2011 YEAR-END HEALTH CARE COMPLIANCE UPDATE

To Our Clients and Friends:

Health care compliance enforcement exploded in 2011. The trends we have seen in recent years--historical settlements, increased enforcement activity, stricter settlement terms, and tougher penalties for individuals--not only continued unabated in 2011, but the pace of enforcement activity skyrocketed.

This was a year of unparalleled settlements, with state and federal governments recovering approximately $6.8 billion from the health care industry--vastly outpacing the nearly $4 billion recovered in 2010. There can be no question that, with each passing year, the industry is being hit harder and wider by broadening enforcement efforts.

Indeed, fighting health care fraud remained an avowed "top priority" for the Obama Administration.[1] As Tony West, the Assistant Attorney General for the Civil Division of the Department of Justice (the "DOJ"), proclaimed at the end of 2010: "From 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."[2]

This "laser" focus on health care fraud is no doubt a reaction, at least in part, to the budgetary woes that have dominated our political discourse in recent years. With health care taking up 21% (or $732 billion) of the federal budget in 2010,[3] it is not surprising that health care compliance is--now more than ever--an indispensable tool for cutting health care spending. After all, in addition to the revenue the government is able to generate through its enforcement efforts, health care compliance has been consistently singled out as an effective means of cutting rising national health care costs through the elimination of fraud, waste, and abuse.

Putting aside the long-term cost-cutting goals, it is clear that health care compliance enforcement has become a smart short-term investment for the government. Indeed, the DOJ's enforcement efforts over the last three years have offered an almost seven-fold "return on investments"--meaning the DOJ recovered nearly $7 for every dollar it spent on enforcement.[4]

In 2011, federal and state prosecutors targeted their enforcement efforts on "tried-and-true" areas of prosecution, such as off-label marketing, illegal kickbacks, and fraudulent billing practices. This approach paid off, with the DOJ procuring the largest settlement of all time for off-label marketing--a $3 billion fine on GlaxoSmithKline.[5]

Prosecutors continued to employ the False Claims Act as one of the primary weapons in their arsenal. Putting aside the GlaxoSmithKline settlement, the government recovered a staggering $2.4 billion in fiscal year 2011 from the health care industry through False Claims Act settlements alone, with $2.2 billion of that amount paid by pharmaceutical companies.[6] The vast majority of these cases originated as qui tam actions, brought by whistleblowers on behalf of the government pursuant to the
False Claims Act. *Qui tam* suits hit a peak of 638 this past year, after hovering in the 300s and low 400s for much of the last decade, and *qui tam* whistleblowers made far more in share awards in 2011 than in any other year.[7]

Individuals continued to be singled out this year by the DOJ, the Department of Health and Human Services ("HHS"), the Food and Drug Administration (the "FDA"), and other agencies. The interagency efforts between HHS and the DOJ through the Health Care Fraud Prevention and Enforcement Action Team ("HEAT") expanded considerably and resulted in charges against nearly 250 individuals across the country.[8] And while the average health care fraud prison sentence at the beginning of 2011 was 40 months, 2011 saw sentences that obliterated previous records, including a 50-year prison sentence—the longest health care fraud sentence ever issued.[9] HHS even launched a list of Most Wanted Fugitives.[10] This high-profile focus on individual liability is part of a forceful effort to disincentivize health care fraud and to ensure that the fines and penalties imposed on corporations are not viewed as simply part of the cost of doing business.

Given these aggressive enforcement trends, it is crucial that health care companies, and their legal and compliance officers, be as relentless in their efforts to strengthen their compliance policies and procedures as regulators and prosecutors are in enforcing health care laws and regulations.

This Update provides a detailed review of notable settlements and judgments in the health care area in 2011 (Section I) as well as significant actions and investigations (Section II), with a primary focus on the efforts of federal prosecutors and regulators. Section III sets forth an analysis of current trends in health care enforcement and compliance, and Section IV includes a projection of future trends that we anticipate based on the current environment.

I. **Notable Settlements and Judgments**

**Off-Label Marketing**

*GlaxoSmithKline*

In the largest settlement of its kind, the British drug company GlaxoSmithKline agreed to pay $3 billion to settle criminal and civil investigations into its sales practices for numerous drugs in the United States. The settlement resolves the investigation into alleged off-label marketing of the diabetes drug Avandia. The government also alleged that GlaxoSmithKline paid doctors and manipulated medical research to promote the drug. The settlement also resolves a DOJ investigation of GlaxoSmithKline's Medicaid pricing practices and a nationwide investigation into the company's sales and marketing of nine drugs between 1997 and 2004.[11]

*Merck, Sharp & Dohme*

Merck, Sharp & Dohme paid $950 million and pled guilty to a misdemeanor charge for introducing a misbranded drug into interstate commerce. Merck's criminal plea related to the company's promotion of Vioxx for treating rheumatoid arthritis before the drug was approved for that use by the FDA. Merck also entered into a civil settlement agreement, under which it will pay $628,000 to resolve allegations involving off-label marketing of Vioxx, as well as allegations that Merck representatives
made inaccurate, unsupported, and misleading statements about Vioxx's cardiovascular safety in order to increase sales of the drug. As part of the settlement, Merck agreed to enter into an expansive corporate integrity agreement with HHS.[12]

**Elan Pharmaceuticals, Inc.**

Elan Pharmaceuticals, Inc. pled guilty to a misdemeanor charge for illegal promotion of the epilepsy drug Zonegran. Elan was sentenced to a criminal fine of $97 million and agreed to forfeit $3.6 million in assets. Elan also agreed to pay $102 million to resolve civil allegations stemming from the company's alleged illegal promotion of Zonegran for off-label uses, including for treatment of psychiatric disorders, migraine headaches, eating disorders, and Parkinson's Disease. As part of the settlement, Elan agreed to enter into a corporate integrity agreement with HHS. The civil settlement resolves a whistleblower suit brought under the *qui tam* provisions of the False Claims Act.[13]

**Forest Pharmaceuticals, Inc.**

Drug manufacturer Forest Pharmaceuticals Inc., a subsidiary of Forest Laboratories, Inc., pled guilty to one felony count of obstructing justice, one misdemeanor count of distributing an unapproved new drug in interstate commerce, and one misdemeanor count of distributing a misbranded drug in interstate commerce. The company was sentenced to pay a criminal fine of $150 million and to forfeit assets of $14 million. The criminal pleas relate to alleged obstruction of justice in connection with an FDA regulatory inspection, as well as the distribution of Levothroid, a drug used to treat hypothyroidism, which at the time was an unapproved drug, and the alleged off-label promotion of the anti-depressant Celexa for use in treating adolescents and children. The sentencing was the final component of a global resolution totaling more than $313 million. As we reported in our 2010 Year-End Health Care Compliance Update, last year Forest Laboratories and Forest Pharmaceuticals entered a related civil settlement to resolve False Claims Act charges involving the drugs Levothroid, Celexa and Lexapro, in which Forest agreed to pay more than $149 million. The company also entered into a corporate integrity agreement with HHS.[14]

**Genentech Inc. and Roche**

Genentech Inc., a subsidiary of the Swiss pharmaceutical company Roche, paid approximately $20 million to resolve allegations involving off-label marketing. The DOJ intervened in a whistleblower lawsuit, which alleged that Genentech promoted, and turned a blind eye toward, rampant off-label use of its Rituxan drug. The suit also alleged kickbacks to, and improper entertainment of, physicians. The whistleblower, a former company sales development manager, will receive $5.7 million out of the proceeds of the settlement.[15]

**Novo Nordisk**

Danish pharmaceutical manufacturer Novo Nordisk reached a settlement to resolve allegations of off-label promotion of the hemostasis management drug, NovoSeven, used to treat bleeding disorders in hemophiliacs. The company paid $25 million to resolve civil liability arising from the alleged promotion of the drug for off-label uses, including as a coagulatory agent for trauma patients and in general surgery, cardiac surgery, liver surgery, and liver transplants, and for intra-cerebral
hemorrhage. Novo Nordisk entered into an expansive corporate integrity agreement with HHS as part of the settlement. The settlement resolved a *qui tam* whistleblower lawsuit, with the whistleblowers receiving $3.5 million from the settlement proceeds.[16]

**UCB S.A.**

The U.S. subsidiary of Belgian pharmaceutical manufacturer UCB S.A. pled guilty to off-label promotion of its epilepsy drug Keppra. The company was sentenced to pay a $7.55 million criminal fine for the alleged misbranding of Keppra, along with forfeiture of $1 million. Keppra was approved as an anti-epileptic drug, but was allegedly marketed for treatment of headaches, migraines, psychiatric conditions, and pain management. UCB also paid $25.7 million to resolve related civil allegations under the False Claims Act, bringing the total penalty to more than $34 million.[17]

**Johnson & Johnson**

Johnson & Johnson disclosed that it reached an agreement to settle a misdemeanor criminal charge related to the alleged off-label marketing of its anti-psychotic drug Risperdal, though the settlement has not yet been finalized.[18] Johnson & Johnson is also facing lawsuits by several states over its marketing of Risperdal. For example, a South Carolina judge upheld a jury verdict that found that the company's marketing practices violated the South Carolina Unfair Trade Practices Act, and assessed $327 million in damages to be paid to the State of South Carolina. Another case is set for trial in January 2012, in which the State of Texas is seeking more than $1 billion in damages.[19]

In a separate action, Johnson and Johnson subsidiary, Scios, Inc., paid $85 million and pled guilty to a misdemeanor charge for off-label marketing of the drug Natrecor. The company was accused of marketing the drug, which is approved to treat congestive heart failure patients in hospitals and emergency rooms, for allegedly off-label use as a routine, outpatient infusion. The criminal resolution does not end a related civil suit, which was brought by a whistleblower under the False Claims Act.[20]

**Anti-Kickback Violations**

**Serono Laboratories, Inc.**

Pharmaceutical giants Serono Laboratories, Inc., EMD Serono Inc., Merck Serono S.A., and Ares Trading S.A. agreed to pay $44.3 million to resolve allegations regarding the marketing of the drug Rebif, an injectable used to treat relapsing forms of multiple sclerosis. Serono allegedly paid health care providers to promote Rebif, including compensating providers for participating in hundreds of training meetings and programs, as well as entertainment functions at upscale resorts. As part of the False Claims Act settlement, HHS extended Serono's existing corporate integrity agreement by three years, and imposed more robust compliance procedures, including requiring that the company's directors and senior executives take personal responsibility for ensuring and monitoring compliance with federal laws.[21]
Medtronic Inc.

Medtronic Inc. agreed to pay $23.5 million to settle claims that it violated the False Claims Act by inducing doctors to implant the company's pacemakers and defibrillators through kickbacks in the form of payments for post-market studies and device registries. The settlement resolves two *qui tam* lawsuits in Minnesota and California. The whistleblowers will receive payments totaling nearly $4 million from the federal share of the recovery.[22]

Medical Device Manufacturer

A medical device manufacturer agreed to pay $16 million to resolve allegations that the company used post-market clinical studies and a registry (a collection of data maintained by device manufacturers concerning products that have been sold and implanted in patients) to pay kickbacks to induce physicians to implant the company's defibrillators and pacemakers. The government alleged that the company paid participating physicians a fee that ranged up to $2,000 per patient to implant the company's products. The False Claims Act case was commenced by a *qui tam* whistleblower, who recovered more than $2.6 million as part of the settlement.[23]

Cardinal Health, Inc.

A whistleblower paved the way for an $8 million settlement by Cardinal Health, Inc. to resolve allegations that it violated the False Claims Act by making payments to induce referral orders for its prescription drugs in violation of the Anti-Kickback Statute. The whistleblower, a former pharmacy owner, claimed that Cardinal Health paid him $440,000 in exchange for an agreement that he purchase prescription drugs from Cardinal Health for his stores.[24]

Novo Nordisk

Novo Nordisk paid $1.725 million to resolve allegations that sales representatives in four states and the District of Columbia made payments to pharmacists in a major chain in exchange for the pharmacists recommending the drugs Novolin and Novolog to patients with diabetes. The pharmacists allegedly worked with Novo Nordisk sales representatives to identify patients who were candidates to use the drugs, then communicated with physicians, patients, or other pharmacists to encourage them to use or recommend the drugs. The company also entered into a corporate integrity agreement as part of the settlement.[25]

Wright Medical Technology, Inc.

The one-year deferred prosecution agreement entered into by Wright Medical Technology, Inc. in September 2010 was extended for an additional 12 months after the company acknowledged a breach of the original agreement. The deferred prosecution agreement related to allegations that Wright Medical entered into consulting agreements with orthopaedic surgeons as an inducement to use the company's hip and knee replacement products. The new agreement also extends the federal monitorship of Wright Medical.[26]
Medicare and Medicaid Billing Fraud

**Quest Diagnostics**

Quest Diagnostics agreed to pay $241 million to the State of California, the state's largest recovery in the history of its False Claims Act. The State alleged that Quest systematically overcharged the Medi-Cal program for more than 15 years and gave illegal kickbacks in the form of discounted or free testing to doctors, hospitals, and clinics that referred Medi-Cal patients and other business to their labs. The State alleged that Quest charged Medi-Cal up to six times more than it charged other customers for the same tests.[27]

**Renal Care Group**

Following a trial, a federal judge awarded $82 million plus costs to the United States, finding that Renal Care Group, Renal Care Group Supply, and Fresenius Medical Care Holdings, Inc. recklessly disregarded federal law when billing the Medicare program for home dialysis supplies and equipment from 1999 to 2005. The court found that defendants set up a sham billing company to help create illicit revenue. The case was brought by a whistleblower and investigated by the FBI and HHS.[28]

**CVS Pharmacy, Inc.**

CVS Pharmacy Inc., the retail pharmacy division of CVS Caremark Corporation, which operates more than 7,000 pharmacies in 41 states, agreed to pay $17.5 million to resolve allegations that it submitted inflated prescription claims to the federal government. The company allegedly billed Medicare and Medicaid for prescriptions even though beneficiaries were also eligible for payment through third-party insurance plans which excluded Medicare as the primary payor. The company will pay the federal government nearly $8 million, and ten states will split an additional $9.5 million. As part of the settlement, CVS executed an amendment to its already-existing corporate integrity agreement with HHS.[29]

**Watson Pharmaceuticals, Inc. and Sandoz**

Generic-drug maker Watson Pharmaceuticals, Inc. paid $79 million to resolve claims that it defrauded federal and state governments by causing them to overpay for drugs manufactured by the company. Similarly, Sandoz, a Novartis subsidiary specializing in generic drugs, agreed to pay $66 million to resolve claims that it overcharged federal and state governments for drugs it manufactured. Both lawsuits originated from a *qui tam* lawsuit by Ven-A-Care of the Florida Keys, Inc., a specialty pharmacy that has to date settled at least 18 lawsuits, allowing state and federal governments to collect at least $2.2 billion, with Ven-A-Care obtaining more than $380 million in whistleblower fees.[30]

**LabCorp**

LabCorp agreed to pay $49.5 million to settle a Medicaid fraud suit brought by the State of California. The lawsuit apparently originated from information relayed to Medi-Cal by Hunter Laboratories, one of LabCorp's rivals, alleging that LabCorp was charging the State more than five times what it billed
other customers for certain tests. California law requires that companies charge Medi-Cal no more than they charge any other company or patient for the same product or service.[31]

**New York City**

New York City paid $70 million to resolve allegations that it improperly administered the Medicaid personal care services program by authorizing personal care services for Medicaid beneficiaries without the legally required assessments and approvals. The DOJ alleged that, between 2000 and 2010, the United States paid tens of millions of dollars in reimbursements for these services. The case originated from a *qui tam* whistleblower suit.[32]

**New York Downtown Hospital**

New York Downtown Hospital paid $13.5 million to settle Medicaid fraud and kickback allegations by the federal government and the State of New York. The hospital allegedly admitted the same patients multiple times to its unlicensed inpatient detoxification program. It also allegedly paid a monthly fee of $38,500 to its co-defendant, Special Care Hospital Management, for patient referrals, in violation of the Anti-Kickback Statute.[33]

**GE Healthcare Inc. and Amersham Health Inc.**

GE Healthcare Inc., agreed to pay $30 million, plus interest, to settle allegations against Amersham Health, Inc., which it acquired in 2004. The government alleged that Amersham Health provided false or misleading information to Medicare regarding the number of available doses of its Myoview drug. Since Medicare payments were based on the amount of the drug that was available, the information the company provided to Medicare allegedly caused Medicare to pay for the drug at inflated prices. The allegations were first raised in a *qui tam* action under the False Claims Act. The whistleblower will receive $5.1 million of the government's recovery.[34]

**KV Pharmaceutical Company and Ethex Corporation**

KV Pharmaceutical Company, the parent of now-defunct Ethex Corporation, agreed to pay $17 million to resolve False Claims Act allegations that Ethex failed to advise Medicare and Medicaid that two unapproved products did not qualify for coverage under federal health care programs. The government alleged that Ethex misrepresented the regulatory status of Nitroglycerin ER and Hyoscamine ER, and failed to advise Medicare and Medicaid that the FDA had determined that the drugs were not eligible for reimbursement. The settlement also resolved a *qui tam* lawsuit. The federal government will receive approximately $10 million, state Medicaid programs will receive approximately $7 million, and the whistleblower will receive about $1.5 million of the federal share.[35]

**Janzen, Johnston & Rockwell**

Janzen, Johnston & Rockwell Emergency Medicine Management Services, Inc., a provider of medical billing services, paid $4.6 million to settle allegations that it submitted false claims to Medicare and Louisiana's Medicaid program. The government alleged that the company utilized a coding formula that generated higher levels of billing for evaluation and management than the physicians provided.
The company also allegedly billed routinely for services provided by teaching physicians which were not eligible for reimbursement. The lawsuit was initially brought by a former employee under the *qui tam* provisions of the False Claims Act.[36]

**Geisinger Medical Center**

The Geisinger Medical Center of Danville, Pennsylvania, agreed to pay $1.3 million to resolve allegations that it erroneously submitted improper claims to Medicare. The company allegedly billed Medicare for evaluation and management services provided to patients on the same day that medical procedures were performed. Such services, known as "Modifier 25," may be submitted as part of a claim to Medicare, but only when they are performed separately from the care associated with a given procedure.[37]

**Dartmouth-Hitchcock Medical Center**

Dartmouth-Hitchcock Medical Center in New Hampshire reached a $2.2 million settlement resolving allegations that the hospital improperly billed federal programs by billing for services performed by resident physicians in training when no attending physician was present. The suit originated from a *qui tam* lawsuit brought by a former physician at the hospital.[38]

**Vanguard Healthcare**

Tennessee-based Vanguard Healthcare paid $2 million to resolve allegations of Medicare billing fraud. The government alleged that the firm double-billed for certain services and submitted bills for ineligible patients. As part of the settlement, the firm agreed to implement an internal monitoring program and to educate its employees on compliance with federal laws and regulations.[39]

**LifePoint Hospitals**

LifePoint Hospitals paid nearly $1 million to settle allegations that it improperly billed outpatient care as inpatient care at its Mayfield, Kentucky hospital. As part of the settlement, the company entered into a five-year corporate integrity agreement with HHS.[40]

**Guidant LLC**

Boston Scientific wholly-owned subsidiary Guidant LLC agreed to pay $9.25 million to resolve False Claims Act allegations that the company inflated the cost of replacement pacemakers and defibrillators to federal health care programs by failing to grant warranty credits and rebates to hospitals, thereby increasing the overall price of the products.[41]

**Select Medical Holdings**

Select Medical Holdings settled a False Claims Act suit involving a former employee for $7.5 million. The plaintiff had claimed that Select made clinical decisions on patients’ lengths of stays in rehabilitation hospitals based on weekly reports on patients’ insurance reimbursements, regardless of
medical need. The company signed a five-year corporate integrity agreement as part of the settlement, as HHS intervened in some of the plaintiff's claims.

**HIPAA**

**Cignet Health Center**

The HHS Civil Rights Office fined Cignet Health $4.3 million in connection with delays in producing patient medical records. The fine was the first time the federal government imposed a monetary civil penalty on a covered entity for a HIPAA violation. Forty-one patients filed complaints with HHS's Office for Civil Rights, claiming Cignet denied them access to their medical records within the requisite 60 days from the patients' requests. After an investigation, HHS determined a civil monetary penalty for these violations of $1.3 million. HHS further found that Cignet refused to cooperate with HHS's investigation because it failed to respond to HHS's demands to produce records (HHS filed a petition to enforce its subpoena and obtained a default judgment in 2010), and that the failure to cooperate was due to Cignet's willful neglect to comply with HIPAA; HHS imposed an additional $3 million penalty for these alleged violations.

**Massachusetts General Hospital**

Massachusetts General Hospital agreed to pay $1 million to settle allegations of a HIPAA violation. The purported violation arose because documents that included protected health information for 192 patients from the hospital's Infectious Disease Associates outpatient practice were allegedly left on the subway by a hospital employee.

**Individual Sentences**

2011 saw a notable uptick in sentences for individuals who were found to have violated criminal health care statutes.

In September, the lengthiest ever health care fraud sentence was imposed on Lawrence Duran of Miami-area mental health care company American Therapeutic Corporation ("ATC"). Duran was sentenced to 50 years in prison after pleading guilty to a $205 million Medicare fraud scheme. The two other owners of the company were each sentenced to 35 years in prison. The three defendants were ordered to pay $87 million in restitution to the government. The defendants were accused of masterminding a scheme to defraud Medicare from 2002 to 2010 by submitting false and fraudulent claims through ATC, which purportedly operated "partial hospitalization programs," a form of intensive treatment for several mental illness; the defendants were also accused of using a related company, American Sleep Institute ("ASI"), to submit fraudulent Medicare claims. According to evidence introduced at trial, the defendants paid millions of dollars in bribes and kickbacks to owners and operators of assisted living facilities and halfway houses and to patient brokers in exchange for delivering ineligible patients to ATC and ASI, using an extensive money laundering scheme. The government further alleged that the defendants caused the alteration of patient files and therapist notes to make it falsely appear that patients being treated by ATC qualified for partial hospitalization treatment.
Michel Dinkel, the owner of Drew Medical, was banned from doing business with Medicare for eight years after an administrative judge found that, over a two-year period, Dinkel caused the submission of nearly 9,500 false claims to the Medicare and Medicaid program seeking inappropriate reimbursements for a procedure known as venography. The DOJ previously entered into a civil False Claims Act settlement with Dinkel, Drew Medical, and Central Florida Radiology, for more than $1.1 million. However, prior to its settlement, HHS informed Dinkel that it intended to exclude him from the settlement, making way for individual punishment.[48]

Several physicians lost their medical licenses and are under investigation for allegedly implanting unnecessary heart stents, charging Medicare and Medicaid millions in unnecessary reimbursements. A Maryland surgeon was convicted of health care fraud in July for implanting as many as 100 unnecessary cardiac stents; the surgeon faces up to 10 years in prison,[49] and the hospital that employed him settled for $1.8 million for failure to address complaints of unnecessary stenting lodged against the surgeon.[50] Similar investigations and convictions have occurred in other hospitals in Maryland, as well as in Tennessee and Pennsylvania.

Finally, a former InterMune Inc. CEO was sentenced to a $20,000 fine, three years' probation, community service, and six months in confinement for wire fraud concerning the issuance of a press release which stated that the drug Actimmune treated idiopathic pulmonary fibrosis, an allegedly off-label use of the drug.[51]

**Foreign Corrupt Practices Act ("FCPA")**

**Johnson & Johnson**

Johnson & Johnson agreed to pay $70 million to resolve investigations by the DOJ and the Securities and Exchange Commission (the "SEC") into alleged violations of the FCPA between 1998 and 2006. The settlement stems from a voluntary disclosure by the company in 2007 that its international subsidiaries may have made improper payments with regard to the sale of medical devices. The company also entered into a three-year deferred prosecution agreement.[52] Shortly after this settlement, Johnson & Johnson shareholders brought a derivative lawsuit in the federal court in New Jersey, alleging the company failed to create internal controls to detect FCPA violations and breached its duty to shareholders by concealing the specifics of the alleged offenses.[53]

Johnson & Johnson subsidiary, DePuy International Ltd., agreed to pay $7.9 million to settle allegations by the UK’s Serious Fraud Office that it paid bribes to Greek officials to win contracts to supply orthopaedic products.[54] A former DePuy International marketing director was sentenced to one year in prison, though the sentence was later overturned by an appeals court.[55]

Separately, the FDA filed a consent decree against Johnson & Johnson unit McNeil-PPC and two of its officers for failing to comply with good manufacturing practice requirements. The consent decree follows extensive recalls of products manufactured at McNeil's facilities. As part of the consent decree, the company agreed to retain an independent consultant to inspect the sites and recommend improvements, which will then be submitted to the FDA.[56]
**Pfizer Inc.**

Pfizer Inc. announced that it would pay more than $60 million to settle allegations that it paid bribes to win overseas business. Pfizer announced that the settlement with the DOJ and SEC regarded "potentially improper payments" made by Pfizer and Wyeth, which Pfizer acquired in 2009. The settlement has not yet been finalized, and is subject to change.[57]

**Other Notable Settlements and Judgments**

**Google, Inc.**

Online giant Google, Inc. forfeited $500 million for allowing online Canadian pharmacies to place advertising targeting consumers in the United States through its AdWords program, resulting in alleged unlawful importation of controlled and non-controlled prescription drugs into the United States. Google allegedly was made aware of the problem as early as 2003, but failed to resolve it.[58]

**Daiichi Sankyo Co. Ltd. and Ranbaxy Laboratories Ltd.**

Ranbaxy Laboratories Ltd., a subsidiary of Japanese pharmaceutical company Daiichi Sankyo Co. Td., announced that it would settle criminal and civil DOJ claims for approximately $500 million, pending court approval of the consent decree. The FDA accused Ranbaxy in 2009 of falsifying data and rest results, and halting review of certain medications. The DOJ alleged that Ranbaxy lied about the ingredients and formulations in some of its products.[59]

**II. Notable Investigations and Actions**

**Off-Label Marketing**

**Merck**

Merck disclosed that it received a subpoena from the DOJ seeking documents relating to its marketing of three drugs: Temodar, which treats brain tumors; PegIntron, which treats hepatitis C; and Intron A, which treats certain cancers and other conditions. In 2010, Merck was charged with offering Vietnamese doctors kickbacks for prescribing PegIntron, and in 2006, Merck settled a claim involving off-label marketing of PegIntron; the current inquiry appears to be unrelated to the prior investigations.[60]

The DOJ also issued a subpoena to Merck requesting information about the marketing of the heart drug Integrisin and the antibiotic Avelox.[61]

Separately, the DOJ issued a civil investigative demand to Inspire Pharmaceuticals, which Merck acquired in May 2011, in connection with alleged off-label uses of the drug AzaSite.[62]
Cephalon

Cephalon received a subpoena from the U.S. Attorney's Office for the Southern District of New York requesting documents relating to promotion of its leukemia drug Treanda. Cephalon is currently operating under a corporate integrity agreement from a 2007 settlement of an investigation into off-label promotion of several of its medications, including the wakefulness drug Provigil.[63]

Abbott Laboratories

The DOJ joined in a False Claims Act whistleblower lawsuit against Abbott Laboratories that alleges off-label promotion of the seizure drug Dekapote. The lawsuit claims Abbott promoted Depakote as a treatment for Alzheimer's disease and dementia, even though the drug was not approved for such uses. As of October 2011, Abbott had reached a tentative settlement agreement and recorded a $1.5 billion charge for the third quarter to cover related payments.[64]

Anti-Kickback Violations

North Broward Hospital District

HHS is investigating North Broward Hospital District in connection with potential violations of the federal Stark and Anti-Kickback laws. HHS has served a subpoena on North Broward for documents related to contracts between North Broward and more than 27 physicians.[65]

Medicare and Medicaid Billing Fraud

Community Health Systems Inc.

Community Health Systems is under investigation by the SEC and HHS in connection with allegations concerning patient admission practices and related billing.[66] The investigation is believed to be related to the company's ultimately unsuccessful takeover bid for Tenet Healthcare.[67] Two class action lawsuits were also filed recently against Community Health Systems, alleging inflation of the company's stock price over a multi-year period.[68]

CardioNet

CardioNet received a civil investigative demand from the DOJ relating to allegations that the company used inappropriate codes with respect to Medicare claims for its heart-monitoring services. The demand was issued in the course of an investigation under the False Claims Act and seeks documents that date back to 2007.[69]

Health Management Associates, Inc.

Health Management Associates, Inc. has received two federal subpoenas seeking records relating to patient referrals and emergency room management.[70]
Nurses' Registry and Home Health Corporation

The DOJ intervened in a *qui tam* False Claims Act lawsuit filed in 2008 by two former Nurses' Registry Employees against the Nurses' Registry and Home Health Corporation. The lawsuit alleges that the Nurses' Registry made false claims to Medicare for medically unnecessary home health services.[71]

**BestCare Laboratories, Inc.**

The DOJ filed a complaint against BestCare Laboratories, Inc. and its founder, alleging the defendants knowingly misrepresented the distances traveled by various lab technicians in order to artificially increase the Medicare reimbursement for travel allowance fees. The original lawsuit was filed by a *qui tam* whistleblower.[72]

**Actions Against Individuals**

In 2011, HEAT's Medicare Fraud Strike Force charged 111 defendants in nine cities across the country for $225 million in false billing claims. The defendants face charges of falsely billing Medicare for treatments that did not occur or were medically unnecessary.[73]

Another nationwide takedown by the Medicare Fraud Strike Force resulted in charges against 91 individuals in eight cities for approximately $295 million in false billings. The defendants are charged with various health care related crimes, including conspiracy to defraud Medicare, health care fraud, violations of the Anti-Kickback Statute, and money laundering.[74]

In another significant HEAT prosecution, the DOJ and HHS brought a 38-count indictment against 20 individuals in Florida for Medicare fraud, kickbacks, and money laundering. The defendants, employees of American Therapeutic Corporation and Medlink Professional Management Group Inc., allegedly altered therapy charts and notes to show that mental health patients qualified for partial hospitalization programs even though they were ineligible. The falsification of these records was used by those charged in these schemes to justify services that were unapproved or medically unnecessary.[75]

The Medicare Fraud Strike Force also charged 12 individuals, including three medical doctors and other licensed health professionals, for their roles in several alleged health care fraud schemes which resulted in more than $95 million in false claims to the Medicare program.[76]

**Other Notable Investigations and Actions**

**Forest Laboratories Inc.**

Forest Laboratories received a document subpoena from the U.S. Attorney's Office for the District of Massachusetts in connection with three of its blood pressure drugs, Benicar, Benicar HCT, and Azor.[77]
Gilead Sciences Inc.

Gilead, a leading AIDS and HIV drug manufacturer, received a subpoena from the U.S. Attorney's Office for the Northern District of California seeking documents regarding its manufacturing and distribution practices. The investigation focuses on five marketed drugs and an experimental compound.[78]

AstraZeneca and Medco Health Solutions

AstraZeneca and Medco Health Solutions, a pharmacy benefits manager, received subpoenas from the DOJ requesting information about four AstraZeneca drugs--the acid reflux drugs Nexium and Prilosec, and the hypertension drugs Plendil and Toprol XL.[79]

Boston Scientific Corp.

The DOJ filed a civil lawsuit against Boston Scientific Corp. and related Guidant entities under the False Claims Act for conduct relating to several of the company's cardiac devices. The government alleges that Guidant sold cardioverter defibrillators even though it knew those devices were defective, and hid the problems with those devices from patients, doctors, and the FDA. The lawsuit originated from a qui tam whistleblower suit brought by a patient who allegedly received one of the defective devices. In 2010, Guidant pled guilty to misleading the FDA about problems with the devices; a federal court in Minnesota accepted the company's plea in early 2011. Boston Scientific Corp. had acquired Guidant in 2006.[80]

III. Current Trends

Growing Strength of the False Claims Act

The DOJ has continued to use the False Claims Act as one of its primary weapons against health care fraud (see Gibson Dunn's 2011 Year-End False Claims Act Update).[81] In fiscal year 2011, the DOJ secured more than $3 billion in settlements under the False Claims Act--a staggering $2.4 billion of which involved health care fraud. Nearly $2.2 billion was recovered from pharmaceutical companies. Indeed, since January 2009, the federal government has collected $8.7 billion in recoveries under the False Claims Act, which is "the largest three-year total" in history. The vast majority of those collections were in the health care industry. According to the DOJ, "[s]ince January 2009 alone, the department has used the False Claims Act to recover more than $6.6 billion in federal health care dollars. This is more recovered under the Act than in any other three-year period."[82]

As noted in our 2010 Year-End Update,[83] the Patient Protection and Affordable Care Act (the "PPACA") amended the False Claims Act to provide additional incentives for whistleblowers to report fraud and strengthened the provisions of the federal Anti-Kickback Statute. It is thus not surprising that $2.8 billion of the $3 billion in recoveries for fiscal year 2011 came from suits filed under the whistleblower provisions of the False Claims Act. Indeed, whistleblowers initiated more new matters in 2011 than in any other prior year on record--638 (or 84%) of the 762 new False Claim Act matters--and earned more than $532 million in share awards.[84]
Increased Use by HHS of Corporate Integrity Agreements

2011 saw the continued increasing use by HHS of corporate integrity agreements with settling corporations. These settlements show that HHS will no longer let offending corporations pay and move on; instead, HHS is demanding expensive post-settlement monitoring. As part of 2011 settlements, HHS required each of the following companies to sign or extend a corporate integrity agreement: Merck, Elan Pharmaceuticals, Forest Pharmaceuticals, Novo Nordisk, Serono Laboratories, CVS Pharmacy, LifePoint Hospitals, and Select Medical Holdings. These settlements related to a wide array of alleged health care compliance violations, including misbranding of drugs, off-label marketing, kickbacks to physicians, kickbacks to pharmacists, and improper billing of Medicare and Medicaid.

Park Doctrine and Continued Focus on Prosecution of Individuals

In 2011, government prosecutors continued the trend of increased enforcement actions against individuals, including health care industry executives. As discussed above (Sections I and II), 2011 saw record sentences for health care executives, as well as increased enforcement activity against individuals (executives, physicians, and other health care professionals), primarily undertaken by the DOJ/HHS HEAT unit.

Though prosecutors have traditionally declined to seek criminal liability for corporate officials, the government has indicated that trend is changing. FDA Deputy Chief for Litigation Eric Blumberg warned in late 2010, executives will be increasingly "under the criminal microscope."[85] Assistant Attorney General Tony West addressed this point in a November 2, 2011, speech to the 12th Annual Pharmaceutical Regulatory and Compliance Congress, telling the gathered executives and compliance officials that prosecutors would "demand[] accountability" of corporate officers by continuing to "consider prosecutions against individuals."[86] His statement followed on the heels of the FDA's February 2011 addition to its regulatory manual for when to recommend Park Doctrine prosecutions.[87] The Park Doctrine enables the government to prosecute corporate officials for violations by their companies of the Food, Drug and Cosmetic Act, even absent knowledge or intent, based on their position within the company of responsibility and authority to prevent and correct violations. Individuals convicted under the Park Doctrine are subject to criminal fines, disbarment by the FDA, and exclusion from participating in federal health care programs.

Under the new criteria, relevant factors the FDA will consider in determining whether or not to recommend a Park Doctrine indictment include:

- The individual's position in the company;
- Whether he or she had the authority to prevent or correct the violation;
- Whether the violation involves actual or potential harm to the public;
- Whether the violation is obvious;
- Whether the violation reflects a pattern of illegal behavior and/or failure to heed warnings;
• Whether the violation is widespread;
• Whether the violation is serious;
• The quality of the legal and factual support for the proposed prosecution; and
• Whether the proposed prosecution is a prudent use of agency resources.

Prosecutors had some ground-shifting wins against individual defendants, including the sentencing of four former Synthes Inc. executives to prison terms between five and nine months each.[88] Additionally, Forest Laboratories CEO Howard Solomon received a letter from HHS noting that HHS was considering his exclusion from federal health care programs under the Park Doctrine, even though he was not named in civil or criminal proceedings against Forest, or in the eventual settlement. However, in August 2011, HHS announced that it would not pursue the exclusion.[89]

**Continuing Prominence of the Foreign Corrupt Practices Act**

In 2011, U.S. authorities continued to focus on non-compliance of health care sector companies with the FCPA (see Gibson Dunn’s 2011 Year-End FCPA Update).[90] Because of the nature of the health care systems in many countries, health care companies come into constant contact with government officials internationally, including physicians at government hospitals. It is thus not surprising that the DOJ, SEC, and HHS are aggressively focusing on international anti-corruption enforcement.

While the full extent of the government’s interest in the health care sector is not known, as we reported in our 2010 Year-End Health Care Compliance Update, 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. Further, as noted above, Johnson & Johnson settled a six-year-long FCPA investigation, as well as a separate investigation by the U.K.’s Serious Fraud Office.[91] Meanwhile, the SEC broadened its FCPA investigation of Zimmer Holding's operations in the Asia-Pacific region.[92]

**Disclosures of Physician-Industry Relationships**

The Physician Payments Sunshine Act, enacted in 2010 as Section 6002 of the PPACA[93], requires that, beginning on January 1, 2012, health care companies track all cash, in-kind items or services, stocks, consulting fees, honoraria, gifts, entertainment, travel, meals, education research, charitable contributions, royalties, ownership interests, grants, 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, and all cumulative payments of $100 per year per physician. Beginning on March 31, 2013, companies will be required to make annual public reports of such payments, with a searchable database available as of 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.[94]

In our 2010 Year-End Health Care Compliance Update, we reported on the steady movement toward disclosure of industry's financial relationships with physicians even in advance of the Physician
Payments Sunshine Act. Indeed, at least eight drug makers and medical device manufacturers, including Eli Lilly, Merck, GlaxoSmithKline, Pfizer, Cephalon, Johnson & Johnson, Medtronic, and AstraZeneca, already publicly report payments to physicians, either voluntarily or as required under settlement agreements with government authorities. The nature of these disclosures, however, is not uniform, as the companies currently disclosing this information use varying minimum thresholds and report different types of fees and expenses. The Sunshine Act, however, should bring much-needed uniformity to these disclosures.

To implement the Sunshine Act, the PPACA mandated that, by October 1, 2011, HHS implement procedures to allow manufacturers to submit information on physician payments, and for HHS to make such information available to the public. HHS delegated this task to the Centers for Medicare & Medicaid Services ("CMS"). When CMS missed its October 1, 2011 deadline to provide rules for manufacturers, Senators Charles Grassley and Herb Kohl pressed CMS to come forward with regulations, asked why CMS had failed to meet the statutory deadline, and requested a timeline for establishing the regulations.[95] CMS Administrator Donald Berwick responded on October 28, 2011, blaming the delay on the Presidential directive for agencies to reduce regulatory burden.[96]

The rule proposed by CMS was finally made public on December 19, 2011. Perhaps most importantly, the proposed rule declared that companies need not collect information required under the Sunshine Act beginning on January 1, 2012. Instead, companies need to begin to do so only 90 days after the publication of the final rule. As expected, the rule proposes the requirements for the content and organization of payment reports. The rule also would require manufacturers to maintain books and records to enable an audit for compliance with the law, for at least five years. Additionally, the proposed rule would expand the definition of an applicable manufacturer to encompass any company that manufactures a covered product for sale in the U.S. The rule would clarify the definition of "covered products" and "covered recipients."[97]

As part of the debate over the proposed rule, the Office of Management and Budget ("OMB") will consider the rule's likely economic impact on industry and the government. Indeed, the OMB website lists the rule as "economically significant."[98] This proposed rule, which may be amended or withdrawn at any time, is unlikely to be finalized and released prior to summer 2012, given the anticipated back and forth between CMS and OMB on its economic impact.[99] Comments on the proposed rule are due by February 17, 2012.[100]

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 been joined in his efforts by Republican Senator Kohl of Wisconsin, the Chairman of the Senate's Special Committee on Aging. Senator Grassley has been a driving force behind the federal government's efforts to expose those relationships--ultimately resulting in passage of the Sunshine Act. Naturally, he has also been active in pushing for its expeditious implementation, as described above. Over the past year, Senator Grassley's other attempts to publicize the health care industry's financial relationships, and expose potential conflicts of interest, include:
• In May 2011, Senator Grassley requested that disease and medical advocacy groups publicly disclose industry support they receive. He noted that the lobbying efforts of these groups allow them to influence the way taxpayer dollars are spent, and thus consumers and taxpayers would benefit from additional transparency.[101]

• In June 2011, Senators Grassley and Max Baucus requested information from medical device manufacturer Medtronic about medical researchers with financial ties to Medtronic, which allegedly failed to report evidence of issues with Medtronic's Infuse product.[102]

• Senators Grassley and Baucus also sent a letter to the FDA, detailing "the financial relationship between the pharmaceutical company Sanofi-Aventis and physicians' groups that lobbied the agency against approving generic drugs that would compete with Sanofi products." Senator Grassley noted that the FDA should conduct diligence of this kind itself.[103]

Senator Grassley has repeatedly spurred legislative investigation of various financial arrangements in the health care arena by capitalizing on media reports and other sources of information identifying potential conflicts of interest. We expect these efforts to continue gaining steam, as the codification under the PPACA may alter norms with respect to disclosures, and increase the scrutiny and investigation of additional types of financial arrangements going forward.

**Continued Congressional Scrutiny Led by Senator Grassley**

Senator Grassley's focus on health care compliance has not been limited to exposing financial relationships that create potential conflicts of interests. Indeed, he has also led the charge in various other areas related to health care compliance. For example:

• After a news report alleged that Pfizer agreed to provide discounts to pharmaceutical benefit management companies ("PBMs") and insurance companies in exchange for their agreement to block prescriptions for the generic equivalent of certain Pfizer medications, Senators Grassley and Kohl sent a letter in December 2011 to Pfizer, PBMs (Express Scripts, Medco, and Catalyst RX), and insurance companies (Coventry Health Care and United Health), in which they requested information and a detailed list of agreements which block generics or favor brand-name drugs.[104]

• In November 2011, Senators Grassley and Baucus sent a letter to Cigna, Aetna, United Health Group, Laboratory Corporation of America, and Quest Diagnostics, in which they asked about a practice whereby insurers receive discounted pricing from labs in exchange for referrals. They noted that the HHS has called such arrangements "particularly suspect" and that they raise kickback concerns.[105]

• Senator Grassley argued, ultimately unsuccessfully, that the OMB should not remove a requirement in the HHS rules that would have required a publicly available website to publish the outside financial interests of researchers funded by taxpayers.[106]

• In July 2011, the Senate Judiciary Committee approved the Preserve Access to Affordable Generic Drugs Act, which would limit "pay-for-delay" settlements that keep generic drugs off
the market. The Act would deter the brand name drug company practice of settling patent disputes by paying generic drug manufacturers in exchange for the promise that the generic version of the drug would be kept off the market. Under the bill, such agreements would be presumed illegal and the Federal Trade Commission would be given the authority to stop the arrangements.[107] In October, Senators Grassley and Kohl urged the Joint Select Committee on Deficit Reduction to include the bill, which the Congressional Budget Office estimates would save taxpayers $4.8 billion over a decade, as part of its budget-cutting efforts.[108] The bill is currently pending.

**Free Speech Challenges to Off-Label Marketing Rules**

Several suits filed in 2011 challenge on First Amendment grounds the government’s ban on off-label marketing. While similar arguments have failed previously, ongoing cases may be supported by the Supreme Court’s June 2011 ruling in *Sorrell v. IMS Health Inc.*, in which the Court held that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment."[109]

For example, in *United States v. Caronia*, a health care company's sales representative was convicted by a federal trial court of promoting and selling a drug for off-label uses. The plaintiff appealed the ruling to the Second Circuit Court of Appeals, in which he raised a First Amendment defense that the federal government's restrictions on off-label marketing impair his exercise of free expression in marketing drugs. Eleven companies, including Pfizer, GlaxoSmithKline, and Johnson & Johnson, filed amicus briefing in support of the plaintiff, arguing that "off-label use is a necessary and common practice," and that applying the FDA's off-label rules to plaintiff's alleged conduct "appears to be constitutionally indefensible," given the Supreme Court's holding in *Sorrell*. The Second Circuit has requested additional briefing in light of the *Sorrell* decision, and has not yet issued a decision.[110]

Additionally, Par Pharmaceutical and Allergan both sued the FDA, claiming that its off-label marketing restrictions trampled on the drug makers' free speech rights. Par's suit, which is still ongoing, claims a constitutional right to provide truthful information about its drugs, and argues that the FDA's rules prohibit the company from talking about its drugs to doctors that might prescribe them off-label.[111] Meanwhile, Allergan claimed it sued in order "to get better clarity" about its rights to share information with doctors. However, Allergan dropped its suit as part of its off-label settlement and guilty plea with the DOJ for off-label marketing of Botox.[112]

While no court has found off-label marketing regulations to be unconstitutional, the pending cases may restrict or eliminate the government's ability to enforce current off-label marketing regulations. At a minimum, these suits are likely to result in decisions that provide additional guidance regarding appropriate behavior and restrictions surrounding marketing practices. Given the tremendous scrutiny given to off-label marketing, and the value of fines paid for violation of those rules, we expect continued and increased focus by industry in attempts, including those based on the First Amendment, to reign in government enforcement in this area.
Clarification of Preemption Rules in Labeling Lawsuits

In *Pliva v. Mensing*, the Supreme Court held that certain lawsuits against generic drug-makers for inadequately labeling their products in violation of state law were pre-empted by the FDA's federal drug regulations, which require generic drugs to bear the same drug label as those used by the brand manufacturer. Writing for the 5-4 majority, Justice Clarence Thomas acknowledged that, for consumers, it would make little sense that brand-name manufacturers could be sued for the labels on their products while generic drug-makers could not be sued for identical labels, but that result was required by the law. In dissent, Justice Sonia Sotomayor pointed out that whether a harmed consumer can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug.[113]

Even after the Supreme Court's ruling in *Pliva*, these issues continue to be litigated. For example, months after the *Pliva* ruling, a state court judge in Pennsylvania held that the *Pliva* decision did not "foreclose any state law cause of action against generic prescription drug manufacturers." Thus, the court found that every claim must undergo a state-by-state examination to determine if abiding by the state law would be in direct conflict with the FDA rule, and thus preempted by the federal rule.[114] We expect continued litigation in this area, as plaintiffs and generic drug manufacturers test which state laws are in direct conflict with the FDA rule, and thus preempted under *Pliva*.

The Sixth Circuit Court of Appeals rejected an argument that the preemption mandated by *Pliva* either "altered state law claims against brand manufacturers whose products were not ingested or undermined the prior weight of authority that a brand manufacturer owes no duty to a consumer of generic products."[115] The court held that, "[a]s have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company."[116] This decision is strongly favorable for brand manufacturers because it holds that *Pliva's* restriction on suits against generic manufacturers does not create additional causes of action against *brand* manufacturers. In other words, if a plaintiff is harmed by a generic drug, but its labeling suit against the generic manufacturer is preempted because the generic manufacturer was required to copy the label of the brand manufacturer, the plaintiff cannot bring suit against the brand manufacturer, whose products it did not use.

IV. Future Trends

With the Supreme Court granting *certiorari* to the constitutional challenge to the PPACA by 26 states, the outlook of some recent areas of reform—including the disclosure rules of the Sunshine Act—is uncertain. More assured, however, is that, whatever the outcome of the health care entitlement debate, there is broad bipartisan agreement on a continuing determined effort to reduce health care spending through the elimination of fraud, waste, and abuse.

The President and Congress have proven their commitment to fighting health care fraud. At a time when most federal prosecutors' budgets are frozen, funding for health care fraud enforcement continues to increase—and for good reason. Spending on health care fraud enforcement has gone from a good government investment to a great one. Since 2009, return-on-investment for health care fraud enforcement spending has grown from $4.41[117] to nearly $7[118] for every dollar spent.
That increase is especially significant because it demonstrates that prosecutors have stretched their dollars further even as they have been given more money to spend. The results have been momentous, with yet another year of blockbuster recoveries in 2011. This year saw the continuation of several trends: (1) Total recoveries set yet another new record—almost $7 billion; (2) settlements grew in size and severity, with the largest by GlaxoSmithKline reaching a new record of $3 billion; (3) regulators continued to heavily employ the False Claims Act, with more and more cases initiated by whistleblowers who stood to gain millions of dollars from the lawsuits; (4) prosecutors increasingly pursued individual liability for corporate executives; and (5) HEAT--HHS's interagency effort with DOJ--established itself as a formidable presence in the enforcement arena, with several nationwide takedowns that resulted in charges against nearly 250 individuals.

Perhaps the most significant continuing trend is the increased focus on prosecution of individual defendants, including health care executives. As Assistant Attorney General Tony West recently noted, prosecutors will "demand[] accountability" of corporate officers by continuing to "consider prosecutions against individuals."[119] This proclamation came on the heels of the FDA's recent addition to its regulatory manual of special procedures and considerations for Park Doctrine prosecutions, as we have described above.[120]

Another important trend, which we expect to continue into 2012 and beyond, is the increased activity of qui tam whistleblowers empowered to bring actions on behalf of the government pursuant to the False Claims Act. Qui tam plaintiffs, who may receive up to 30% of any recovery, earned a record $532 million in share awards in 2011, a more than $140 million increase over 2010 share awards.[121] Given these tremendous awards, we expect that whistleblowers will remain just as active in the coming year, and that the government will increasingly rely upon these private plaintiffs to detect and expose fraud.

The common thread behind the increase in both corporate and individual liability is, as West articulated, that enforcement officials "seek to disprove the ill-advised notion that health care fraud enforcement is simply the cost of doing business," and that prosecutors will therefore "insist[] on judgments, convictions, settlements, penalties and fines that eliminate any benefit that may be obtained from engaging in unlawful conduct in the first place."[122]

Enforcement officials have long recognized that the potential budgetary savings that could be realized through eliminating fraud, waste, and abuse are far greater than the money recovered through judgments and settlements.[123] With this larger purpose in mind, and armed with bigger budgets and staff, we can expect that enforcement actions will continue to increase in the years to come.

But the DOJ has also signaled that its door is open to companies that wish to come forward and voluntarily disclose instances of fraud. Saying that it wants to "encourage" companies to be proactive in eliminating abuses of the federal budget, the DOJ renewed its promise to credit early disclosure and "consider that disclosure in deciding whether or how to charge or resolve a health care fraud matter."[124] Given the trend toward more onerous corporate and individual penalties, we expect that companies will increasingly avail themselves of this option in the years ahead. While this creates a great opportunity for companies to be proactive in stamping out fraud, it could at the same time generate added problems for those companies with ineffective compliance programs which remain
idle, and which could find themselves enmeshed in the voluntary disclosures of a competitor, supplier, or customer.

For all those responsible for health care compliance--individual practitioners and institutional providers, corporate compliance officers, and health care executives--all signs indicate that recent trends will continue, and that health care compliance will remain a critical enforcement area in 2012 and beyond. The risk of liability is more present than ever, and can be minimized only through a concerted and continual effort to refine and strengthen compliance policies and procedures. Companies with long-standing compliance programs should take steps to re-evaluate and re-energize them in light of existing enforcement priorities and trends. And companies that have struggled with under-resourced compliance programs must invest in the policies, procedures, and personnel necessary to protect not only the companies themselves, but also the executives who run them. There is no doubt that the consequences--both financial and personal--that can be avoided through the implementation of an effective compliance program will far outweigh the costs of such a commitment. More than ever, compliance is just a matter of good business.


[7] Id.


Christopher Matthews & Joe Palazzolo, Pfizer Near Settlement on Bribery, WSJ.com (Nov. 21, 2011), available here.


[67] Id.

[68] Id.


[92] Joe Palazzolo, SEC Subpoenas Zimmer Holdings In Foreign Bribery Probe, WSJ.com (May 5, 2011); available here.

[93] In March 2012, the Supreme Court of the United States will hear arguments on the constitutionality of the PPACA. Thus, the outlook for the disclosure rules of the Sunshine Act is, as of now, uncertain.

[94] 42 U.S.C. § 1320a-7h.


[97] Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, A Rule Proposed by the Centers for Medicare & Medicaid Services on 12/19/2011, available here.


[100] Medicare, Medicaid, Children's Health Insurance Programs; Transparency Reports and Reporting of Physician Ownership or Investment Interests, A Rule Proposed by the Centers for Medicare & Medicaid Services on 12/19/2011, available here.


[112] Ben Comer & Matthew Arnold, Allergan drops FDA lawsuit as part of off-label settlement (Sept. 2, 2010), available here.


[119] Id.


The White Collar Defense and Investigations Practice Group of Gibson, Dunn & Crutcher LLP successfully defends corporations, senior corporate executives, and public officials in a wide range of federal and state investigations and prosecutions, and conducts sensitive internal investigations for leading companies in almost every business sector. The Group has members in every domestic office of the Firm and draws on more than 75 attorneys with deep government experience, including numerous former federal and state prosecutors and officials, many of whom served at high levels within the Department of Justice and the Securities and Exchange Commission.

Our attorneys bring a unique breadth of experience and talent to handle complex health care enforcement matters, as well as to conduct delicate internal investigations in the health care arena. We have used that experience and perspective for a wide range of health care compliance counseling engagements, including, as examples, reviews of company protocols and policies concerning interactions with health care providers, conceptualizing and instituting needs assessment reviews for the utilization of physician-consultants, and conducting analyses of how compliance policies are effectuated in the field. Our practice is cross-disciplinary in nature, at times relying on experts in various areas to address issues such as health care privacy and data breaches, intellectual property licensing, and fair market value rates, including members of our Health Care Practice Group and our Life Sciences Practice Group.

Los Angeles
Debra Wong Yang (213-229-7472, dwongyang@gibsondunn.com)
Marcellus McRae (213-229-7675, mmcrae@gibsondunn.com)
Michael M. Farhang (213-229-7005, mfarhang@gibsondunn.com)
Douglas Fuchs (213-229-7605, dfuchs@gibsondunn.com)
Kevin S. Rosen (213-229-7635, krosen@gibsondunn.com)

New York
Joel M. Cohen (212-351-2664, jcohen@gibsondunn.com)
Lee G. Dunst (212-351-3824, ldunst@gibsondunn.com)
Mark A. Kirsch (212-351-2662, mkirsch@gibsondunn.com)
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