticals, a unit of Teva Pharmaceutical Industries Ltd., will pay $14 million to resolve allegations that it paid $8 million in kickbacks in exchange for Omnicare's agreement to buy $50 million of IVAX drugs. The case was brought under the False Claims Act.

The DOJ alleged that Omnicare regularly paid kickbacks to nursing homes to induce them to refer their patients to the company for pharmacy services. Moreover, Omnicare allegedly solicited and received kickbacks from Johnson & Johnson in

exchange for agreeing to recommend that doctors prescribe J&J's anti-psychotic drug Risperdal. In January the DOJ filed a lawsuit against J&J under the False Claims Act. The company's corporate filings suggest that employees of several subsidiaries have been subpoenaed to testify before a grand jury in connection with the investigation.[10]

Boston Scientific Corp.

Boston Scientific announced Nov. 6 that it had reached an agreement in principle with the U.S. attorney's office in Minneapolis to settle claims that product advisories issued by its Guidant subsidiary in 2005 violated the federal law. Under the terms of the agreement, Guidant will plead to two misdemeanor charges related to failure to include information in reports to the FDA, and Boston Scientific will pay $296 million on behalf of Guidant. The product advisories involved defibrillators sold under the names Ventak Prizm 2, Contak Renewal and Contak Renewal 2.[11]

Pharmacia Inc.

A Wisconsin court imposed a forfeiture award of nearly $4.6 million against Pharmacia, a subsidiary of Pfizer, in connection with fraudulent-pricing litigation brought by the state attorney general. The court imposed a $1,000 forfeiture for each of the 4,578 acts of misrepresentation it found Pharmacia to have made or caused to be made that purportedly defrauded the Wisconsin Medicaid program.

The court order followed a February 2008 trial in which the jury found damages totaling $9 million arising from alleged fraudulent pricing. In total the state has brought actions against 36 pharmaceutical companies, alleging violations of the state's Medicaid fraud laws. Pharmacia was the first of the defendants to contest the allegations at trial. Amgen, Immunex and Baxter Healthcare settled prior to the Pharmacia trial. Thirty-two defendants remain in the litigation, and more are trials scheduled for March through May.[12]

Synthes

In the first settlement in connection with recent inquiries into potential conflicts of interest with health care providers, medical device manufacturer Synthes reached a settlement with the New Jersey attorney general arising from allegations that it had failed to disclose financial conflicts of interest among doctors involved in clinical research activities for the company. The settlement called for Synthes to disclose any future payments or investments held by doctors involved in clinical research trials; the company agreed to make this information publicly available through its Web site. Synthes also agreed to stop paying doctors who conduct clinical trials of its products with stock or stock options. In addition, the company paid a fine of more than $230,000.

The state had pursued the case as a matter of consumer fraud. As discussed below, the attorney general had issued subpoenas to five major device makers, requesting information on conflicts of interest with physicians involved in clinical research activities. Synthes is the only company to date to settle these claims.[13]

UMDNJ

In September the University of Medicine and Dentistry of New Jersey agreed to pay $8.3 million to settle charges that it paid illegal kickbacks to cardiologists. According to the Justice Department, in 1995 UMDNJ was having trouble finding enough patients to perform the minimum number of cardiac procedures needed to keep

its governmental funding and accreditation as a level-one trauma center. UMDNJ created part-time employment contracts with community cardiologists, who in turn referred patients to the facility. The DOJ alleged that the part-time contracts were masked kickbacks to cardiologists for patient referrals. Six cardiologists involved in the scheme settled with the government as part of this prosecution.

This is not the first time the Justice Department has settled with UMDNJ. In the last several years, a federal monitor found that the school had double-billed Medicaid for $5 million in procedures. The school paid $2 million to settle that claim. In 2005 it paid $4.9 million to the federal government and the state Jersey as part of a deferred prosecution agreement.[14]

ACTIONS AGAINST INDIVIDUALS

In addition to these enforcement actions involving corporations, 2009 saw a number of notable individual prosecutions and settlements. For example, Miami physician Roberto Rodriguez was sentenced to 97 months in prison and ordered to pay $9 million in restitution for Medicare fraud. Rodriguez co-owned a clinic that allegedly had routinely billed Medicare for unnecessary or unperformed services for HIV patients.

In the 2009 fiscal year, the Justice Department recovered $2.4 billion in settlements and judgments from False Claims Act cases, about $2 billion of which was a result of *qui tam* ***actions.***

A Miami-area clinic was found to have charged Medicare for willfully performing improper services for HIV patients, resulting in four criminal convictions and hefty fines. The Midway Medical Center purposely removed platelets from blood samples of HIV patients, then billed Medicare for treatment for those low-platelet-count patients. Participants in the scheme were fined more than $20 million in combined restitution payments and were given prison sentences ranging from 37 months to 90 months.

Health care executives were not spared in 2009. In April a former Bristol-Myers Squibb senior executive pleaded guilty to making a false statement in connection with a false certification to the Federal Trade Commission that no agreement had been made to delay the release of a generic version of Plavix, the most widely-prescribed blood thinner in the world. Andrew Bodnar was sentenced to a $5,000 fine and two years' probation. The judge also ordered him to write a book about his experiences in order to deter future similar conduct.

Bodnar's prosecution followed from a 2007 guilty plea by Bristol-Myers Squibb for the same conduct. In the earlier case, the company was fined $1 million, the statutory maximum, for allegedly making illegal agreements with competitors and misleading the government regarding the patent for Plavix.

In another case, Rebecca Sharp, the owner of a health care agency, pleaded guilty in October to soliciting and collecting kickbacks for referring Medicare patients to home health care agencies. Sharp is currently awaiting sentencing. She faces 57 months in prison, $5.2 million in restitution to Medicare, a $25,000 fine and forfeiture of assets.

Finally, a former CEO of biopharmaceutical company InterMune Inc. was convicted in September of a felony charge of wire fraud for his role in the alleged creation and dissemination of false and misleading information about the efficacy of the drug Actimmune. Federal prosecutors indicted F. Scott Harkonen in 2008, about a year and a half after InterMune had resolved related claims with the Justice Department and HHS by entering into a deferred prosecution agreement and a corporate integrity agreement and paying nearly $37 million in fines.

The government's case against Harkonen primarily relied on an InterMune press release announcing the results of a clinical trial of Actimmune for the treatment of idiopathic pulmonary fibrosis. The DOJ alleged that Harkonen had caused the issuance and distribution of this press release, which misstated the results of the clinical trial by suggesting that Actimmune helped IPF patients live longer. According to the DOJ, the clinical trial had in fact failed. After a seven-week jury trial, Harkonen was acquitted of a misbranding charge under the Food, Drug and Cosmetic Act but was convicted of wire fraud. The maximum statutory penalty for wire fraud is 20 years in prison, a $250,000 fine and three years supervised release.[15]

FALSE CLAIMS ACT ACTIONS AND COLLATERAL CIVIL ACTIONS

One crucial factor in health care compliance is the interplay between civil and government actions. Qui tam, or whistle-blower, lawsuits often have resulted in government intervention. In the 2009 fiscal year, the Justice Department recovered $2.4 billion in settlements and judgments from False Claims Act cases, about $2 billion of which was a result of qui tam actions. Health care fraud recoveries, many of which were outlined above, accounted for two-thirds of the total, amounting to $1.6 billion. In addition, as detailed below, many of the investigations initiated by the government in 2009 spawned from whistle-blower suits.[16]

Conversely, news of a government settlement can generate related civil lawsuits, further increasing a targeted health care company's exposure to liability. For example, after the government settled anti-kickback charges against the five largest orthopaedic companies, culminating in a dismissal of charges in 2009, a group of salespeople who worked for a smaller competitor filed a lawsuit charging that the companies had illegally steered business away from smaller businesses, thus depriving the salespeople of commissions. A federal judge dismissed the case against two of the companies, and the remaining three ultimately settled.[17]

In the next issue of Westlaw Journal Health Care Fraud, the authors will look at the significant investigations and actions that were commenced in 2009, review some of the current trends in health care compliance, and take a peek at what lies in store in 2010 and beyond.

NOTES

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2 Gardiner Harris, *Pfizer Pays $2.3 Billion to Settle Marketing Case*, N.Y. TIMES, Sept. 3, 2009.
3 *Effective Strategies for Preventing Health Care Fraud: Hearing Before the S. Judiciary Comm.* (Oct. 28, 2009) (statement of Assistant Attorney General Tony West).
4 *Id.*; Tom Perrelli, Associate Attorney General, Remarks as at Pfizer Settlement Press Conference (Sept. 2, 2009); Corporate Integrity Agreement Between the Office of Inspector General of the Dep't of Health and Human Servs. and Pfizer Inc. (Aug. 31, 2009).
5 Corporate Integrity Agreement Between the Office of Inspector General of the Dep't of Health and Human Servs. and Eli Lilly & Co. (Jan. 14, 2009).
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8 Press Release, Dep't of Justice, Quest Diag-nostics to Pay U.S. $302 Million to Resolve Allegations That a Subsidiary Sold Misbranded Test Kits (Apr. 15, 2009).
9 Press Release, Dep't of Justice, Four Pharm-aceutical Companies Pay $124 Million for Submis-
sion of False Claims to Medicaid (Oct. 19, 2009).
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Nursing Home Pharmacy (Jan. 15, 2010); Brent Kendall, *Omnicare Settles Charges in Kickback Case,* WALL ST. J., Nov. 30, 2009.

11 Press Release, Boston Scientific Corp., Boston Scientific Announces Agreement With DOJ on Pre-Acquisition Investigation of Guidant (Nov. 6, 2009).

12 Press Release, Dep't of Justice, Jury Finds Pharmacia Committed Fraud on Wisconsin Medicaid Program; Van Hollen's Department of Justice Wins State $9 Million (Feb. 17, 2009).

13 Press Release, N.J. Attorney Gen., Landmark Settlement Reached With Medical Device Maker Synthes (May 5, 2009).

14 Press Release, Dep't of Justice, UMDNJ to Pay More Than $8 Million to Settle Kickback Case Related to Cardiology Program (Sept. 30, 2009).

15 Press Release, Dep't of Justice, Miami Physician Sentenced to 97 Months in Prison for Role in $10 Million Medicare Fraud Scheme (June 29, 2009); Press Release, Dep't of Justice, Four Miami-Area Residents Sentenced in $10 Million Medicare Fraud Scheme (June 5, 2009); Press Release, Dep't of Justice, Former Bristol-Myers Squibb Senior Executive Pleads Guilty for Role in Dishonest Dealings With the Federal Government (Apr. 6, 2009); Press Release, Dep't of Justice, Owner of Health Care Agency Pleads Guilty in Medicare Kickback Scheme (June 15, 2009); Press Release, Dep't of Justice, W. Scott Harkonen, Former Biotech CEO, Convicted of Wire Fraud (Sept. 29, 2009).

16 *Id.*; Press Release, Dep't of Justice, Justice Department Recovers $2.4 Billion in False Claims in Fiscal Year 2009; More Than $24 Billion Since 1986 (Nov. 19, 2009).

17 *McCullough v. Zimmer Inc. et al.*, No. Civ. 08-cv-1123, 2009 WL 775402 (W.D. Pa. Mar. 18, 2009).

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