

January 14, 2011

## 2010 YEAR-END HEALTH CARE COMPLIANCE UPDATE

To Our Clients and Friends:

2010 was another blockbuster year in health care compliance enforcement. The trends commenced in 2009--historical settlements, increased enforcement activity, stricter settlement terms, and tougher penalties for individuals<sup>[1]</sup>--became entrenched in 2010.

In the words of Attorney General Eric Holder, the government has taken the "fight against health-care fraud to a new level."<sup>[2]</sup> Indeed, as Tony West, the Assistant Attorney General for the Civil Division of the Department of Justice ("DOJ"), recently affirmed, "[f]rom Day One, President Obama and Attorney General Eric Holder have been focused like a laser beam on tackling health care fraud in all of its many forms."<sup>[3]</sup>

This "laser" focus is reflected in the sheer size of the financial settlements and penalties that government regulators have been able to extract. The DOJ recently boasted that since January 2009 it has "commenced more health care fraud investigations, secured larger fines and judgments, and recovered more taxpayer dollars lost to health care fraud than in any other two-year period."<sup>[4]</sup> 2009 was characterized by some record settlements, such as Pfizer's (\$2.3 billion) and Eli Lilly's (\$1.4 billion) settlements for off-label drug promotion. Excluding those outsized amounts, settlements in 2010 almost tripled compared with 2009, totaling approximately \$4 billion. There can be no question that the industry as a whole has been hit harder and wider than ever before.

If, as we predicted last year, the industry might grow to consider such fines and penalties as simply part of the cost of doing business, then the cost of doing business is exploding across a wide swath of the industry. Large and small players alike have been targeted. This means that companies hit hardest in the past may find themselves again the target of investigations, with the prospect of being considered recidivists and facing amplified penalties.

Kickbacks, improper marketing targeting off-label uses, improper Medicare/Medicaid claims, and outright fraud--all were common subjects of enforcement activity in 2010. With even more vigor than in years past, prosecutors employed the False Claims Act as one of their primary weapons--with more than 80% of False Claims Act recoveries coming from the health care industry. Regulators also struck at core company products, including claims of adulterated drugs and other unsafe manufacturing conditions. And prosecutors continued--and intensified--the recent trend of pursuing health care companies for violations of the Foreign Corrupt Practices Act.

2010 saw a concurrent trend toward increased liability for individuals. The interagency efforts of the Department of Health and Human Services ("HHS") and the DOJ have expanded considerably and have netted more and more prosecutions. Officers of large

corporations are finding themselves subject personally to scrutiny for company-wide practices. While there is long-standing (but little-used) legal precedent for individual liability for corporate conduct in the health care arena, the Food and Drug Administration ("FDA") has declared its intention to invoke those precedents and bring its enforcement activities closer to home for company officials--in the stated hope that this will affect a deeper change in corporate culture and compliance practices.

Nonetheless, while many of the trends seen in 2009 continued in 2010, the future direction of health care compliance enforcement remains uncertain in crucial respects. Enforcement will remain a likely focus of efforts to control waste and abuse in the future. But the success of that strategy--which was promoted as a central component of the Obama Administration's campaign to pass health care reform--will be closely monitored and debated in political and legislative circles. The new Patient Protection and Affordable Care Act ("PPACA"), passed by Congress in 2010, brought an even greater emphasis on detecting and preventing health care fraud. Still, the fight over the direction of national health care policy continues. And, while that battle will be most intense on Capitol Hill, its implications will reverberate in every corner of the industry and take different forms--including hearings, subpoenas, investigations, and other forms of vigorous enforcement and regulatory activity.

For health care companies, and their legal and compliance officers, the implications are clear. Their efforts to strengthen company policies and procedures must be as relentless as the efforts of the state and federal regulators seeking to monitor and evaluate corporate conduct.

This annual update provides a detailed review of notable settlements and judgments in the health care area in 2010 (Section II) as well as significant actions and investigations (Section III). Section IV sets forth an analysis of current trends in health care enforcement and compliance, and Section V includes a projection of future trends that we anticipate based on the current environment.

## **I. Notable Settlements and Judgments**

State and federal governments continued to take in billions of dollars in settlements from the major health care companies in 2010--approximately \$4 billion in total was recovered. All of the top ten DOJ fraud settlements in 2010 were with pharmaceutical companies.<sup>[5]</sup> 2010 thus continued the trend of blockbuster health care settlements seen in recent years. Indeed, according to a study by the Public Citizen's Health Research Group that focused specifically on civil and criminal settlements in the pharmaceutical industry, "[o]f the 165 settlements comprising \$19.8 billion in penalties during [the last] 20-year interval, 73 percent of the settlements (121) and 75 percent of the penalties (\$14.8 billion) have occurred in just the past five years (2006-2010)."<sup>[6]</sup>

In 2010, prosecutors were armed with the usual arsenal of statutory weapons, including the Food, Drug, and Cosmetic Act, the Anti-Kickback Statute, the Stark Act, HIPAA<sup>[7]</sup>, and--now more than ever--the False Claims Act.

# GIBSON DUNN

Almost every 2010 health care settlement included a False Claims Act component, often combined with other statutory violations such as off-label marketing and illegal kickbacks. Following the trend of the past decade, the overwhelming majority of False Claims Act recoveries last year came from the health care arena.[\[8\]](#) For its fiscal year ending September 30, 2010, the DOJ secured over \$3 billion under the False Claims Act--more than 80% of which came from health care companies.[\[9\]](#)

Off-label marketing allegations were also prominent, resulting in some of the largest settlements of 2010, with Allergan, AstraZeneca and Novartis all paying out nine-figure settlements. Interestingly, the largest settlement in 2010 was with GlaxoSmithKline in connection with allegations that one of its Puerto Rico plants produced adulterated drugs due to unsafe conditions--a potential investigative focus that strikes at core products and manufacturing processes rather than at marketing tactics or relationships with health care providers.

## **Off-Label Marketing**

### *Allergan*

Allergan entered a guilty plea and agreed to pay \$600 million to resolve criminal and civil allegations arising from the company's alleged illegal off-label promotion of Botox Therapeutic. The settlement included a criminal fine and forfeiture totaling \$375 million and a civil settlement with the federal government and several states totaling \$225 million.[\[10\]](#)

In 1989, the FDA approved Botox to treat strabismus (crossed eyes) and involuntary eyelid muscle contraction. The FDA later approved Botox for use for excessive underarm sweating, neck muscle contractions, and upper-limb spasticity. Allergan pleaded guilty for marketing the drug for off-label uses, including headache and pain relief, general spasticity relief, and controlled juvenile cerebral palsy.[\[11\]](#)

As part of the settlement, Allergan resolved three separate False Claims Act lawsuits. The suits alleged that Allergan's unlawful marketing of Botox caused false claims to be submitted to government health care programs such as Medicare, Medicaid, TRICARE, the Federal Employee Health Benefit Program, the Department of Veterans' Affairs, and the Department of Labor's Office Workers' Compensation Programs. Allergan also entered into a five-year Corporate Integrity Agreement with HHS.[\[12\]](#)

### *AstraZeneca*

AstraZeneca LP and AstraZeneca Pharmaceuticals LP paid \$520 million to resolve allegations that they illegally marketed the anti-psychotic drug Seroquel--the largest amount ever paid by a company in a civil-only settlement for off-label marketing.[\[13\]](#) The drug was approved to treat acute manic episodes associated with bipolar disorder and schizophrenia, but allegedly was marketed by AstraZeneca to treat anger management, attention deficit hyperactivity disorder, Alzheimer's disease, and sleeplessness, among other unapproved uses.[\[14\]](#) The government alleged that Medicare and Medicaid paid

# GIBSON DUNN

millions of dollars in false claims for prescriptions for off-label uses. As part of the settlement, the federal government will receive upwards of \$301 million, and state Medicaid programs will share approximately \$218 million. AstraZeneca entered into a five-year Corporate Integrity Agreement with HHS as part of the settlement.[\[15\]](#)

## *Novartis*

In September 2010, Novartis Pharmaceuticals Corporation agreed to pay more than \$422 million to settle criminal and civil claims in connection with the company's alleged off-label marketing of several drugs.

Novartis pled guilty to a misdemeanor and agreed to pay a \$185 million combined criminal fine and civil forfeiture for the alleged off-label promotion of the drug Trileptal in violation of the Food, Drug and Cosmetic Act. The FDA had approved Trileptal as an anti-epileptic, but the company allegedly marketed the drug for psychiatric uses and as a pain medication.

Novartis also agreed to pay \$237.5 million to resolve a False Claims Act case alleging that the company unlawfully marketed Trileptal and five other drugs, causing the government, through Medicare, to pay for unapproved uses of the drug. The False Claims suit also alleged that Novartis paid kickbacks to health care professionals to induce them to prescribe Trileptal and five other drugs (Diovan, Zelnorm, Sandostatin, Exforge and Tekturna). Novartis entered into a five-year Corporate Integrity Agreement with the government as part of the settlement.[\[16\]](#)

Earlier, in May 2010, Novartis Vaccines & Diagnostics, Inc. and Novartis Pharmaceuticals Corporation agreed to pay more than \$72 million to resolve False Claims Act allegations arising from the off-label marketing of the cystic fibrosis drug TOBI. The settlement resolved allegations that between 2001 and 2006 Novartis and its predecessor, Chiron Corporation, caused false claims to be submitted to federal health care programs for off-label uses of the drug.[\[17\]](#)

## *Elan Corporation and Eisai Inc.*

Irish pharmaceutical manufacturer Elan Corporation PLC and its U.S. subsidiary Elan Pharmaceuticals Inc. agreed to pay more than \$203 million to resolve criminal and civil investigations arising from their advertising of the epilepsy drug Zonegran. Elan allegedly promoted the drug for mood stabilization for mania and bipolar disorder, eating disorders, obesity, weight loss, and other unapproved uses. Elan agreed to pay a criminal fine of just under \$1 million, and will forfeit \$3.6 million in assets. Elan will also pay \$102 million to resolve civil allegations under the False Claims Act. The civil settlement resolves a whistleblower lawsuit brought by a Massachusetts physician, who will receive approximately \$11 million as part of the settlement.

In a related civil settlement, Japanese drug marketer Eisai Inc. agreed to pay \$11 million to settle civil liability for its off-label marketing of the drug Zonegran.[\[18\]](#)

# GIBSON DUNN

## ***Johnson & Johnson***

Two subsidiaries of Johnson & Johnson (Ortho-McNeil Pharmaceutical LLC and Ortho-McNeil-Janssen Pharmaceuticals, Inc.) agreed to pay more than \$81 million to resolve criminal and civil claims arising from alleged off-label illegal promotion of the epilepsy drug Topamax. The company will pay \$6.14 million as a criminal fine, and \$75 million to resolve civil allegations made under the False Claims Act.[\[19\]](#)

The government alleged that Ortho-McNeil Pharmaceuticals promoted the sale of Topamax for off-label psychiatric uses through its "Doctor-for-a-Day" program. The company allegedly hired outside physicians to join sales representatives in visits to the offices of health care providers and to speak at meetings and dinners about prescribing Topamax for unapproved uses and doses. As part of the settlement, Ortho-McNeil entered into a Corporate Integrity Agreement.[\[20\]](#)

## **Anti-Kickback Statute and Stark Act**

### ***Kos Pharmaceuticals (Abbott Laboratories)***

Kos Pharmaceuticals, Inc., a subsidiary of Abbott Laboratories, Inc., agreed to pay more than \$41 million to resolve criminal and civil claims alleging off-label marketing and violations of the Anti-Kickback Statute.

Kos agreed to pay more than \$38 million to settle civil allegations brought under the False Claims Act that it offered to pay doctors, physicians groups and other managed care organizations illegal kickbacks in the form of money, free travel, grants, honoraria and other goods and services to induce doctors to prescribe or recommend the drugs Niaspan and Advicor. Kos also entered into a Deferred Prosecution Agreement which carried with it a \$3.36 million criminal fine.

The civil settlements came as a result of two whistleblower lawsuits brought under the False Claims Act. The whistleblowers were all former employees of Kos, who will receive payments totaling more than \$6.4 million from the federal share of the civil recovery. The company also settled claims that it off-label marketed the drug Advicor.[\[21\]](#)

### ***Detroit Medical Center***

Detroit Medical Center agreed to pay \$30 million to settle allegations that it violated the Anti-Kickback Statute, Stark Act and False Claims Act. Detroit Medical Center voluntarily disclosed that it had improper office lease agreements and independent contractor relationships that were either inconsistent with fair market value or not memorialized in writing. Detroit Medical Center learned of these relationships as it prepared for its sale to Vanguard Health Systems, Inc. Vanguard participated in the signing of the settlement.[\[22\]](#)

# GIBSON DUNN

## ***Exactech***

Orthopedic implant maker Exactech, Inc. agreed to pay \$3 million to settle allegations that it offered or solicited payments to orthopedic surgeons in exchange for the surgeons' use of Exactech's hip and knee reconstruction and replacement products in violation of the Anti-Kickback Statute. As part of the settlement, the company entered into a Deferred Prosecution Agreement, which requires an independent monitor for at least one year.[\[23\]](#)

## ***Wright Medical Technology, Inc.***

Wright Medical Technology, Inc. entered into a deferred prosecution agreement and agreed to pay \$7.9 million to settle allegations that the medical device maker's marketing practices and consulting deals with orthopedic surgeons amounted to illegal kickbacks and induced false claims. As part of the settlement, Wright Medical entered into a five-year Corporate Integrity Agreement.[\[24\]](#)

## ***Medical Device Manufacturer***

A medical device manufacturer paid \$3.8 million to resolve a False Claims Act allegation that it paid illegal kickbacks to two hospitals in Ohio and Kentucky to secure business. The kickbacks included alleged rebates that were paid retroactively after the hospitals had decided to purchase the equipment from the manufacturer. Rebates were also allegedly paid to induce hospitals to buy the equipment to replace similar equipment sold to the hospitals by the manufacturer's competitors.[\[25\]](#)

## ***Cincinnati Hospitals***

The Health Alliance of Greater Cincinnati and one of its former hospitals, The Christ Hospital, agreed to pay \$108 million to settle claims that they violated the Anti-Kickback Statute and the False Claims Act by paying unlawful remuneration to doctors in exchange for referring cardiac patients to The Christ Hospital in a pay-to-play scheme. This case, like so many others in 2010, was initiated by a whistleblower under the False Claims Act.[\[26\]](#)

## ***Cochlear Americas***

Cochlear Americas, a Colorado-based hearing-aid implant manufacturer, agreed to pay \$880,000 to resolve allegations that it illegally paid health care providers to encourage purchases of its implants. The original lawsuit was brought by a whistleblower under the False Claims Act in 2004. The DOJ intervened in 2007 and resolved the case in June 2010.[\[27\]](#)

## ***St. Joseph Medical Center***

St. Joseph Medical Center in Maryland agreed to pay \$22 million to resolve False Claims Act allegations that it paid kickbacks to MidAtlantic Cardiovascular Associates. The

# GIBSON DUNN

government alleged that St. Joseph entered into professional services agreements in return for referrals of patients to the medical center for lucrative cardiovascular procedures. The settlement concluded an investigation into 11 professional services agreements which allegedly provided for remuneration above fair market value or provided for services that were not commercially reasonable or not rendered at all. As part of the settlement, the company entered into a five-year Corporate Integrity Agreement with HHS.[\[28\]](#)

## *Florida Orthopedic Surgeon*

A Florida orthopedic surgeon entered into a civil monetary penalty settlement with HHS, which included a \$650,000 fine, to settle allegations that the surgeon had received kickbacks from device makers. The government alleged that the physician received consulting payments from device makers DePuy Orthopaedics and Smith & Nephew in exchange for ordering, or continuing to order, those manufacturers' products.[\[29\]](#) The investigation followed the DOJ's investigation of the top five orthopedic device makers which resulted, in 2007, in Deferred Prosecution Agreements with four companies, including DePuy and Smith & Nephew, and a Non-Prosecution Agreement with a fifth company.

## **Unapproved and Adulterated Drugs**

### *Forest Labs*

Forest Pharmaceuticals agreed to pay over \$300 million, including \$164 million in criminal penalties, for allegedly selling unapproved and misbranded drugs and for obstructing the government's investigation of the company. The company has entered into a five-year Corporate Integrity Agreement. [\[30\]](#)

The company pled guilty for its improper marketing of Levothroid, an unapproved drug for the treatment of hypothyroidism. According to the government, Levothroid was considered a "new drug" within the meaning of the Food, Drug and Cosmetic Act, and Forest was supposed to obtain approval from the FDA by August 2000 to continue marketing the drug. Forest did not obtain the approval, and was told by the FDA to phase out the product by mid-2003. Instead, Forest allegedly increased distribution of Levothroid and ignored a subsequent warning letter to stop the manufacture and distribution of the drug.

Forest was also charged with off-label marketing and misbranding of Celexa, a drug approved for treating depression in adults. Forest allegedly marketed the drug for pediatric use.[\[31\]](#)

### *Schwarz Pharma*

Schwarz Pharma, Inc. agreed to pay \$22 million to settle False Claims Act allegations that it failed to advise the Centers for Medicare and Medicaid Services that two unapproved products did not qualify for coverage under the federal health care programs. The company allegedly submitted false quarterly reports to the government relating to the

# GIBSON DUNN

drugs Deponit, a skin patch used to prevent angina, and Hyoscyamine Sulfate ER, an anti-spasmodic medication used to treat stomach and intestinal issues. The government claimed that the company obtained payments from Medicare and Medicaid for the drugs despite their unapproved status. [\[32\]](#)

## *GlaxoSmithKline*

The largest monetary settlement of 2010 came from GlaxoSmithKline in connection with allegations of adulterated drugs. The company agreed to pay a \$150 million criminal fine and \$600 million to settle a False Claims Act suit alleging that 20 different drugs were made with questionable or inappropriate safety measures at the company's now-closed Puerto Rico plant. The suit originally was brought by a whistleblower, the company's quality manager at the plant, who allegedly was fired after complaining to supervisors at the company about the inappropriate safety standards. The drugs affected included Avandia, Coreg, and Paxil.[\[33\]](#)

## **Medicare Price Fraud**

At the end of 2010, the DOJ announced several major settlements for Medicare price fraud and drug price inflation in connection with suits originally brought by False Claims Act relators (private individual whistleblowers). The state of Wisconsin claimed a major settlement as well.

## *Boehringer Ingelheim*

A subsidiary of German-based Boehringer Ingelheim, Roxane Laboratories, Inc., and affiliated entities agreed to pay \$280 million to settle claims that they engaged in a scheme to report false and inflated prices for numerous pharmaceutical products knowing that federal healthcare programs relied on those reported prices to set payment rates. The actual sale prices for the drugs were allegedly far less than what Roxane Laboratories reported. The DOJ intervened in a False Claims suit brought against the company alleging price inflation for the drugs Azathioprine, Diclofenac Sodium, Furosemide, Hydromorphone, Ipratropium Bromide, Oramorph SR, Roxanol, Roxicodone and Sodium Polystyrene Sulfonate.[\[34\]](#)

Separately, Boehringer Ingelheim agreed to pay \$7.75 million to settle allegations that four of its subsidiaries committed price fraud in Wisconsin. The subsidiaries were accused of reporting inflated drug prices to the agencies that determine Medicaid reimbursements, resulting in Medicaid paying more than the actual price of the drug. The company agreed to pay \$7 million to the state of Wisconsin and another \$750,000 for the state's legal costs.[\[35\]](#)

## *Abbott Laboratories*

Abbott Laboratories, Inc. agreed to pay \$126.5 million to resolve allegations that it inflated the price of dextrose solutions, sodium chloride solutions, sterile water, and vancomycin, in order to obtain higher rates from Medicare. Abbott was named in two separate False



# GIBSON DUNN

Claims Act cases, the second filed by a whistleblower, involving Abbott's pricing of the drug Erythromycin, an oral antibiotic.[\[36\]](#)

## ***Braun Medical, Inc.***

B. Braun Medical, Inc., a U.S. subsidiary of German pharmaceutical company B. Braun Melsungen AG, agreed to pay \$14.7 million to resolve allegations that it caused Medicare and Medicaid to pay inflated amounts for 49 different drugs. The drugs and products involved in the investigation included water-based solutions that facilitate the intravenous infusion of other drugs and fluid replacement, intravenous nutritional solutions and other intravenously administered drugs.[\[37\]](#)

## ***Dey Inc.***

Dey Inc., Dey Pharma L.P. (formerly known as Dey, L.P.), and Dey L.P. Inc. agreed to pay \$280 million to resolve allegations that they engaged in a scheme to report false and inflated prices for numerous drugs, including Albuterol Sulfate, Albuterol MDI, Cromolyn Sodium and Ipratropium Bromide. The settlement resolved a whistleblower action filed under the False Claims Act by Ven-A-Care of the Florida Keys Inc., a Florida home-infusion company, and its principals. As part of this settlement, the Ven-A-Care whistleblowers will receive a share of approximately \$67.2 million.[\[38\]](#)

## **HIPAA**

### ***Rite-Aid***

Rite Aid Corporation and its 40 affiliated entities agreed to pay \$1 million to settle potential violations of HIPAA. Rite Aid was investigated by HHS's Office for Civil Rights and the Federal Trade Commission. Those agencies videotaped incidents in which pharmacies allegedly disposed of prescriptions and labeled pill bottles containing patient information in industrial trash containers that were accessible to the public.[\[39\]](#)

## **II. Notable Investigations and Actions**

Matching the rapid rise in settlements and judgments in the health care compliance area, numerous health care investigations and lawsuits were initiated in 2010, both at the federal and state levels, against corporations and individuals alike. Over the past year, the targeted conduct included a wide range of practices, including off-label marketing, False Claims Act violations, Medicare and Medicaid fraud, kickback schemes, fraudulent marketing practices, and violations of the Foreign Corrupt Practices Act.

### ***Stryker Biotech LLC***

Stryker Biotech, LLC, along with its former and current executives, was charged criminally in federal court in Massachusetts with participating in a fraudulent marketing scheme relating to the use of certain medical devices meant to stimulate bone growth. The

company and its former CEO were also charged with making false statements to the FDA.[\[40\]](#)

The indictment alleges that the defendants participated in an illegal marketing scheme to promote and sell a combination of Calstrux, a bone void filler, and OP-1, a protein that promotes bone growth, to surgeons and medical staff despite the fact that the FDA had not approved the combination. Two versions of OP-1 had been approved by the FDA pursuant to a highly restrictive Humanitarian Device Exemption. One of the restrictions was that the device could only treat conditions that affect fewer than 4,000 patients in the United States when comparable devices do not exist, and the devices could not be sold for a profit. Calstrux was approved to be sold on its own, but Stryker allegedly marketed a combination of the two compounds in a manner not approved by the FDA.[\[41\]](#) In August 2010, Stryker agreed to pay \$1.4 million to Massachusetts to settle a civil suit related to the marketing of Calstrux and OP-1.[\[42\]](#)

### ***Johnson & Johnson***

The Department of Justice filed a civil False Claims Act complaint (in the form of two consolidated whistleblower lawsuits) in Massachusetts federal court against Johnson & Johnson and two of its subsidiaries, Ortho-McNeil-Janssen Pharmaceuticals and Johnson & Johnson Health Care Systems. The complaint alleged that the companies paid millions of dollars in kickbacks to Omnicare Inc., the nation's largest pharmacy specializing in dispensing drugs to nursing home patients. In late 2009, Omnicare reached a \$98 million settlement with several states and the federal government to resolve allegations related to kickbacks.[\[43\]](#) The complaint alleges that the kickbacks were intended to induce Omnicare to purchase and recommend Johnson & Johnson drugs, including Risperdal, for use in nursing homes.[\[44\]](#) Risperdal was once Johnson & Johnson's top seller with almost \$5 billion in sales in 2007, before it faced competition from cheaper generic brands.[\[45\]](#)

Separately, in August 2010, the FDA issued a warning letter to Johnson & Johnson subsidiary DePuy Orthopaedics, Inc., stating that DePuy had failed to get appropriate marketing approval or clearance for its TruMatch Personalized Solutions System and Corail Hip System in violation of the Food, Drug, and Cosmetic Act. The FDA informed DePuy that the Corail Hip System had been misbranded and asked the company to immediately halt marketing Corail for unapproved uses. The FDA warned that should DePuy fail to immediately take steps to address the problems, the FDA would take action, including injunctive relief or monetary penalties.[\[46\]](#)

### ***Wyeth***

In September 2010, the DOJ sought to intervene in a whistleblower suit against Wyeth (which was purchased by Pfizer last year) involving allegations of off-label marketing of the transplant drug Rapamune. The lawsuit was filed by two former Wyeth sales representatives and alleges that the company marketed Rapamune for off-label uses and gave kickbacks to doctors to induce them to prescribe Rapamune to their patients.[\[47\]](#)

Separately, the DOJ filed suit against Wyeth for offering big discounts to hospitals across the country for the stomach drug Protonix. According to the government, hospitals that met certain market-share targets received discounts of up to 94% on the oral form of Protonix and 80% on the IV form. The DOJ's lawsuit alleges that Wyeth did not pass similar discounts on to Medicaid--which by law should receive the lowest prevailing price for any given drug--costing Medicaid programs hundreds of millions in rebates. In May 2010, 17 states sought to intervene in the suit.[\[48\]](#)

## ***GlaxoSmithKline***

In October 2008, the DOJ launched an investigation of GlaxoSmithKline in connection with allegations that the company tried to suppress the fact that its diabetes drug Avandia increased the risk of heart attacks. A Senate report filed earlier in 2010 accused GlaxoSmithKline of suppressing the risks of Avandia by intimidating scientists and withholding data, and indicated that many officials at the FDA had been advocating for a recall of Avandia.[\[49\]](#)

## ***Abbott Laboratories***

The U.S. Attorney's Office for the Western District of Virginia is investigating Abbott Laboratories for potential violations relating to its alleged off-label marketing of the drug Depakote. Depakote is approved by the FDA to treat seizure disorders and acute manic episodes associated with bipolar disorder, and to prevent migraine headaches. The government alleges that Abbott improperly promoted use of the drug to treat agitation and aggression in the elderly.[\[50\]](#)

## ***Boston Scientific***

The U.S. Attorney's Office in Massachusetts launched a criminal investigation of Boston Scientific. Though the details of the investigation have not been publicly disclosed, Boston Scientific received a grand jury subpoena just one week after it instituted a recall of its implantable cardioverter defibrillators and cardiac resynchronization therapy defibrillators. As part of the recall, Boston Scientific indicated that it had not received approval from federal regulators for changes made to its manufacturing processes.[\[51\]](#)

## ***Guidant Corporation***

A Minnesota district court judge rejected a plea agreement between the federal government and Guidant Corporation which would have resolved claims that Guidant failed to alert doctors and patients that some of its defibrillators had a defect that might cause them to fail, allegedly resulting in at least six deaths. The deal would have required Guidant to plead guilty to two misdemeanors and pay a \$296 million fine. The court found that the plea agreement did not hold the company sufficiently accountable for its actions, and that prosecutors should have sought, among other things, probation for Guidant and its parent company as well as charitable activities by Guidant to improve heart device safety and medical care among minority patients.[\[52\]](#)

## *Allergan*

Allergan received an "investigative demand" from the DOJ regarding its acne drug Aczone. Allergan also received a subpoena from the Delaware Attorney General's Office relating to dry-eye drug Restasis and Acular LS, an eye-drops brand.[\[53\]](#)

## *Medical Device Manufacturer*

The DOJ intervened in a whistleblower lawsuit against a medical device manufacturer in Massachusetts federal court. The whistleblower, a technical service specialist hired by the company in 2004, filed suit in 2006, alleging that the company's corporate accounts division had offered special deals to hospitals that purchased minimum amounts of the company's products. The DOJ intervened, alleging that the company had given doctors and hospitals kickbacks in return for use of the company's pacemakers and defibrillators.[\[54\]](#) The DOJ also alleges that the company used clinical trials as a platform to pay doctors for implanting its devices.[\[55\]](#) In fall 2010, the company and the DOJ began to engage in settlement talks, and there are indications that a settlement may be close.[\[56\]](#)

## *Bradford Regional Medical Center*

The District Court for the Western District of Pennsylvania found that Bradford Regional Medical Center's relationship with two physicians violated the Stark Act, which prohibits hospitals from submitting claims to Medicare based on referrals from physicians with whom the hospitals have a financial relationship. The lawsuit alleged that Bradford received thousands of improper inpatient and outpatient referrals resulting in several millions of dollars of Medicare payments. The original suit was brought by a whistleblower under the False Claims Act.[\[57\]](#)

## *Medtronic Inc.*

The U.S. Attorney's Office for the Western District of New York issued a subpoena to Medtronic Inc. relating to the company's sales, marketing and reimbursement support practices regarding certain neurostimulation devices. Medtronic manufactures neurostimulators to relieve pain, control overactive bladders, and treat movement and psychiatric disorders.[\[58\]](#)

## *Edwards Lifesciences*

The FDA issued a warning letter to Edwards Lifesciences alleging the company failed to appropriately report complaints concerning serious problems in patients treated with Edwards' heart devices, specifically its annuloplasty ring devices and pericardial heart valve device. The FDA asked that the company correct the violations or face product seizure, injunctions, or fines.[\[59\]](#)

## *FCPA Investigations*

Also on the rise in 2010 were investigations and actions by the DOJ and the Securities and Exchange Commission ("SEC") involving alleged violations of the Foreign Corrupt Practices Act ("FCPA").

The DOJ and the SEC launched an investigation of Merck's foreign operations related to possible violations of the FCPA. The details of the investigation have not been made public.[\[60\]](#)

The DOJ and the SEC also began an investigation of SciClone Pharmaceuticals for possible violations of the FCPA. The government has sought information concerning the company's sale, licensing, and marketing of products in foreign countries, including but not limited to China, where the company has a major presence with its hepatitis B drug Zadaxin.[\[61\]](#)

In addition, the DOJ and the SEC expanded an investigation of Eli Lilly & Co. in connection with allegations of FCPA violations. The SEC notified Lilly in 2003 that it was investigating whether Polish units of certain drug makers, including Lilly, had violated the FCPA. In 2010, the DOJ and the SEC expanded the investigation to several other countries.[\[62\]](#)

AstraZeneca, Bristol-Meyers Squibb and GlaxoSmithKline have also come under investigation by the DOJ and the SEC for alleged FCPA violations, as has Baxter International.[\[63\]](#)

Finally, Pfizer and Johnson & Johnson are reportedly close to reaching an agreement with the DOJ to settle allegations of FCPA violations.[\[64\]](#)

## *Actions Against Individuals*

2010 saw a number of significant lawsuits and enforcement actions against individual corporate executives and physicians.

Perhaps most notable among these is the DOJ's criminal indictment of a former GlaxoSmithKline executive for allegedly covering up the company's off-label marketing of its Wellbutrin SR drug. The executive faces a number of charges including obstruction of justice and making false statements. The indictment alleges that the executive signed letters to the FDA that hid the company's promotion of Wellbutrin SR for off-label uses, including weight loss. The executive allegedly knew that two doctors had repeatedly promoted the drug for off-label use but failed to turn over that evidence during an agency probe, and made affirmative statements that the company had, apart from isolated deficiencies, only promoted Wellbutrin for approved uses.[\[65\]](#)

Another important development was the nationwide investigation by the Health Care Fraud Prevention and Enforcement Action Team ("HEAT") Medicare Fraud Strike Force, which

resulted in charges against 94 individuals across the country--in Brooklyn, Miami, Baton Rouge, Detroit, and Houston--for their roles in various Medicare fraud schemes.<sup>[66]</sup> The government alleges that the schemes involved submission of more than \$251 million in false Medicare claims, and billing for medical equipment and services that were medically unnecessary and, in some cases, never provided.<sup>[67]</sup>

Separately, in what was referred to as the "largest Medicare fraud scheme ever perpetrated by a single criminal enterprise," 73 people were charged with submitting to Medicare more than \$163 million in phony bills from 118 non-existent medical clinics spanning 25 states. The alleged scam netted the participants nearly \$36 million. Many of the defendants were allegedly members of an Armenian-American organized crime syndicate, which also allegedly masterminded a similar fraud scheme involving staged car accidents and false claims to insurance companies.<sup>[68]</sup>

The Colorado U.S. Attorney's office filed a 12-count criminal indictment accusing three former executives of Spectranetics Corporation with illegally importing unapproved medical devices. The charges included conspiracy, making false statements, receipt of illegal imports, sales of adulterated and misbranded medical devices, and other offenses.<sup>[69]</sup>

In the United Kingdom, a senior marketing executive for a medical products firm pleaded guilty to conspiring to channel \$9 million in bribes to Greek surgeons to induce them to use his company's products. This conviction was noteworthy as the defendant cooperated extensively with the Serious Fraud Office. Notwithstanding, the judge in the case said that the public expected an individual involved in what he called "substantial and long-term" corruption to be jailed immediately rather than be given a suspended sentence, as the Serious Fraud Office had recommended. The executive was sentenced to one year in prison.<sup>[70]</sup>

A Massachusetts anesthesiologist was accused of taking research money from the pharmaceutical industry and fabricating results. Specifically, prosecutors allege the physician faked data that suggested after-surgery benefits from various painkillers, including Merck's Vioxx and Pfizer's Bextra and Celebrex drugs. The physician faces a maximum of 10 years in prison and a \$250,000 fine. <sup>[71]</sup>

### **III. Current Trends**

In addition to the significant enforcement actions discussed above, the health care compliance landscape continued to trend heavily toward increased regulatory enforcement in 2010. Intensive public focus on the health care arena has led to numerous legislative, regulatory, and enforcement efforts aimed at returning monies lost through fraud and waste to the public treasuries. As was the case in 2009, these actions have in turn spawned a movement toward greater self-regulation by companies who perceive a benefit in being ahead of the curve.

## **Continued Congressional Scrutiny Led by Senator Grassley**

Senator Charles Grassley of Iowa, the ranking Republican on the Senate Committee on Finance, which has jurisdiction over the Medicare and Medicaid programs, has focused a great deal of attention over the past few years on the relationships between physicians and the health care industry. Senator Grassley has sought to expose those relationships that could create a conflict of interest between corporations and physicians, and has led the debate on whether the federal government should do more to legislate in this area.

In the past several years, Senator Grassley has used the oversight tools available to him to seek disclosure of health care industry financial ties with research physicians, medical schools, medical journals, continuing medical education companies, and patient advocacy non-profit organizations, among others. Most recently, Senator Grassley conducted an inquiry into industry money paid to pharmacy benefit managers, or PBMs. In March 2010, Senator Grassley sent letters to CVS Caremark Corporation, Express Scripts, Inc., and Pharmaceutical Care Management Association, requesting a description of those PBMs' efforts to enhance the transparency of financial benefits they receive from drug makers.[\[72\]](#)

Senator Grassley has also pressed the pharmaceutical industry to adhere to the whistleblower protections of the False Claims Act. In a July 1, 2010 letter to 16 pharmaceutical companies, Senator Grassley asked a range of questions on this topic, including how employees are informed about the whistleblower protections and how the non-retaliation policies are enforced.[\[73\]](#)

## **The Physician Payment Sunshine Act Becomes Law**

Senator Grassley's long-standing efforts to enact the Physician Payment Sunshine Act came to fruition in 2010 with the passage of the new health care legislation, the PPACA, which incorporated the major components of the Sunshine Act.

The PPACA focuses on the disclosure of the financial relationships between industry and physicians. "The goal of our legislation is to lay it all out, make the information available for everyone to see, and let people make their own judgments about what the relationships mean or don't mean," Senator Grassley said in a 2009 statement.[\[74\]](#) The PPACA does not seek to govern the substance of the relationships between industry and health care providers, but does aim to make those relationships transparent.

Under this legislation, beginning in 2012, health care companies are required to report all consulting fees, honoraria, gifts, entertainment, travel, meals, research, charitable contributions, and many other benefits provided to physicians. Moreover, the PPACA establishes a national online registry for all industry payments of \$10 or more to physicians--a sharp change from earlier versions of the Sunshine Act which included a \$100 threshold. Companies will be required to report payments by March 31, 2013, with a searchable database available beginning September 30, 2013. Fines for failure to comply--

whether intentional or not--are severe. Companies could be fined up to \$150,000 per year for inadvertent violations, and up to \$1 million for knowing violations.[\[75\]](#)

The new law only preempts state laws that are less restrictive than the federal law. As a result, given that a number of states already have or are looking to enact tougher laws (as detailed below), there will likely be inconsistencies in the application of the PPACA's disclosure requirements.

## **State Laws With More Teeth Than the PPACA**

A number of states have enacted laws that go beyond the new federal disclosure legislation by altogether prohibiting certain types of gifts or payments to physicians. As explained in our 2009 Year-End Health Care Compliance Update, and briefly summarized below, Massachusetts and Vermont passed sweeping legislation targeting disclosures in 2009. These laws followed Minnesota's 2005 law, which prohibits "any manufacturer or wholesale drug distributor, or any agent thereof, to offer or give any gift of value to a practitioner."[\[76\]](#) New York and New Jersey have considered enacting similar legislation.

### *Massachusetts*

Any company doing business in Massachusetts is subject to a strict health care compliance regime that prohibits providing health care professionals with any entertainment or recreation, travel for continuing medical education or other meetings, or meals other than modest meals provided at a training event. Even the giving of small complimentary items, like branded pens, mugs, and calendars, is prohibited.[\[77\]](#) In 2010, the Massachusetts legislature considered ending the ban on small complimentary items, but ultimately rejected this idea.[\[78\]](#)

Massachusetts requires all pharmaceutical and medical device companies to adopt training programs, conduct annual audits to ensure compliance, develop and implement policies and procedures for investigating and correcting violations, and identify a compliance officer. All companies doing business in Massachusetts must file annual reports with the Department of Public Health outlining their adherence to the new law, and on an annual basis must also disclose payments to health care professionals. The penalty for violations is a fine of up to \$5,000 for each violation.

### *Vermont*

Vermont similarly prohibits certain kinds of gifts or payments to physicians and other health care professionals, and requires disclosure to the state of most other kinds of gifts or payments, regardless of the amount. This legislation is more comprehensive than the new federal legislation, and more sweeping than other states' gift disclosure laws.

The law's broad definition of "gift" includes "anything of value provided to a health care provider for free" and, with a few named exceptions, "any payment, food, entertainment, travel, subscription, advance, service, or anything else of value provided to the health care provider." Certain gifts are exempt under the law--though they still need to be disclosed--



such as patient samples, normal rebates and discounts, devices loaned for evaluation, academic literature, and FDA-approved labels.

All gifts must be disclosed--there is no *de minimus* exception to the reporting requirement. The manufacturer is required to disclose information about the value, nature, and recipient for every gift. The law provides for penalties of up to \$10,000 for each unlawful gift or \$10,000 for failure to report a lawful gift.[\[79\]](#)

## *New Jersey*

New Jersey continues to contemplate legislation that would ban gifts to physicians.

On December 3, 2009, the New Jersey Attorney General released a report from the Division of Consumer Affairs recommending new regulations to curtail the potential for conflicts of interest between physicians and industry. The report sets forth new policies to be considered by the Board of Medical Examiners, the Board of Pharmacy, the Department of Health and Senior Services, and academic medical centers. The new policies would go beyond the voluntary industry codes (PhRMA and AdvaMed), and would ban doctors from accepting any gifts or travel expense reimbursements from any pharmaceutical or medical device manufacturer. In addition, the proposed reforms bar physicians from accepting free food in office settings or at promotional dinners.

Recommended regulations would also require doctors who serve as consultants to pharmaceutical companies or medical device manufacturers to publicly disclose every two years the acceptance of more than \$200 in consulting fees, honoraria, or funding for research or education.

The report also recommends tight controls on what is known in the pharmaceutical industry as "data mining," or tracking physician prescription information. All physicians would have to be notified when renewing their licenses that they can opt out of having information about their prescriptions sold by pharmacists to health care information organizations, which collect information on prescriptions for pharmaceutical company marketing.

In the area of continuing medical education, the report recommends that CME credit only be available for courses that are accredited by the Accreditation Council for Continuing Medical Education, and specifically bars the CME provider from obtaining advice from a company that subsidizes the course, thus creating a separation between educational content and the source of the subsidy.[\[80\]](#)

Although New Jersey did not move forward with legislation in this area in 2010, Governor Chris Christie has historically been a proponent of transparency in the health care industry, and New Jersey thus may be poised to re-examine these proposals in 2011.

## *New York*

New York has similarly toyed with the possibility of banning industry gifts to physicians. Outgoing Governor David Paterson noted in 2010 that he supported such legislation.[\[81\]](#) The New York legislature did not act on the proposal during Paterson's final year in office. Incoming Governor Andrew Cuomo has not made public comments on the matter, but as Attorney General was active in investigating health care compliance matters.

### **Movement Toward Voluntary Disclosures of Physician-Industry Relationships**

There is a clear movement toward voluntary disclosure of the industry's financial relationships with physicians. In 2010, an increasing number of companies voluntarily disclosed payments to physicians. Several companies, including Eli Lilly, Merck, and GlaxoSmithKline, began disclosing payments in 2009. Others, including Pfizer, Cephalon, Johnson & Johnson, Medtronic, and AstraZeneca, joined the ranks in 2010.

The voluntary disclosures have come under varying terms. For example, Medtronic discloses payments of \$5,000 or more.[\[82\]](#) Eli Lilly uses a much lower threshold, but its disclosures are limited to payments to speakers and health care professionals who provide advice on educational and promotional efforts; the disclosures do not include other forms of compensation to health care professionals, though the company is required, under the terms of its Corporate Integrity Agreement, to begin tracking and reporting these payments beginning in 2011.[\[83\]](#)

Many companies that have chosen to disclose have made their databases searchable. Although the databases have generally been formatted to prevent users from downloading and analyzing the data, independent investigators have already begun piecing the information together and cross referencing it against other public sources. One of these investigative groups has reportedly discovered hundreds of physicians who had a history of misconduct or discipline, or who lacked proper credentials for the products they were being paid to promote. That group's findings include a physician who earned nearly a quarter of a million dollars from three drug companies after being ordered by the FDA to stop making "false or misleading" statements about the drug; 92 speakers on one drug company's payroll who had been sanctioned or received FDA warnings; and another physician who earned over \$100,000 just one year before pleading no contest to fraud-related charges.[\[84\]](#)

Doctors who received payments from health care companies found themselves subject to scrutiny as well. A report released by the Archives of Internal Medicine found that more than half of the physicians who earned greater than \$1 million in consulting fees from the medical device industry failed to disclose those ties in their publications.[\[85\]](#) Of course, the failure by a physician to disclose such payments may reflect poorly on the sponsoring company as well and may even invite scrutiny from enforcement agencies.

As public disclosures become the norm over the next few years, public interest groups will likely continue to mine the data to discover evidence of questionable payments to health

care providers. Companies should bear in mind that these groups not only review the consultants' histories, but also closely scrutinize possible patterns in the payments.[\[86\]](#)

## **Increased Relevance of Foreign Corrupt Practices Act**

The aggressive enforcement efforts by federal and state prosecutors in the national arena are matched and perhaps even surpassed by the recent skyrocketing of international anti-corruption enforcement efforts. Because of the nature of the health care systems in many countries, health care companies come into constant contact with government officials internationally. So it should come as no surprise that the DOJ, HHS, and the SEC have begun to aggressively investigate perceived international corruption in the health care industry. As Assistant Attorney General Lanny A. Breuer recently declared, "FCPA enforcement is stronger than it's ever been -- and getting stronger."[\[87\]](#)

Indeed, the DOJ has moved swiftly to investigate the practices of health care companies abroad. While the full extent of the government's interest is not known, many of the industry's heavy-hitters--including Merck, AstraZeneca, Bristol-Meyers Squibb, GlaxoSmithKline, and Eli Lilly--have disclosed that they are under investigation for possible FCPA violations.[\[88\]](#) Other companies, such as Pfizer,[\[89\]](#) Johnson & Johnson,[\[90\]](#) SciClone,[\[91\]](#) and Baxter International[\[92\]](#) have also been linked to DOJ and/or SEC investigations for violations of the FCPA. The companies have indicated that they are part of a broader review by the DOJ of industry practices in foreign countries.[\[93\]](#)

## **Intensified Focus of HHS**

In 2009, Corporate Integrity Agreements ("CIAs") imposed by HHS increasingly required companies to retain one or more "compliance experts," similar to the corporate monitors often required by the DOJ as part of Deferred Prosecution Agreements ("DPAs")--in addition to the Independent Review Organization ("IRO"), which HHS has traditionally required. The compliance experts were vested with the authority to review the company's compliance program and to make binding recommendations, similar to a DPA monitor. Often, these experts were tasked with reporting directly to the company's Board of Directors.

In 2010, HHS transitioned away from requiring "compliance experts" in its CIAs. Instead, the more recent CIAs have significantly bolstered the responsibilities and powers of the IRO. IROs have traditionally undertaken a "systems review" and a "transactions review." The scope of both these areas of review grew substantially in the 2010 CIAs:[\[94\]](#)

- The systems review is a comprehensive look at the company's compliance policies and procedures. While the nature of the systems review has not changed in the more recent CIAs, because the new CIAs require companies to establish certain policies and procedures (as described below), the breadth of the IRO's role in the systems review has increased from years past.
- The scope of the transactions review has been significantly augmented. Older CIAs required that the IRO review records relating to a sample of payments to

# GIBSON DUNN

health care providers, and also provided for a review by the IRO of up to three additional items identified by HHS. In 2010, CIAs also included: a review of a sample of requests from health care providers for information about the company's government reimbursed products; a review of the company's plans for calling on, and distributing samples to, health care providers; and a review of "sampling events" (instances where the company provided samples of the product to health care providers).

As a result, IROs are now vested with much more authority and, like DPA monitors, are tasked with overseeing often significant changes in a company's compliance infrastructure.

HHS's tougher stance on health care compliance is also evidenced by a number of new requirements in its recent CIAs, many of which are substantial undertakings. The onerous requirements of the recent CIAs include:[\[95\]](#)

- *Needs Assessment*: CIAs now require companies to conduct extensive "needs assessments" that establish the *bona fide* need for services conducted by health care providers for the upcoming year and validate the retention of each consultant hired.
- *Policies and Procedures*: The most recent CIAs mandate that the company draft and implement over 20 policy and procedure documents. The policy documents are broad in nature and govern nearly every aspect of the company's relationships with health care professionals. The policy documents are then subject to review by the IRO.
- *Consulting Monitoring Program*: Companies are required to create a "consultant monitoring program," which entails conducting live monitoring of at least 30 consultant arrangements per year to ensure that these arrangements are in line with the company's needs assessment, its policies and procedures, and its contractual obligations.
- *Field Force Monitoring Program*: Companies must establish a comprehensive "field force monitoring program" to evaluate and monitor sales representatives' interactions with health care professionals. This program includes field observations of sales representatives, which entails "full day ride-alongs" with sales representatives to observe meetings between the sales representative and health care professionals.
- *Inquiries Database*: Companies are required to develop a database to track all requests for information about government reimbursed products from health care professionals as well as the company's response to the request (including a record of the materials provided to the health care professional). This database is the subject of extensive review by the IRO.

## **Cooperation between HHS and DOJ**

Now more than ever, the DOJ and HHS are conducting a coordinated battle against health care fraud. Last year, the departments created an interagency group known as HEAT, which was specifically tasked with combating health care fraud. As part of HEAT's efforts, the government expanded the Medicare Fraud Strike Force operations from South Florida and Los Angeles to an additional five health care fraud hot spots including Houston, Detroit, Brooklyn, Baton Rouge, and Tampa.

The DOJ and HHS also held four health care fraud regional summits this year--in Miami, Los Angeles, Brooklyn, and most recently Boston. The purpose of the summits was to bring together a wide array of federal, state and local partners, beneficiaries, and providers to discuss innovative ways to eliminate fraud within the U.S. health care system.[\[96\]](#) Each summit coincided with major announcements of arrests or settlements, most notably the nearly \$700 million in settlements immediately prior to the December 16 conference in Boston.[\[97\]](#)

Moreover, as noted in Section III, an investigation by HEAT's Medicare Fraud Strike Force resulted in charges against 94 individuals across the country for their alleged roles in various Medicare fraud schemes that allegedly involved submission of more than \$250 million in false Medicare claims.

## **Increased Focus of the FDA**

Not to be outdone by federal and state prosecutors, in May 2010, the FDA announced that it was launching a new endeavor, dubbed the "Bad Ad Program," in an effort to deputize health care professionals to anonymously report false or misleading advertising to the FDA. The FDA had traditionally reviewed promotional materials by relying on submissions of the sponsoring companies, industry complaints, and limited field surveillance. But the agency found it was constrained by staffing limitations and was unable to adequately review the considerable universe of industry advertising. The new program appeals directly to health care professionals.[\[98\]](#)

Importantly, the FDA has indicated that it intends to revive the *Park* doctrine and prosecute corporate officials for off-label marketing violations by their companies. The Food, Drug, and Cosmetic Act is one of the few statutes that permits vicarious criminal liability. As the Supreme Court held in *United States v. Park*, 421 U.S. 658 (1975), a corporate executive can be held criminally liable for his company's violation of the Act if that individual "had a responsible relation to the situation and by virtue of his position . . . had . . . authority and responsibility to deal with the situation." But prosecutors have traditionally declined to seek criminal liability for corporate officials. This long-standing practice is changing. On October 13, FDA Deputy Chief for Litigation Eric Blumberg made public remarks suggesting that large monetary payments by corporations were not enough to curb illegal behavior, and that pursuing individual criminal liability was needed to disincentivize companies from violating the law.[\[99\]](#)

There are other signs that more individual prosecutions may be on the way. After GlaxoSmithKline settled with the DOJ over manufacturing violations, the U.S. Attorney for Massachusetts, Carmen M. Ortiz, was conspicuously coy when asked if there would be individual liability in the case. Her responses that "the corporate aspect is finally settled" and that "the investigation is ongoing" have led to speculation that individual prosecutions may be in the pipeline.[\[100\]](#)

## **Growing Strength of the False Claims Act**

As discussed in detail in Gibson Dunn's 2010 Year-End False Claims Act Update, 2010 saw sweeping legislative changes to the False Claims Act.[\[101\]](#) The PPACA made widespread changes to the Act, including (a) a change to the public disclosure bar for *qui tam* suits that made it easier for putative relators (or whistleblowers) to bring suit; and (b) an expansion of the definition of a "false claim" that increased the scope of conduct giving rise to a False Claims Act violation, including an explicit provision that makes violating the Anti-Kickback Statute a false or fraudulent claim under the False Claims Act. Furthermore, the Dodd-Frank Wall Street Reform and Consumer Protection Act, signed into law in 2010, includes an amendment to the False Claims Act that expands protected whistleblower conduct to anyone "associated" with the whistleblower as well as to a broad range of activities related to bringing a False Claims Act suit or stopping potential violations under the Act.[\[102\]](#)

As Assistant Attorney General Tony West remarked halfway through 2010, recent "legislation has greatly increased the [False Claims] Act's power and effectiveness."[\[103\]](#) With the increased strength of the False Claims Act, it is likely that prosecutors will continue to use this statute to garner more record settlements in the years to come.

## **IV. Future Trends**

Although the PPACA was passed by Congress in 2010, the debate over health care reform threatens to rage on. No consensus has emerged over national health care policy, except perhaps, as noted in our 2009 Year-End Health Care Compliance Update, that any workable approach must focus on limiting costs to the greatest extent possible while still striving to expand coverage.

That focus--on the costs of health care and the funding of government programs that regulate the industry and finance coverage--is by no means new. As in the past, we would expect oversight of existing programs, such as Medicare and Medicaid, to be tightened in the future, and for litigation under the False Claims Act and other regulations governing these federal programs to remain commonplace. The sheer volume of settlements in 2010, totaling over \$4 billion--nearly triple 2009's total when excluding the two large, outsized settlements with Pfizer and Eli Lilly last year--speaks to the growing importance of enforcement actions to state and federal regulators. Also telling is the ever-increasing use of the Foreign Corrupt Practices Act as a prosecutorial tool, as the DOJ and the SEC have both focused on the foreign operations of health care companies in recent years.

# GIBSON DUNN

With the entry of a new Congress in 2011, Congressional involvement is also anticipated to intensify. This will take several forms. As in the past, Senator Grassley and other avowed industry watchdogs will likely continue hearings and other inquiries into federal health care entitlement programs. But in the coming year also expect a new front to open in Congress in the battle over how to reverse the federal government's expanding health care obligations.

One of the signature goals of the PPACA was to reign in the practices that raise health care costs for all and bloat the federal deficit. President Obama highlighted this during his campaign for the law, decrying "a system that is currently full of waste and abuse."[\[104\]](#) The costs of this legislation were in large part to be "paid for by finding savings within the existing health care system," and by "eliminat[ing] . . . hundreds of billions of dollars in waste and fraud."[\[105\]](#)

Several Republican legislators have publicly declared the intention to fight against financing for the new health care law. The effect of this ongoing struggle over the PPACA is likely to result in hearings and counterproposals for regulatory reform, as well as possibly subpoenas and other inquiries. Several provisions of that law are not designed to go into effect for several years in any case, and it is widely acknowledged that the full effect of the law on the industry and the federal budget is currently unclear. The coming Congressional skirmishes between supporters of the law and its detractors threaten to muddy the waters even further.

At the state level, leaders in the health care enforcement field--such as former Attorney General Andrew Cuomo and U.S. Attorney Chris Christie--have now moved into the governors' mansions in New York and New Jersey. We would expect their agendas to continue to focus on civil and criminal investigations and other strategies for controlling health care costs for individuals and government agencies.

In this legislative and regulatory environment--short on widely-accepted solutions or broadly-popular comprehensive strategies--the focus is likely to remain on tactical methods, "tried-and-true" techniques, as well as ad hoc, but potentially innovative, approaches.

At the federal level, regulators enter 2011 retooled and well positioned to continue their efforts to stem unlawful health care practices. In the area of rules and regulations, less controversial elements of the new health care legislation contain numerous anti-fraud provisions and also strengthen existing ones, including making violations of the Anti-Kickback Statute also illegal under the False Claims Act. In the area of funding, the PPACA allocates an additional \$350 million over the next decade to health care fraud enforcement.[\[106\]](#) And HHS is poised to receive a \$250 million increase in anti-health care fraud financing, bringing the annual total in this area to a record \$1.7 billion.[\[107\]](#) HHS already has made clear its intention to pursue violators more aggressively, as evidenced by the arduous requirements of the more recent Corporate Integrity Agreements.

# GIBSON DUNN

2010 saw how monies are being put to use by federal agencies--and points in the direction of future enforcement trends. For example, HEAT--HHS's interagency effort with DOJ--took down nearly 100 individuals accused of Medicare fraud.<sup>[108]</sup>

This emphasis on individual liability is perhaps most prominently reflected in the FDA's stated intention to invoke the *Park* doctrine in prosecuting corporate officials for off-label marketing violations. FDA Deputy Chief for Litigation Eric Blumberg: "If you're a corporate executive or are advising a corporate executive, now is the time to comply. . . . That conduct may already be under the criminal microscope."<sup>[109]</sup> Whether it is a reaction to popular resentment and a poor economy, or a hardheaded assessment of what will work best in this environment, expect high-profile enforcement actions against more and more individuals in 2011.

One thing is not expected to change in the coming year. For the practitioner, the in-house legal advisor, or the corporate executive, health care compliance is and will remain a crucial focus area. It is more important than ever for companies to take a hard look at their policies and procedures and act to strengthen them. For companies with long-standing compliance programs, now is the time to re-evaluate and re-energize them in light of existing enforcement priorities and trends. And for companies that have struggled with under-resourced compliance programs, now is the time to invest in the policies, procedures, and personnel necessary to protect not only the companies themselves, but the executives who run them.

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[1] See Gibson Dunn's [2009 Year-End Health Care Compliance Update](#).

[2] Press Release, Office of Pub. Affairs, Dept. of Justice, Departments of Justice and Health and Human Services Team Up to Crack Down on Health Care Fraud (Nov. 5, 2010), available at <http://www.justice.gov/opa/pr/2010/November/10-ag-1256.html>.

[3] Tony West, Assistant Attorney Gen. for the Civil Div., Dept. of Justice, Remarks at the GlaxoSmithKline Press Conference (Oct. 26, 2010) available at <http://www.justice.gov/civil/opa/pr/speeches/2010/civ-speech-101026.html>.

[4] Press Release, Dept. of Justice, Department of Justice Recovers \$3 Billion in False Claims Cases in Fiscal Year 2010 (Nov. 22, 2010), available at <http://www.justice.gov/opa/pr/2010/November/10-civ-1335.html>.

[5] Patrick Burn, *Over \$3 Billion in Fraud Recoveries Under the False Claims Act in FY 2010*, Taxpayers Against Fraud Education Fund (Oct. 25, 2010), available at <http://www.taf.org/whistle295.htm>.

[6] Sammy Almashat, Charles Preston, Timothy Waterman & Sidney Wolfe, *Rapidly Increasing Criminal and Civil Monetary Penalties Against the Pharmaceutical Industry: 1991-2010*, PublicCitizen (Dec. 16, 2010), available at <http://www.citizen.org/hrg1924>.



# GIBSON DUNN

[7] HIPAA refers to the Health Insurance Portability and Accountability Act of 1996.

[8] *See also* Gibson Dunn's [2010 Year-End False Claims Act Update](#).

[9] Press Release, Dept. of Justice, Department of Justice Recovers \$3 Billion in False Claims Cases in Fiscal Year 2010 (Nov. 22, 2010), *available at* <http://www.justice.gov/opa/pr/2010/November/10-ag-1256.html>.

[10] Press Release, Dept. of Justice, Allergan Agrees to Plead Guilty and Pay \$600 Million to Resolve Allegations of Off-Label Promotion of Botox (Sept. 1, 2010), *available at* <http://www.justice.gov/opa/pr/2010/September/10-civ-988.html>.

[11] *Id.*

[12] *Id.*

[13] Eric Holder, U.S. Attorney Gen., Remarks Regarding the AstraZeneca Settlement Announcement (Apr. 27, 2010), *available at* <http://www.justice.gov/ag/speeches/2010/ag-speech-100427.html>.

[14] Press Release, Dept. of Justice, Pharmaceutical Giant AstraZeneca to Pay \$520 Million for Off-label Drug Marketing (Apr. 27, 2010), *available at* <http://www.justice.gov/opa/pr/2010/April/10-civ-487.html>.

[15] *Id.*

[16] Press Release, Dept. of Justice, Novartis Pharmaceuticals Corp. to Pay More Than \$420 Million to Resolve Off-Label Promotion and Kickback Allegations (Sept. 30, 2010), *available at* <http://www.justice.gov/opa/pr/2010/September/10-civ-1102.html>.

[17] Press Release, Dept. of Justice, Novartis Vaccines & Diagnostics to Pay More Than \$72 Million to Resolve False Claims Act Allegations Concerning TOBI (May 4, 2010), *available at* <http://www.justice.gov/opa/pr/2010/May/10-civ-522.html>.

[18] Press Release, Dept. of Justice, Pharmaceutical Companies to Pay \$214.5 Million to Resolve Allegations of Off-label Promotion of Zonegran (Dec. 15, 2010), *available at* <http://www.justice.gov/opa/pr/2010/December/10-civ-1444.html>.

[19] Press Release, Dept. of Justice, Epilepsy Drug Approved by FDA Promoted for Psychiatric Uses (Apr. 29, 2010), *available at* <http://www.justice.gov/opa/pr/2010/April/10-civ-500.html>.

[20] *Id.*

# GIBSON DUNN

[21] Press Release, Dept. of Justice, Kos Pharmaceuticals to Pay More Than \$41 Million to Resolve Kickback and Off-Label Promotion Allegations (Dec. 7, 2010), *available at* <http://www.justice.gov/opa/pr/2010/December/10-civ-1402.html>.

[22] Press Release, Dept. of Justice, Detroit Medical Center Pays U.S. \$30 Million to Settle False Claims Act Allegations (Dec. 30, 2010), *available at* <http://www.justice.gov/opa/pr/2010/December/10-civ-1484.html>.

[23] Jacqueline Bell, *Exactech to Pay \$3M to Settle Kickbacks Case*, Law 360, New York (Dec. 7, 2010), *available at* <http://www.law360.com/competition/articles/213954>.

[24] Eric Hornbeck, *Wright Medical to Pay \$7.9M Over False Marketing*, Law 360, New York (Oct. 1, 2010), *available at* <http://www.law360.com/web/articles/198013>.

[25] Press Release, Dept. of Justice, Heart Device Manufacturer in Minnesota and Hospitals in Ohio & Kentucky to Pay Nearly \$4 Million to Resolve Fraud Allegations (June 4, 2010), *available at* <http://www.justice.gov/opa/pr/2010/June/10-civ-658.html>.

[26] Press Release, Dept. of Justice, The Health Alliance of Greater Cincinnati and the Christ Hospital to Pay \$108 Million for Violating Anti-Kickback Statute and Defrauding Medicare and Medicaid (May 21, 2010), *available at* <http://www.justice.gov/opa/pr/2010/May/10-civ-602.html>.

[27] Press Release, Dept. of Justice, United States Settles False Claims Act Allegations with Cochlear Americas for \$880,000 (June 9, 2010), *available at* <http://www.justice.gov/opa/pr/2010/June/10-civ-673.html>.

[28] Press Release, Dept. of Justice, St. Joseph Medical Center in Maryland to Pay U.S. \$22 Million to Resolve False Claims Act Allegations (Nov. 9, 2010), *available at* <http://www.justice.gov/opa/pr/2010/November/10-civ-1271.html>.

[29] Nina Yangstrom, *Swept Up in Major Medical Device Case, Physician Pays \$650,000 to Settle Kickback Charges*, AIS Health Business Daily (May 3, 2010), *available at* [http://www.aishealth.com/Compliance/ResearchTools/RMC\\_MD\\_Pays650K.html](http://www.aishealth.com/Compliance/ResearchTools/RMC_MD_Pays650K.html).

[30] News Release, U.S. Food & Drug Admin., Forest Pharmaceuticals agrees to guilty plea for violating FDA laws (Sept. 15, 2010), *available at* <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm225890.htm>.

[31] *Id.*

[32] Press Release, Dept. of Justice, Schwarz Pharma Pays \$22 Million to Settle False Claims Allegations Concerning Reimbursements for Unapproved Drugs (Apr. 29, 2010), *available at* <http://www.justice.gov/opa/pr/2010/April/10-civ-499.html>.

# GIBSON DUNN

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