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Expert Analysis

Health Care Compliance in 2009 And Going Forward: *Part 2*

NOTABLE INVESTIGATIONS AND ACTIONS

Matching the rapid rise in significant settlements and judgments in the health care compliance area, numerous significant health care investigations and lawsuits were initiated in 2009 at both the federal and state levels. Like the matters resolved in 2009, those instigated in the past year targeted a wide range of alleged conduct, including off-label marketing, False Claims Act violations, Medicare and Medicaid fraud, kickback schemes, and fraudulent marketing practices.

Amgen

Fourteen states and the District of Columbia filed suit Oct. 30, 2009, against the biotechnology giant Amgen Inc., accusing the company of engaging in illegal kickbacks to promote sales of the Aranesp anemia drug. The lawsuit alleges that Amgen provided free samples to doctors and clinics by putting tiny extra amounts of the drug in each vial. The medical practices could then make a profit by billing insurers, including state Medicaid programs, for the extra drug.

The lawsuit also alleges that Amgen, in cooperation with a division of AmerisourceBergen, invited doctors to weekend retreats, paying for their food and lodging and giving them extra payments as "advisers." The suit joins a whistle-blower suit with similar allegations filed by a former Amgen sales representative.[1]

Biomet

In January 2009 the U.S. attorneys' offices in Massachusetts and West Virginia launched separate investigations into Biomet Inc., a leading orthopedic device manufacturer, for improper sales, promotion and billing by its spinal device unit, EBI. The company allegedly promoted the off-label use of its spine stimulation devices, resulting in fraudulent Medicare and Medicaid billing.

The West Virginia investigation stemmed from a whistle-blower lawsuit alleging that a surgeon engaged in clinical research implanted the devices without asking for the consent of the patients. The complaint also alleges that on 15 occasions, a representative of the EBI unit was in the operating room while the spinal products were used for off-label proposes.

The Massachusetts investigation may have stemmed from another whistle-blower suit, which claimed that Biomet was improperly billing bone-growth stimulators as

devices that must be purchased, rather than rented. *See* Thomas M. Burton & David Armstrong, *Biomet Sales of Bone-Growth Devices Investigated*, WALL ST. J., Apr. 20, 2009.

Stryker Biotech

Stryker Biotech LLC, along with its former president and three current sales managers, were charged criminally Oct. 28, 2009, in federal court with participating in a fraudulent marketing scheme of medical devices used during invasive spinal and long bone surgeries. The company and its former CEO were also charged with making false statements to the Food and Drug Administration.

The indictment alleges the defendants participated in an illegal marketing scheme to promote medical devices used during invasive surgeries and in doing so defrauded medical professionals and the FDA. These devices were approved by the FDA only pursuant to a highly restrictive "humanitarian device exemption." One of the restrictions was that the device could only treat a condition that affected fewer than 4,000 patients in the United States and could not be sold for a profit. The indictment charges that the defendants promoted the use of these devices in a manner that was different from their FDA-approved uses.[2]

Stryker, Biomet, DePuy, Medtronic

Numerous health care cases were initiated in 2009 at both the federal and state levels, including off-label marketing, Medicare and Medicaid fraud and kickback schemes.

Just a week after its settlement with Synthes in May 2009, the New Jersey attorney general's office issued to Stryker Corp., Biomet Inc., DePuy Orthopaedics Inc. and Medtronic Inc. subpoenas seeking documents related to the financial interests of, and the companies' arrangements with, physicians participating in clinical trials on behalf of the companies. Each company disclosed receipt of the subpoena in various public filings.[3] The subpoenas sought documents regarding clinical studies, financial arrangements with certain physicians and health care providers, and research by certain physicians and health care providers.

Scios Inc.

In December 2009 it was reported that the U.S. Department of Justice was considering filing off-label marketing charges against Johnson & Johnson subsidiary Scios Inc. The government apparently believes Scios methodically pitched the drug Natrecor for chronic heart problems besides heart failure.

According to reports, doctors gave patients off-label infusions of the IV drug, helping to push sales to $111.2 million in 2002 — more than double the $47.3 million the previous year. By 2005 safety worries arose, leading Medicare to restrict reimbursement for the drug; the government program would only pay when Natrecor was used in hospitals.

The Scios case began with a whistle-blower. In 2005, a *qui tam* suit accused Scios of an "extensive and far reaching" off-label marketing campaign for Natrecor. According to those allegations, sales representatives were told to talk up the off-label uses to doctors, and the company sponsored seminars about the benefits of using Natrecor off-label. *See* Dan Levine, *Marketing Tactics Put Johnson & Johnson Under DOJ Microscope*, THE RECORDER, Dec. 3, 2009.

Siemens Medical Solutions

Criminal investigators from the U.S. Department of Defense raided the Siemens Medical Solutions headquarters facility in Malvern, Pa., in April 2009, just weeks

after Siemens won a $267 million medical-imaging contract from the DOD. The raid, which sought documents and other information, was reportedly related to a False Claims Act whistle-blower lawsuit filed in January 2009. That suit alleged Siemens disregarded the best-value requirements in federal contracts for a range of medical imaging equipment by offering commercial customers deeper discounts than it gave federal customers, including the DOD, the Department of Veterans Affairs and the Federal Bureau of Prisons. *See* MaryClaire Dale, *Defense investigators raid Siemens Medical in Pa.*, Associated Press, Apr. 22, 2009.

CURRENT TRENDS

In addition to the significant enforcement actions discussed above, 2009 has seen dramatic developments on several fronts. The intensive public focus on the health care arena has prompted a heightened degree of legislative and regulatory scrutiny as well as groundbreaking new legislation at the federal and state levels. These actions have in turn spawned a movement toward greater self-regulation, both by the pharmaceutical and medical-device industries and by individual companies who perceive a benefit in being ahead of the curve. Finally, in late 2009, the government gave the industry a sharp and unequivocal warning of its intent to launch a targeted assault on international corruption in the health care field.

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Continued congressional scrutiny led by Sen. Grassley

U.S. Sen. Charles Grassley of Iowa, the ranking Republican on the Finance Committee, which has jurisdiction over the Medicare and Medicaid programs, has focused a great deal of attention during the past few years on the relationships between physicians and industry. Grassley's stated goals are twofold: first, to shed light on relationships that may create a conflict of interest between corporations and physicians, and second, to determine whether the federal government should do more to legislate in this area.

Grassley's committee lately has investigated various aspects of the health care industry, concentrating in particular on the relationships between health care professionals and the pharmaceutical industry — and on a perceived lack of transparency as to those relationships. Throughout 2009, Grassley's subpoenas to companies and doctors have been making headlines in major national newspapers including the New York Times and the Wall Street Journal.

Additionally, Grassley's focus on "ghostwriting" — articles drafted by drug company-sponsored ghostwriters and then attributed to independent academic authors — has garnered attention and calls for change. In a recent editorial, the editors of the medical journal PLoS Medicine, from the Public Library of Science, called for a zero-tolerance policy under which medical journals would identify and retract ghostwritten articles and refuse to publish future work by their authors.

That editorial comes on the heels of a July 2009 request in which the senator asked eight leading medical journals to describe their policies and practices regarding ghostwriting. This request followed Grassley's earlier communications with other institutions, including Wyeth, Merck, DesignWrite and Scientific Therapeutics Information.[4]

The Physician Payment Sunshine Act of 2009

Sen. Grassley, along with Wisconsin Democratic Sen. Herb Kohl, introduced the Physician Payment Sunshine Act of 2009 Jan. 22, 2009. The law is a strengthened

version of a bill previously introduced in 2007, which some health care companies had supported.

The 2009 version focused on the disclosure of the financial relationships between industry and physicians but does not govern those relationships. The law includes language mandating public disclosure of physician investments in and ownership of manufacturers, and it has sharper teeth.

"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," Grassley said in a statement.

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.

While the bill itself languished at the committee level, all its major elements appear in the health care reform legislation recently passed by Congress and signed into law by President Obama.[5]

The Physician Payment Sunshine Act is not the only new statute governing these interactions. As drafted, the federal law will not preempt state law, and some states already have enacted even tougher rules. Other states are looking to follow suit, as detailed below. And, of course, while the federal legislation focuses only on the disclosure of relationships, Congress could always seek to govern the substance of those relationships in the future.

New state laws in 2009

Several states passed new legislation in 2009 aimed at regulating interactions between health care professionals and the industry. These laws follow 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."

Massachusetts, Vermont and New Jersey all moved strongly in the direction of regulating the physician-industry relationship. Massachusetts now 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 of the code, and identify a compliance officer. It also prohibits gifts of any kind to physicians — even small branded items. And it requires that any payments to physicians more than $50 be publicly disclosed.

Vermont's new law limits gifts to health care professionals; while it allows small branded items, it mandates that they be disclosed, with no *de minimis* exception. Both states' laws include severe penalties for violations.

In New Jersey, late in 2009, the state attorney general released a report from the Division of Consumer Affairs recommending new regulations to curtail the potential for conflicts of interest between doctors and pharmaceutical companies and medical device manufacturers. The report recommends a ban on gifts and travel expense reimbursement to doctors from any pharmaceutical or medical device manufacturer. In addition, the proposed reforms bar physicians from accepting free food and meals in office settings or at promotional dinners. The threshold for public disclosure would be $200 over two years.

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.[6]

Increased focus of HHS

In recent months, HHS has taken a tougher stance against health care fraud. Increasingly, corporate integrity agreements imposed by HHS require companies to retain one or more "compliance experts," similar to the corporate monitors often required by the DOJ as part of deferred prosecution agreements. The compliance experts are vested with the authority to review the company's compliance program and to make binding recommendations, similar to a DPA monitor. Often, these experts are tasked with reporting directly to the company's board of directors.

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Signed in late 2008, Bayer's CIA mandated a compliance expert panel. Similarly, Quest's CIA in 2009 required a compliance expert. And Pfizer's CIA, signed in 2009, in addition to requiring a more expansive mandate for the independent review organization than most CIAs, also called for an outside reviewer to monitor the company's compliance with its obligations.[7]

If this trend continues, it will constitute an important development in health care compliance enforcement. Companies signing CIAs would be bound by some of the same onerous monitoring requirements imposed by DPAs.

HHS strengthening HIPAA enforcement

HHS issued an interim final rule, with request for comments, Oct. 30, 2009, to strengthen its enforcement of the rules promulgated under the Health Insurance Portability and Accountability Act. The Health Information Technology for Economic and Clinical Health (HITECH) Act, which was enacted as part of the federal government's economic stimulus package in February 2009, modified HHS' authority to impose civil monetary penalties for violations occurring after Feb. 18, 2009. These HITECH Act revisions substantially increase the penalty amounts that may be imposed for violations of the HIPAA rules and encourages prompt corrective action.

The HITECH Act significantly strengthened the civil monetary penalty scheme by establishing tiered ranges of increasing minimum penalty amounts, with a maximum penalty of $1.5 million for all violations of an identical provision. A covered entity can no longer bar the imposition of a civil monetary penalty for an unknown violation unless it corrects the violation within 30 days of discovery.[8]

2009 advancements in industry codes of conduct

New PhRMA code

The Pharmaceutical Research and Manufacturers of America represents the country's leading pharmaceutical research and biotechnology companies. PhRMA's board of directors adopted measures July 10, 2008, to enhance the 2002 PhRMA Code on Interactions with Health Care Professionals. The revised PhRMA code, which is voluntary, took effect in January 2009.

The revised PhRMA code prohibits the distribution of all non-educational items, including small branded promotional items such as pens, mugs and pads, to health care professionals and staff. It also provides restrictions on meals provided by company sales representatives and reaffirms the PhRMA code's pre-existing prohibition on providing entertainment or recreation to health care professionals. And it mandates training on applicable laws and standards that govern interactions with health care professionals, provides various compliance certification guidelines, and requires detailed standards on the independence of continuing medical education programs.

New AdvaMed code

In December 2008 the board of directors of the Advanced Medical Technology Association unanimously approved a major update of AdvaMed's Code of Ethics on Interactions with Health Care Professionals. AdvaMed represents its member companies that develop, provide, market and manufacture medical products, technologies, and related services and therapies. The revised code, effective July 1, 2009, further clarifies and distinguishes between appropriate and inappropriate activity between health care professionals and representatives of AdvaMed member companies. It also presents non-member companies with an opportunity to adopt the AdvaMed code's principles and seeks to unite industry in addressing common issues in a consistent manner.

AdvaMed's revised code explicitly prohibits companies from providing to health care providers any entertainment or recreation, as well gifts of any type or value — including minor branded promotional items. It also provides strict guidelines on meals, requiring that they be both modest in nature and incidental to a bona fide professional meeting in an appropriate setting. Additionally, the new AdvaMed code provides guidelines on such topics as giving of demonstration products, royalty agreements, consulting agreements, training and education, grants, and many other areas.

Companies adopting stricter policies than required by law

In 2009 several companies, including Eli Lilly, Pfizer, Merck, GlaxoSmithKline and Medtronic, voluntarily decided to publicly disclose compensation paid to physicians through various consulting and other arrangements.

The voluntary disclosures have come under varying terms. For example, Eli Lilly, the first drug maker to voluntarily disclose payments to physicians, discloses on its Web site all payments of more than $500 made to physicians for advice, speeches and other services, as well as educational grants for medical conferences.

Pfizer has also indicated it will disclose all payments that total more than $500 annually to a physician.

Merck has begun to disclose all payments to U.S.-based health care professionals who speak on behalf of Merck and its products, and it reports all grants more than $500.

Medtronic, whose disclosures are scheduled to begin in 2011, will report consulting fees, royalties or honoraria for physicians who are paid $5,000 or more annually.

In late 2009 GlaxoSmithKline began disclosing payments made to U.S. health care professionals in connection with clinical trials, consulting services and speaking engagements, and eventually will disclose payments for other types of research to health care professionals and institutions outside the United States.[9]

GlaxoSmithKline also announced that beginning in 2010, it will no longer fund commercial CME programs; instead, it will only sponsor medical education provided by academic medical centers and their affiliated teaching hospitals and by "national-level" professional medical associations. The company will invite grant applications from 20 education providers and will choose programs that do the most to close "clinical gaps" in patient care, according to a company statement. All the grants will be posted on the GlaxoSmithKline Web site. *See* Andrew Jack, *GSK to Publish Level of Doctors' Advisory Fees,* Fin. Times, Oct. 22, 2008.

Focus on international corruption

Assistant Attorney General Lanny Breuer stated the DOJ is committed to prosecuting all who commit health care fraud, including "corporate wrongdoers."

These aggressive enforcement efforts are matched and perhaps even surpassed by the recent skyrocketing of anti-corruption enforcement efforts. So, it should come as no surprise that both in the United States and abroad, government officials have been cracking down on perceived corruption in the health care industry.

DOJ focus on FCPA

In the keynote address of the Nov. 12, 2009, 10th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum, Assistant Attorney General Lanny Breuer warned of increased DOJ enforcement of the Foreign Corrupt Practices Act in the pharmaceutical industry.

He noted that about one-third of total sales of PhRMA members were generated outside the United States, and the "depth of government involvement in foreign health systems, combined with fierce industry competition and the closed nature of many public formularies, creates a significant risk that corrupt payments will infect the process."

He explained that "the types of corrupt payments that violate the FCPA because they are given to obtain or retain business in other countries are not any different than the items of value that would violate the Anti-Kickback Statute if given within the United States — cash, gifts, charitable donations, travel, meals, entertainment, grants, speaking fees, honoraria, and consultant arrangements."[10]

Breuer described increased DOJ staffing and expertise in the FCPA generally, and in the pharmaceutical context specifically, and noted that the DOJ's FCPA and health care fraud units "are already working together to investigate FCPA violations in the pharmaceutical and device industries." Further, the DOJ is working with the SEC and foreign law enforcement in various investigations.

DePuy International

In December 2009 Britain's Serious Fraud Office charged a former vice president of marketing development at DePuy International Ltd. with conspiracy to corrupt in connection with payments to medical professionals in the Greek public health care system. The SFO alleges the defendant made corrupt payments to Greek medical professionals in order to sell orthopedic devices. *Former Johnson & Johnson exec charged in Britain,* Associated Press, Dec. 1, 2009.

In 2007 DePuy International's parent company, Johnson & Johnson, made voluntary disclosures to U.S. government officials that foreign subsidiaries were believed to have made improper payments in connection with the sale of medical devices in two small-market countries.[11] These disclosures may have triggered the SFO investigation, which reportedly began in 2008.

FUTURE TRENDS

The debate over health care reform has revealed a near-unanimous consensus that any national health care policy should strive toward providing coverage for the maximum number of people at the lowest cost. Implicit in this movement is a sense of urgency to root out practices that bloat the cost of health care without providing value to patients.

President Obama highlighted this during his Sept. 9, 2009, address to a joint session of Congress, when he said that most of his health care plan "can be paid for by finding savings within the existing health care system, a system that is currently full of waste and abuse. Right now, too much of the hard-earned savings and tax dollars we spend on health care don't make us any healthier. ... [T]his plan would eliminate ... hundreds of billions of dollars in waste and fraud."[12]

This is not the first time Obama has warned that health care fraud is in his cross hairs. As discussed above, in May, the administration announced that the DOJ and HHS were creating an interagency program, known as HEAT, to investigate and prosecute health care fraud.

The president's 2010 budget invests $311 million — a 50 percent increase from 2009 funding — to strengthen program integrity activities within the Medicare and Medicaid programs. These funds are not limited to investigating "street-level" fraud by individuals.

In Senate testimony, Assistant Attorney General Breuer stated the DOJ is committed to prosecuting all who commit health care fraud, including "corporate wrongdoers." The DOJ is looking to add high-profile names to its leadership as well as several "in the trenches" attorneys to bolster its fraud section, with a special focus on health care fraud.

In fact, Obama administration officials have described fighting health care fraud as a priority of the DOJ, and health care fraud investigations as "among the highest priority investigations within the FBI's white-collar crime program."[13]

Enforcement officials have not lost sight of their goal to help reduce the cost of health care in the United States. While anti-fraud funding has yielded a 441 percent return on investment ($4.41 returned to victims of health care fraud for every $1 spent on enforcement), Breuer has testified that "we believe that the deterrent effects from our efforts may produce far greater 'returns on investment' through dramatic reductions in fraudulent billings to and payments from Medicare."[14]

With this larger purpose in mind, and armed with bigger budgets and staff, agencies will continue to increase their enforcement actions in the future. Investigations by HHS, DOJ and state attorneys general will likely continue in the "tried-and-true" areas, such as relationships with physician consultants, misbranding, false claims, and violations of the anti-kickback statute and Stark laws.

But enforcement officials have recently begun adding to their list of practices under scrutiny, including, most recently, billing practices, "ghostwriting" and executive compensation at nonprofit health care companies. Furthermore, health care companies conducting business overseas are increasingly under scrutiny for possible FCPA violations.[15]

The field of enforcement officials' scrutinizing health care companies is growing as well. Whereas federal prosecutors once were predominant in this arena, state attorneys general are becoming more active, with Martha Coakley of Massachusetts and Anne Milgram of New Jersey being most involved. New York's Andrew Cuomo has also been active in the related field of conflicts of interest in the health insurance industry.

These factors — the political climate, the success of recent enforcement actions, the injection of new funds and federal enforcement officials, the additional practices now facing scrutiny, and the state prosecutors who have joined the fray — all point to an obvious conclusion: Health care compliance will continue to be a burgeoning enforcement area. In this climate, it is more important than ever before that companies institute and maintain rigorous health care compliance systems and practices.

NOTES

1 *United States v. Amgen Inc.,* No. 06-10972-WGY (D. Mass. Oct. 30, 2009); Andrew Pollack, *Amgen Is Accused of Illegal Kickbacks*, N.Y. Times, Oct. 30, 2009.

2 *United States v. Stryker Biotech LLC et al.,* No. 1:09-cr-10330-GAO, *grand jury indictment filed* (D. Mass. Oct. 28, 2009).

3 Stryker Corp. Form 8-K (May 11, 2009); Johnson & Johnson Form 10-Q (Aug. 4, 2009); Biomet Inc. Form 8-K (May 4, 2009); Medtronic Inc. Form 10-Q (Dec. 9, 2009).

4 Letter from Sen. Charles Grassley to Jeffrey B. Kindler, CEO, Pfizer Inc. (Mar. 3, 2009); Press Release, Office of Sen. Charles Grassley, Grassley Asks Top Medical Journals About Ghostwriting (July 2, 2009); Natasha Singer & Duff Wilson, *Medical Editors Push for Ghostwriting Crackdown,* N.Y. Times, Sept. 17, 2009.

5 *House Clears Reconciliation Bill with Loads of Disclosure Provisions*, Thompson Publ'g Group (Mar. 22, 2010).

6 Minn. Stat. 151.461 (2009); Press Release, Massachusetts Office of Health & Human Servs., Patrick Administration Passes Tough New Rules Governing Pharmaceutical and Medical Device Industries (Mar. 11, 2009); 105 CMR 970.000, Pharmaceutical and Medical Device Manufacturer Conduct (Apr. 3, 2009); Vermont Legislation 247572.1, Bill S.48 (June 8, 2009); Press Release, Office of the Attorney General of New Jersey, Tighter controls recommended to prevent conflicts of interest between doctors and pharmaceutical companies (Dec. 3, 2009).

7 Corporate Integrity Agreement Between the Office of Inspector General of the Dep't of Health & Human Servs. and Bayer Healthcare LLC (Nov. 21, 2008); Corporate Integrity Agreement Between the Office of Inspector General of the Dep't of Health & Human Servs. and Quest Diagnostics (Apr. 14, 2009); Corporate Integrity Agreement Between the Office of the Inspector General of the Dep't of Health and Human Servs. and Pfizer Inc. (Aug. 31, 2009).

8 Press Release, U.S. Dep't of Health & Human Servs., HHS Strengthens HIPAA Enforcement (Oct. 30, 2009).

9 Press Release, Eli Lilly, Lilly Set to Become First Pharmaceutical Research Company to Disclose Physician Payments (Sept. 24, 2008); Press Release, Pfizer Inc., Pfizer to Publicly Disclose Payments to U.S. Physicians, Healthcare Professionals and Clinical Investigators (Feb. 9, 2009); Press Release, Medtronic, Medtronic to Voluntarily Disclose Payments to U.S. Physicians (Feb. 24, 2009); GlaxoSmithKline, Fees Paid to U.S. Based Healthcare Professionals for Consulting & Speaking Services, 2nd Quarter 2009.

10 Lanny A. Breuer, Assistant Attorney General, Criminal Division, Prepared Keynote Address to the 10th Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum (Nov. 12, 2009).

11 Katharine Q. Seelye, *Johnson & Johnson Says Improper Payments Were Made,* N.Y. Times, Feb. 13, 2009.

12 Press Release, Remarks by the President to a Joint Session of Congress on Healthcare (Sept. 9, 2007).

13 Press Release, Attorney General Holder and HHS Secretary Sebelius Announce New Interagency Health Care Fraud Prevention and Enforcement Action Team (May 20, 2009); *Criminal Prosecution as a Deterrent to Health Care Fraud: Hearing Before the Subcomm. on Crime and Drugs of the S. Comm. on the Judiciary,* 111th Cong. (May 20, 2009) (statement of Lanny A. Breuer, Assistant Attorney General); Mike Scarcella, *DOJ Looks for 'Rock Star' to Run Top-Priority Fraud Cases,* Nat'l L.J., Aug. 11, 2009; *Effective Strategies for Preventing Health Care Fraud: Hearing Before the S. Comm. on the Judiciary,* 111th Cong. (Oct. 28, 2009) (statement of Tony West, Assistant Attorney General).

14 Breuer Statement, *supra* note 13.

[15] Press Release, Office of N.Y. Attorney General, Attorney General Cuomo Announces Expansion of Historic Health Insurance Reform: Aetna Will End Relationship with Company that Manipulated Rates to Overcharge Patients by Hundreds of Millions of Dollars (Jan. 15, 2009); Press Release, Or. Dep't of Justice, Attorney General John Kroger Announces Multi-State Pharmaceutical Settlement Concerning Slow Disclosure of Negative Drug Study Results of Vytorin (July 15, 2009); Press Release, Mass. Attorney General, Massachusetts Attorney General Martha Coakley Announces Enhanced Oversight of Non-Profit Executive and Board Compensation (Sept. 2, 2009); Jonathan N. Halpern & Joshua C. Zive, *DOJ to Scrutinize Pharmaceutical Industry Conduct for FCPA Violations,* Bracewell & Giuliani (Dec. 9, 2009).



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