

Rx COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Abbott reserves \$1.5 billion to settle Depakote off-label allegations; GSK announces \$3 billion agreement covering “most significant” investigations

Abbott Laboratories will soon become the third drug company to pass the billion-dollar mark in connection with an off-label investigation. In its earnings statement released last month, the company noted a \$1.5 billion reserve related to a previously disclosed investigation by the U.S. Attorney for the Western District of Virginia into the company’s marketing of the epilepsy drug Depakote. That news was quickly followed by GlaxoSmithKline’s announcement of a \$3 billion agreement-in-principle to settle the company’s “most significant” ongoing federal government investigations.

Despite their magnitude, neither agreement comes as a complete surprise. When the government joined the Depakote case earlier this year, the *qui tam* group, Taxpayers Against Fraud, predicted that it would amount to at least \$1 billion. As for GSK, the agreement-in-principle includes several separate investigations, including a nominal price case under the Medicaid Rebate Program, and the government’s long-running investigation into the development and marketing of Avandia (*see p. 9*).

The lead complaint in the Depakote case was filed by former Abbott sales rep, Meredith McCoy, who alleges that she was routinely directed to engage in the off-label marketing of Depakote as part of a centralized program that covered the entire nation. Her 116-page redacted complaint alleges an almost endless variety of off-label schemes. ▶ *Cont. on page 2*

IN THIS ISSUE

- ▶ Abbott reserves \$1.5 billion to settle off-label allegations surrounding Depakote (p. 1)
- ▶ Amgen reserves \$780 million to resolve ten *qui tam* complaints (p. 1)
 - ▶ Sandoz to pay \$150 million to settle drug pricing case; FY 2011 drug pricing suits tops \$1 billion (p. 6)
 - ▶ Sizing up GSK’s \$3 billion settlement (p. 9)
- ▶ **OFF-LABEL PROMOTION.** Neurontin attorney reaches \$14.5 million settlement with Pfizer in non-intervened off-label case (p. 4)
- ▶ **WHAT’S AHEAD IN Rx COMPLIANCE REPORT.** Merck agrees to pay \$950 million to settle civil and criminal Vioxx investigations; Three Synthes execs sentenced to prison (p. 11)
- ▶ **INVESTIGATIONS.** How to prepare for a government investigation (p. 12)
 - ▶ CIDs are becoming key enforcement tool, says attorney (p. 13)

Amgen reserves \$780 million to resolve ten *qui tam* suits

Novel “overfill” fraud theory drives settlement

Last month, Amgen announced that it has reserved \$780 million to settle as many as 10 *qui tam* suits, including a novel fraud scheme that alleged that Amgen provided intentionally “overfilled” vials of its anti-anemia drug Aranesp to doctors and then encouraged them to bill federal and state healthcare programs for the extra amounts. That case, a *qui tam* brought by former Amgen sales rep, Kassie Westmoreland, was “the tip of the spear” in terms of driving the global resolution to a conclusion, says *qui tam* advocate, **Patrick Burns**.

While the federal government had yet to formally intervene in that case, it was set to go to trial on October 17. However, the case was abruptly “closed” days before the trial, making it a safe bet that a settlement had been reached.

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Abbott reserves \$1.5 billion to settle Depakote allegations; GSK announces \$3 billion agreement

McCoyd says she was part of a division known as the Long-Term Care Division, whose “primary purpose” was the off-label promotion of Depakote to physicians. Her suit was recently consolidated with a separate suit filed by three other former Abbott employees and designated as the lead case.

The other suit was filed by two Abbott specialty reps, Susan Mulcahy and Doreen Merriam, along with a former Abbott employee, Sondra Knowles. That suit is being handled by James Backstrom in Philadelphia, while McCoyd is represented by Rueben Guttman of Grant Eisenhofer in Washington, D.C. This article examines McCoyd’s complaint largely because of its massive scope and its level of detail.

McCoyd claims that Abbott’s off-label Depakote sales came to represent “the fastest growing segment” of Depakote’s total U.S. sales, which amounted to at least \$6.8 billion from 2000 to 2009. In addition to posting “blockbuster profits,” the complaint says that Abbott’s marketing schemes also enabled “the highest levels” of Abbott management to obtain “disproportionately large” compensation packages.”

According to McCoyd, at the inception of Abbott’s LTC division in 1998, about 30 sales reps were assigned to off-label market Depakote to long-term care and skilled nursing facilities. She claims that Abbott continued to add off-label Depakote sales reps each year until the number reached about 180 when she left the company in June 2007.

McCoyd also claims that over the course of her nine years at Abbott that she was directed and trained by the company to engage in numerous tactics designed to maximize off-label sales of Depakote, such as paying physicians to discuss off-label uses of the drug at speaker’s programs for other physicians.

The complaint also alleges that Abbott developed a centralized process for funneling payments to physicians through intermediary medical organizations, including the Alzheimer’s Association, and an Illinois company called ABcomm, which acted “exclusively as a conduit for Abbott to further its unlawful conduct.” McCoyd says Abbott referred to its practice of funneling money through intermediaries as “washing the money.”

The Depakote Market

Depakote is an anti-epileptic drug first approved by the FDA in 1983 to treat “simple and complex partial seizures” in adults and children over the age of 10. The FDA subsequently approved Depakote to treat additional types of seizures for patients over 10 years of age, manic episodes of bipolar disorder for patients over 18 years of age, and for prophylaxis of migraine headaches in adults.

Since Depakote’s approval for epilepsy in 1983, a number of other new generation anti-epileptics have crowded the market, making it more difficult for Depakote to compete, says McCoyd’s complaint. Moreover, the number of cases of epilepsy each year remains fairly stable, it says, leaving few opportunities to expand Depakote’s on-label sales.

According to the complaint, Depakote also has significant competition from a number of migraine drugs marketed

by other companies. Likewise, it says, there are competing drugs for bipolar disorder that treat a broader spectrum of the disease than Depakote’s indication for acute manic or mixed episodes associated with bipolar disorder.

Other competing medications also contain FDA indications for the maintenance treatment of mania associated with bipolar disorder, says the complaint, while Depakote’s package insert states that the “effectiveness of [Depakote] for long-term use in mania, i.e., more than 3 weeks, has not been demonstrated in controlled clinical trials.”

It is against this backdrop that McCoyd alleges that Abbott embarked upon several centrally-organized, illegal marketing schemes to convince physicians to prescribe Depakote for a number of diseases and disorders for which the drug had (and continues to have) no FDA-approved indication. All of this, she maintains, was designed to address the potential stagnation of profits and to exponentially increase its revenues.

Meredith McCoyd’s complaint says Abbott’s off-label Depakote sales represented the fastest growing segment of the drug’s U.S. sales, which amounted to \$6.8 billion from 2000 to 2009.

According to the complaint, Abbott “off-label marketed” Depakote to treat the following:

- Elderly patients suffering from agitation associated with dementia or Alzheimer’s disease;
- Children under age 18 for treatment of mood disorders, ADHD, bipolar depression and development delay;
- Adult bipolar depression, schizophrenia, and other psychological disorders;
- Post-seizure stroke;
- Addictive narcotic withdrawal;
- Children under the age of 10 for epilepsy, and
- Elderly patients unable to swallow Depakote tablets by putting Depakote Sprinkles, only FDA-approved for epilepsy, through feeding tubes (a method of administration not included in Depakote’s package insert).

The “most brazen scheme”

According to the complaint, Abbott embarked on “perhaps its most brazen scheme to off-label market Depakote” in 1998 when it targeted elderly patients suffering from Alzheimer’s disease and dementia. In allegations reminiscent of Eli Lilly’s Zyprexa settlement, the complaint says that Abbott sought to tap into the aging population in the U.S. and rapidly expanding geriatric markets such as long-term care, skilled nursing homes, and assisted living by forming “an entire sales division” devoted to promoting Depakote off-label to geriatric physicians, pharmacy providers, long-term care medical directors, and other healthcare professionals engaged in treating elderly nursing home patients with behavior disorders associated with dementia or Alzheimer’s disease.

As part of its scheme to off-label market Depakote to nursing homes, the complaint says that Abbott paid and/or incentivized at least two other named defendants, whose names are redacted, through direct payments, rebates, and/or free goods and services to assist in promoting Depakote off-label for agitation associated with dementia.

The complaint also charges Abbott with training and encouraging sales reps to market the drug for off-label uses without proper clinical evidence of its safety and efficacy for those off-label purposes.

As a consequence of these activities, the complaint says that patients were harmed and placed at risk of numerous side effects, including serious liver problems and life-threatening pancreatitis. In addition, children born to women taking Depakote were said to be at risk of serious birth defects.

2007 conference call

McCoyd’s complaint devotes significant attention to a nationwide conference call held in February 2007 that allegedly included Abbott’s entire Depakote long-term care sales force, Depakote marketing staff, and upper level managers.

The purpose of the call was to discuss CMS’ guidance issued in September 2006 related to the Omnibus Budget Reconciliation Act (OBRA) reforms that included a restriction of “unnecessary drugs” in nursing homes. During the conference call, an Abbott

Regional Account Manager and a marketing employee instructed Depakote sales reps to inform physicians treating elderly patients suffering from agitation associated with dementia about methods to circumvent regulations that required long-term care facilities to ensure that residents do not receive drugs in excessive dose, or for excessive duration, without adequate monitoring, or without adequate indications for its use.

Those leading the conference call encouraged long-term care reps to actively approach physicians to discuss the new CMS guidance and to inform them that Depakote would not fall within OBRA’s ambit if physicians coded patients as “late onset of bipolar” or “underlying seizure disorder” in the elderly rather than as agitation associated with dementia. They also indicated that the added benefit to physicians’ miscoding “agitation associated with dementia” as other diseases or disorders, rather than a drug used to control behavior, was that physicians would not be required to monitor blood levels, or assess the need for drug holidays or gradual dose reductions.

According to McCoyd’s complaint, Abbott’s most brazen scheme targeted elderly patients suffering from Alzheimer’s disease and dementia.

Another sales rep from McCoyd's district took notes of the nationwide conference call and circulated them to Abbott's National Sales Trainer for Neuroscience and an Abbott Regional Training Specialist in an e-mail dated February 9, 2007. Recounting the instructions on the call, the sales rep wrote, "[t]his conf call was very helpful – thank you for setting it up! After hearing this call I have a positive outlook on these changes instead of it being a negative thing for us."

The attached notes from the call stated: "[u]se Abbott Medinfo.com to get off-label required information to the clinicians." The notes also record the following instructions from the Regional Account Manager: [w]e know safety of Dpk Long Term! Most pts are on multiple meds. Do GDR [gradual dose reduction] on other meds first. Do GDR on Dpk last." According to the complaint, Abbott's instructions to its LTC/SA reps to encourage physicians to reduce the dosage of other drugs, before Depakote, in elderly populations in long-term care facilities had no basis in Depakote's package insert.

Bypassing OBRA

As noted above, part of the complaint is pegged to OBRA 87, which addressed concerns about over-utilization of drugs in nursing homes. The OBRA legislation passed by Congress in 1987 attempts to accomplish this by mandating that nursing home patients be "free from restraints" including drugs used as "chemical restraints for purposes of discipline or convenience and not required to treat... medical symptoms."

OBRA regulates the use of psychopharmacologic drugs in nursing homes and requires that these drugs may be administered "only on the orders of a physician and only as part of a plan... designed to eliminate or modify the symptoms for which the drugs are prescribed and only if, at least annually, an independent, external consultant reviews the appropriateness of the drug plan of each resident receiving the drugs."

"Despite the unambiguous language in OBRA and its implementing regulations," the complaint charges "Abbott trained its sales reps to tell physicians that Depakote was not within the category of drugs, i.e., 'psychopharmacologic drugs,' that were subject to the strict documentation and monitoring requirements of OBRA because it was not a 'antipsychotic drug.'"

Compensation incentives

McCoyd alleges that Abbott encouraged off-label marketing of Depakote through compensation packages that either directly or indirectly rewarded reps for the success of their off-label marketing activities. For example, it says that McCoyd exclusively marketed Depakote off-label and received bonuses based on the weight (kilograms) of Depakote prescribed at each of the facilities she covered in her territory.

According to the complaint, the Abbott incentive plan for its LTC/SA sales force in 2007 specifically discussed how bonuses were based on the attainment of "LTC and Non-LTC quota" by LTC/SA representatives and the "corporate product performance." While some of the prescriptions at nursing home facilities were for "on-label" diagnoses, it says, the vast majority were not.

Defining the market

In defining the market for Depakote, the complaint alleges that Abbott instructed its sales reps that Depakote's competitors were an array of psychopharmacological drugs, including but not limited to, Risperdal, Seroquel, Geodon, Trileptal, Lamictal, and Abilify. Abbott allegedly provided sales reps with detailed data showing utilization of these drugs by particular physicians and institutions.

According to the complaint, reps were challenged by Abbott to "convert" physicians or institutions from prescribing these drugs to prescribing Depakote for patients suffering from agitation associated with dementia or encourage physicians to add Depakote to these drugs.

"Abbott encouraged the conversion from Risperdal, Seroquel, Geodon, Trileptal, Lamictal and Abilify to Depakote even though these drugs' indications and side effects are different from Depakote and were also being used off-label," the complaint charges.

Abbott encouraged its sales reps to "convert" physicians from Risperdal, Seroquel, Geodon, Trileptal, Lamictal and Abilify to Depakote, charges the complaint.

“Working the Wheel”

According to the complaint, McCoyd and the other LTC/SA reps used a system at least up until June 2007, called “Working the Wheel” to target Depakote off-label marketing to physicians and institutions that the company believed would potentially yield the most off-label prescriptions of Depakote associated with dementia.

The complaint alleges that Abbott used this “Wheel” system to direct its LTC/SA reps to the “right customers,” which included three specific groups considered to be in a position to increase off-label use, including three groups.

The first group included medical directors and consultant pharmacies at large long-term care facilities and state hospitals, with a lesser emphasis on the general practitioners and nurses working in these facilities.

The second group included geriatric psychiatrists, general practitioners, and nurse practitioners who devoted at least two-thirds of their practice to the elderly.

The third group is redacted in the complaint.

In order to help target the “right customers” to increase off-label sales, McCoyd’s complaint says that Abbott began purchasing prescription data from Heath Market Science, Inc., in January 2004. These data tracked prescription volume and diagnoses data by medical institution or institutional pharmacy. Abbott LTC/SA representatives nationwide accessed this prescription data on-line in a spreadsheet format called the Functional Institutional Market Report – otherwise known as Functional IMR.

The Functional IMR provided Abbott LTC/SA reps with, among other things:

1. The quantity of prescriptions written by physicians at particular medical institutions and/or provided by long-term care pharmacy providers for Depakote, Risperdal, Seroquel, Zyprexa and other psychoactive drugs;
2. The diagnoses codes for which these drugs were prescribed, and
3. The relative national ranking of each medical institution or long-term care pharmacy based on the volume of Depakote prescriptions written.

Abbott also purchased data from a source whose name is redacted in the complaint. In this instance, the data came in the form of something called the

LTC Key Physician Tracker (LTC KPT), which Abbott LTC/SA representatives used to gather prescribing information about physicians practicing in long-term care facilities. Each physician in the LTC KPT was identified by specialty, location, and market volume of prescriptions written for Depakote, compared with other drugs such as Haldol, Risperdal, Seroquel, and Zyprexa.

In addition, the complaint says that Abbott and the redacted party developed a “metric” for evaluating physician prescription data for each physician tracked by LTC KPT. The metric sorted each physician into a particular category, which provided the means for Abbott LTC/SA reps to target long-term care physicians, determine “call frequency and messaging” for individual physicians, and “establish share goals” for individual physicians, such as Depakote sales goals for physicians.

The complaint cites four physician categories: “loyalist,” “grower,” “bleeder,” “potential,” “maintain,” or “low/no,” which were defined as follows:

- “Loyalist” physicians frequently prescribed Depakote rather than other psychoactive drugs, such as antipsychotics, for off-label uses promoted by Abbott in the long-term care market.
- “Grower” physicians were those Abbott believed would continue to increase prescribing off-label Depakote prescriptions in the long-term care market.
- “Bleeder” physicians formerly prescribed Depakote for off-label uses regularly in the long-term care market, but were, at that time, prescribing other drugs with more frequency.
- “Potential” physicians were those Abbott believed could be converted to using Depakote, over the comparable drugs, in the long-term care market.

The complaint says Abbott used a system at least until June 2007, called “Working the Wheel” to target Depakote off-label marketing to physicians and institutions.

McCoyd's complaint says the LC KPT's designation determined, in part, how Abbott LTC/SA reps spent their time marketing Depakote off-label to physicians, nurses, medical directors and consultant pharmacists. These designations also assisted Abbott and the redacted party in their joint efforts to prescribe Depakote off-label for agitation associated with dementia, as the designations provided LTC/SA reps with physician specific prescribing habits rather than overall sales by institution.

The complaint says the data pertaining to the number of prescriptions written by each physician for other drugs in other classes, such as atypical antipsychotics, was used by Abbott to incentivize its Depakote LTC/SA reps to "convert" physicians using other drugs such as Risperdal for agitation associated with dementia, even though Risperdal is an antipsychotic and Depakote is an antiepileptic.

"The atypical antipsychotics also do not have an indication for agitation associated with dementia," says the complaint, "but Abbott considered them to be 'competitors' from which to capture business in the nursing home setting."

Concealing call notes

The complaint alleges that in a concerted plan to conceal its wrongful conduct, Abbott forbade its LTC/SA representatives from putting their "call

The complaint alleges that Abbott forbade its LTC/SA reps from putting their "call notes" into the company-wide computer system.

notes" into the company-wide computer system used by all Abbott sales reps called "MAX." Instead, McCoyd claims that reps were instructed to record only the office visits with doctors, but to keep separate hand-written notes detailing the subject matter of the calls on

paper, which were later faxed to their managers.

According to the complaint, Abbott's MAX system required sales reps to document the diagnosis discussed with the physician through use of a "drop-down menu" system. Only diagnoses that fell with Depakote's indication — such as epilepsy, migraine, and bipolar mania — were contained on the drop-down menu.

Sandoz to pay \$150 million to settle drug pricing case; FY 2011 drug pricing suits tops \$1 billion

Ven-a-Care of the Florida Keys, a small specialty pharmacy in Florida, became the first relator to hit the \$3 billion mark in terms of money recovered under state and federal False Claims Act statutes. Ven-a-Care and its attorney, Jim Breen, reached that milestone when Novartis' Sandoz unit announced that it will pay \$150 million to settle a drug pricing case originally filed more than ten years ago. By no means has Ven-a-Care concluded its litigation.

The Medicaid Best Price case was filed in 2000, but was never joined by the Department of Justice. The cost of this litigation was born by the relators and their counsel, as well as the states of Florida and California. Nevertheless, \$35 million will be returned to the federal government while \$75 million will be paid to California and roughly \$39 million will be paid to Florida. The federal share actually increases to \$86.5 million once Medicaid cost shifting is taken into account.

The cumulative impact of drug pricing suits

Drug pricing cases continue to take a heavy toll on the industry. In fact, in FY 2010, which ended last month, two of the three largest False Claims Act cases were drug pricing cases, namely a \$421 million settlement by Abbott Labs, B. Braun Medical, and Roxane Labs last December for reporting false and inflated prices for numerous products and Dey's \$280 million settlement the same month, also for reporting false prices for several products.

A \$170 million verdict against Activas, now under appeal, was the sixth largest, while Par Pharmaceutical's recent Average Wholesale Price (AWP) settlement came in at number seven at \$154 million. Another AWP settlement of 40 pharma companies last month for \$82 million ranked number twelve. Watson was next in line at number thirteen with a \$79 million drug pricing case in September. Number fifteen was a separate AWP settlement by Sandoz for \$66 million.

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“Abbott managers instructed LTC/SA representatives to document in MAX the physician’s name, the date of the call, and one of the on-label diagnoses,” says the complaint, “even though the sales representatives were primarily detailing long-term physicians and physicians in community mental health centers about illness, which were not within Depakote’s label.”

Targeting bipolar depression in adults and children

McCoyd alleges that Abbott also encouraged its sales force to unlawfully promote Depakote for childhood and adult bipolar depression. Depakote is indicated for mania associated with bipolar disorder in adults, but not depression associated with bipolar disorder (bipolar depression), maintenance therapy of bipolar disorder, or for children with any type of bipolar disorder, says the complaint.

According to the complaint, Abbott’s primary competition for bipolar disorder is and was Lamictal. McCoyd alleges that she was directed by Abbott to convince community mental health centers in her sales territory to use Depakote off-label for bipolar depression as a first line treatment over Lamictal, even though Depakote does not have the indication for bipolar depression.

McCoyd says LTC/SA reps were trained to off-label market Depakote for bipolar depression through the use of “role plays” designed to show Abbott sales reps how to overcome physician objections to using Depakote off-label over Lamictal.

For children, the complaint says, Depakote sales reps were trained to focus on a negative side effect of Lamictal, such as Stevens-Johnson syndrome, a life-threatening skin disease that is akin to having body-wide third degree burns.

Targeting tools

Apart from the numerous off-label strategies alleged by McCoyd, she also describes an exhaustive array of techniques from role playing to the use of so-called “champions” to achieve those aims, which will be examined separately,

To receive a copy of McCoyd’s complaint:

Readers who wish to receive a copy of the complaint can send an e-mail to: RxCompliance@aol.com

Please put “McCoyd Complaint” in the subject line.

In all, these seven drug pricing cases totaled more than \$1 billion in FY 2010. When GSK’s \$600 million GMP case is added to the list along with Elan’s \$241 million off-label settlement and AstraZeneca’s \$68.5 million off-label settlement, drug companies were responsible for 10 of the top 15 False Claims Act cases in FY 2010.

In all, pharma False Claims Act cases totaled more than \$2 billion in FY 2010.

McKesson boosts reserve to \$424 million

In yet another AWP case of a different kind, McKesson announced October 25 that it has reached an agreement in the matter known as Douglas County to settle the public entity claims brought by a nationwide class of cities and counties relating to First DataBank’s published drug reimbursement benchmarks for \$82 million.

Based on a combination of the Douglas County settlement and progress made toward potentially resolving other public entity claims, the company increased its AWP reserve of \$324 million by \$118 million to bring the total reserve for AWP public entity claims to \$442 million.

In Remembrance of Gabor Danielfy

Gabor Danielfy, a highly-regarded industry professional, passed away in Paris recently after a short illness. His passing is a major loss not only to his family and friends, but also for the global pharma and medical device compliance and ethics movement.

Gabor’s friends and colleagues are invited to attend a memorial ceremony at Eglise of St Germain in Paris on December 8 at 7:00 pm. Those wishing to send condolences may do so via email to dominique.laymand@bms.com or via mail to Mrs. Dominique Laymand, 18 rue Moliere 92400 Courbevoie, France. These will be communicated to the family.

Gabor joined sanofi-aventis as Vice-President and Global Compliance Officer at the beginning of 2011. In this leading role, Gabor was in charge of the Compliance Program of sanofi-aventis focusing on business integrity and anti-bribery. His healthcare scope encompassed the Prescription Drug business (including Generics), the OTC & Consumer activities, Animal Health as well the Medical Devices and R&D activities.

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Amgen reserves \$780 million to resolve ten *qui tam* suits

The Westmoreland case was spearheaded by veteran *qui tam* attorneys Suzanne Durrell and Robert Thomas, Jr. of Robert Thomas & Associates in Boston.

Amgen said it expects the settlement to resolve civil and criminal investigation in the U.S. Attorney's Offices for the Eastern District of New York and the Western District of Washington the federal investigations, related state Medicaid claims, the Westmoreland case, and nine other *qui tam* actions previously disclosed in SEC filings.

"Amgen was going to lose at trial, and that was going to set in motion a lot more losses for the cases still under seal," argues Burns. "If you lose in Boston you definitely lose in New York where the government had intervened."

Several veteran attorneys say that District Court Judge William Young telegraphed that Amgen would face a difficult trial when he issued an opinion two months ago on the kickback component of the Westmoreland case.

In short, Judge Young denied the defendants' motions for summary judgment, making it clear that if the company marketed the overfill in Aranesp vials as an inducement to influence doctors' prescribing habits, that issue would get to the jury as a viable kickback and fraud theory.

The Westmoreland suit

Westmoreland's suit alleges that Amgen engaged in a variety of illegal kickback schemes that caused millions of dollars of overbillings to government healthcare programs. She alleged, for example, that Amgen illegally induced physicians to prescribe its anti-anemia drug Aranesp by encouraging physicians to bill insurers for the "overfill" placed in the pre-packaged vials of the drug.

The suit also alleges that in some instances patients were given more Aranesp than medically indicated, because of the "overfill" billing potential, notwithstanding a "black box warning" from the FDA about the health risks of Aranesp, and the need for minimal dosing.

While a small amount of overfill in product vials is appropriate and mandated under manufacturing protocols, Amgen, according to the lawsuit, intentionally put more overfill in the vials than in its

competitor's vials (which it also manufactured), and then enticed doctors to bill for the extra free product – which both harmed the Medicaid and Medicare programs but also increased its market share against its competitor.

"This was a sinister fraud scheme and an eminently triable case," said Burns. "You had motive, opportunity, vast profits to be made, and the risk of patient harm, all funded by unsuspecting taxpayers." "Amgen was engaged in making and selling a product that was a commodity," says Burns. "If you are selling something that is nearly identical to everything else there should be a race to the basement in terms of price, but that was not the case here."

"What was being sold was not the product," Burns maintains. "What was being sold was the marketing scheme."

According to Burns, those marketing schemes included straight kickbacks and off-label marketing, as well as covert kickbacks in the guise of an 'accidental' or 'incidental' overfill.

Aranesp is an erythropoiesis-stimulating agent (ESA) and injectable drug product developed and

manufactured by Amgen to stimulate and boost the production of red blood cells in the body. It was approved by the FDA in 2001 to treat anemia associated with chronic renal failure and in 2002 to treat chemotherapy-induced anemia in certain types of cancer patients.

Both Westmoreland's complaint and the parallel complaint filed by several intervening states alleged that the Amgen sales force offered free Aranesp product to medical providers and encouraged medical providers to bill third party payers including state Medicaid programs for the free Aranesp.

Amgen also allegedly conspired with its partners International Nephrology Network and ASD Healthcare, both owned by AmerisourceBergen Corporation, to offer illegal kickbacks to medical providers, such as sham "honoraria" to attend all-expense paid meetings with the intention and effect

"Amgen was going to lose at trial, and that was going to set in motion a lot more losses for the cases still under seal," argues *qui tam* advocate, Patrick Burns.

of increasing sales of Aranesp and converting new providers from competitor drugs to Aranesp.

The evidence in the case included spreadsheets in which marketing reps detailed doctors with specific information on how much more money they would make by billing for the extra overfill and switching to Aranesp, and five former Amgen executives took the Fifth Amendment during the discovery phase of the case, a fact that would have been admissible in the Westmoreland trial.

A double whammy

The Westmoreland case has been in active litigation since it was unsealed in 2009. Judge Young initially

Amgen was presented with a double-whammy: Facing the Westmoreland trial in October, and then a second case from the state Attorney General's offices.

dismissed the suit, as well as the parallel complaint filed by several intervening states, but he gave the dismissed parties the choice of either appealing or re-pleading their complaints. The states took an appeal and Westmoreland re-pled, and her re-pled claim was allowed when challenged a second time. As a result, Westmoreland

proceeded through discovery while the states' appeal was pending.

The First Circuit ultimately reversed Judge Young's dismissal, bringing the state Medicaid claims back into play as the Westmoreland case headed toward trial. Late last summer, Judge Young denied Amgen's motion for summary judgment against Westmoreland. As a result, Amgen was presented with a double-whammy: Facing the Westmoreland trial in October, and then a second case from the state Attorney General's offices on the heels of the Westmoreland trial.

Durrell and Thomas, who spearheaded the Westmoreland case, have played a role in several major pharma settlements. They were assisted by Rory Delaney and Charles Kester of Kellogg, Huber, Hansen, Todd, Evans & Figel in Washington, D.C. Larry Isenberg of Kester & Isenberg in Encino, CA, also acted as co-counsel in this case. ■

Sizing up GSK's \$3 billion settlement

The most striking feature of GSK's \$3 billion agreement-in-principle announced earlier this month is its sheer size. However, it is not yet clear exactly what will be included as part of the agreement.

In its statement announcing the agreement, which is expected to be finalized next year, GSK cites only three specific matters: 1) an investigation into GSK's sales and marketing practices initiated by the U.S. Attorney's office of Colorado in 2004 and later taken over by the U.S. Attorney's Office in Boston; 2) DOJ's investigation of possible inappropriate use of the nominal price exception under the Medicaid Drug Rebate Program; and 3) DOJ's investigation into the development and marketing of Avandia.

According to the *qui tam* advocacy group, Taxpayers Against Fraud, the drugs covered by the agreement include Avandia, Wellbutrin, and Paxil.

While Wellbutrin was not mentioned in GSK's statement, the failed prosecution of former GSK attorney, Lauren Stevens, laid bare the sheer dimensions of the government's investigation of the company's purported off-label marketing of Wellbutrin. It is difficult to imagine that the government spent seven years investigating Stevens' role in the Wellbutrin matter, ultimately deciding to bring charges, while declining to charge the company.

What is clear that GSK is trying to "clear the deck" as much as possible with this settlement.

The role of whistleblowers

Also unclear is what portion of the investigation and settlement was driven by whistleblowers. *The New York Times* initially described the investigation on November 4 as a whistleblower investigation. But the *Times* ran a correction two days later indicating that it was a government-led investigation.

Longtime Avandia critic, David Graham, who was also a well-known Vioxx critic, has often been referred to as a "whistleblower" from his perch at the FDA. Whether he will emerge as a player in this instance is unclear. ■

Off-label promotion

Neurontin attorney reaches \$14.5 million settlement with Pfizer in non-intervened off-label case

Recent predictions about “go-it-alone” litigation strategy comes to fruition

Last month, attorney **Thomas Greene** of Neurontin fame announced a \$14.5 million settlement of a lawsuit alleging improper marketing of two Pfizer drugs, Detrol and Detrol LA. The case is notable for several reasons, including the fact that it represents only the second off-label settlement in a case where the government declined to intervene. The first was the landmark Neurontin settlement in 2004, also spearheaded by Greene LLP attorneys in Boston, which the Justice Department widely credits with setting the stage for the roughly two dozen off-label settlements – totaling \$8.6 billion in recoveries – that have since followed.

In a very real way, Detrol represents a new genre of non-intervened off-label settlements. Neurontin was the first such settlement largely because it represented a novel fraud theory under the False Claims Act. Until recently, most sides believed intervention by DOJ was necessary for an off-label case to succeed. However, several veteran attorneys have recently suggested that was about to change (see *Rx Compliance Report*, September 30, 2011).

Needless to say, Greene falls into that camp. “If you file a case you should be willing to take it to the mat,” says Greene. “Attorneys who know how to handle these cases can take declined cases and litigate them successfully,” he says.

That does not make it an easy task, says Greene, because off-label cases are difficult to begin with. One of the challenges in any off-label case, he says, is getting the data to prove the case. “It’s hard to get Medicaid data from CMS,” he says. Medicare is not much easier, although that may change in the future, he adds. “If the agencies are not cooperating with you, it is going to be difficult.”

Nor does it mean that every declined case should be litigated, says Greene. There may well be instances where the government declines intervention with an adequate explanation, he says. For example, if a government agency such as CMS or the FDA refused to back a case dealing with marketing or pricing fraud, the case would likely be doomed, he says, because the defendants will argue that the government would have paid for the drugs or medical devices anyway.

In relative terms, the Detrol case proceeded rapidly. The original complaint included both Bextra and Detrol. The case came out from under seal in September 2009 when the Bextra case was settled along with several other *qui tams* for \$2.3 billion. Greene’s firm filed an amended complaint regarding Detrol and served Pfizer in January of 2010. Following several mediation sessions in the fall of 2010, the basic outline of a settlement was reported to the court in January of 2011. “In one year from the date the amended complaint was served we had a settlement,” says Greene.

Greene says this required a lot of heavy lifting in a relatively short time frame, because the judge indicated the case would go to trial in six months. “We did some targeted depositions,” he says. “We processed millions of pages of documents that they produced. We put them in our database. That’s how we developed the real evidence of fraud in this case.”

The case against Detrol

In a detail-laden complaint, former Pfizer employees, David Wetherholt and Marci Drimer, alleged that Pfizer illegally marketed Detrol for urinary symptoms associated with BPH, Lower Urinary Tract Symptoms (LUTS), and Bladder Outlet Obstruction (BOO), uses for which Detrol has not been approved by the FDA.

Detrol and Detrol LA are approved for the treatment of “over active bladder with symptoms of urge incontinence, urgency and frequency.” The lawsuit alleged that Pfizer improperly marketed the

By successfully litigating Detrol absent government intervention, Greene and his colleagues have now helped alter the off-label enforcement landscape for a third time.

drug to men who were suffering from the signs and symptoms of benign prostate hyperplasia (BPH), which is commonly referred to as an enlarged prostate. Although men suffering from an enlarged prostate exhibit many of the same symptoms as men who have an overactive bladder, the two conditions have different causes. The relators contended that neither Detrol nor Detrol LA have any therapeutic effect on males whose symptoms are caused by an enlarged prostate.

Three milestones

The Detrol suit is also notable in that it marks the third time that Greene's firm has successfully resolved off-label marketing claims against Pfizer in a novel fashion. First, there was the landmark Neurontin case – *Franklin v. Parke-Davis* – which settled for \$430 million in civil penalties and criminal fines. That marked the first False Claims Act case to successfully allege that causing government programs to pay for off-label prescriptions of a drug may be actionable under the False Claims Act.

Last year, Greene's firm helped employ the first successful application of the Racketeer Influenced and Corrupt Organizations (RICO) Act to the

“If you file a case, you should be willing to take it to the mat,” says Thomas Greene.

area of off-label promotion. After a five week trial, a jury awarded a \$142 million RICO Act verdict to Greene's client, Kaiser Foundation Health Plan. In that suit, plaintiffs successfully

argued that Pfizer caused off-label prescriptions of its epilepsy drug Neurontin for migraines, neuropathic pain, and bipolar disorder, despite a lack of any scientifically reliable evidence that Neurontin is effective for those conditions.

By successfully litigating Detrol absent government intervention, Greene and his colleagues have now helped alter the off-label enforcement landscape for a third time.

The relators in the case, Wetherholt and Drimer, will receive 27.5 percent of the federal government's portion of the settlement. Greene credits the investigative efforts of his colleagues, Michael Tabb, Ilyas Rona, and Palko Goldman, MD. ■

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What's ahead in *Rx Compliance Report*

Merck agrees to pay \$950 million to settle civil and criminal investigations into the marketing and promotion of Vioxx

The Justice Department announced last week that Merck has agreed to pay \$950 million to resolve criminal charges and civil claims related to the promotion and marketing of the painkiller Vioxx. Under the terms of the agreement, Merck will plead guilty to violating the Food Drug and Cosmetic Act (FDCA) by misbranding Vioxx and pay a \$321 million criminal fine. The company will also enter into a \$628 million civil settlement to resolve off-label allegations and charges that it made false statements about the Vioxx's cardiovascular safety.

The settlement and plea conclude a long-running investigation of the promotion of Vioxx, which was withdrawn from the marketplace in September 2004.

Three Synthes executives sentenced to prison

Three former Synthes executives were each sentenced to prison last week for charges related to illegal clinical trials of a medical device without the authorization of the FDA. Thomas Higgins, who was president of Synthes North America when the clinical trials were conducted, and Michael Huggins, who was president of Synthes Spine Division during that period, were each sentenced to nine months in prison. John Walsh, director of regulatory and clinical affairs, was sentenced to five months.

“This is not a case of an executive who failed to prevent crimes being committed on his watch only because he was so consumed by other responsibilities,” the government argued in its pre-sentencing memorandum for Huggins, the highest ranking of the four defendants. “Not only was this defendant aware of the rogue clinical trials, but he authorized and participated in them.”

Investigations

How to prepare for a government investigation

Changing enforcement landscape makes investigations policies paramount

Investigations into pharmaceutical sales and marketing practices are now targeting what federal prosecutors often refer to as “more subtle” violations on the part of industry. But all sides agree that the flow of investigations is far from over. This makes it important for companies to develop protocols and strategies for dealing with government investigation before they surface, says former federal prosecutor, **Joshua Levy**, a partner with Ropes & Gray in Boston. If companies wait until they receive a subpoena or a phone call indicating that a sales rep has an FBI agent in their driveway they have waited too long, he says.

In terms of government investigations, the key is to be prepared, says **Elizabeth Jobes**, Chief Compliance Officer at Adolor in Philadelphia, PA. “Do as much as you can prophylactically before anything happens, because the more prepared you are the better off you will be,” says Jobes, herself a former federal prosecutor.

The changing enforcement landscape

According to Levy, it is important for in-house professionals to study new cases and emerging fraud theories so they understand where the government may be going when they learn about developments on the ground within their own company.

It is also important to understand that the *qui tam* landscape is continually changing, says Levy. For example, he says, “you now have doctors who are becoming *qui tam* relators, which represents a whole new cadre of people who may be filing *qui tam* complaints.”

In addition, he says, recent changes to the False Claims Act have armed the government with a host of new investigative tools, such as the expanded use of Civil Investigative Demands (CID), which are having a profound impact on the way investigations unfold (*see box, next page*).

Recent changes to the False Claims Act have also weakened some long-standing defenses, such as the public disclosure defense, says Levy.

“We also have less patient judges who will not keep complaints stayed and under seal indefinitely,” he adds.

In short, the enforcement landscape is becoming increasingly challenging which makes adequate preparation all the more important, says Levy.

“The key is to be prepared”

According to Jobes, many elements of an investigations policy are often overlooked by companies even though they may seem very basic. This is true for both internal and external investigations, she adds.

Jobes says the challenge that companies face in this regard was brought home when a sales rep asked her how she would even know that an investigation was underway. Jobes pointed out that investigators can easily show up at a sales meeting, knock on the door when a rep is in a doctor’s office or, worse yet, show up at their home at any time of the day.

“You now have doctors who are becoming *qui tam* relators, which represents a whole new cadre of people who may be filing *qui tam* complaints,” says Ropes & Gray’s Joshua Levy.

Jobes says she has implemented policies and procedures at Adolor to help sales reps deal with these possibilities. The objective, she says, is to make sure they understand their options so they are not overly intimidated. Her message: “I don’t want you to be afraid or intimidated about speaking to the government. You are not doing anything wrong. This is part of the process.”

It is important *not* to instruct sales reps and others not to speak to the government, says Jobes. “That is not the message that you want to put across,” she says. Rather, she says, the message should be that everyone has a range of options, as well as the absolute right to have an attorney present when they speak to somebody in the government. “As with any conversation that could have legal

consequences,” she adds, “it is always good to have a witness, because that way nothing that is said can be misconstrued.”

In short, Jobes says, she gives sales reps the full panoply of options. “You don’t have to speak with the agent at the time you are approached,” she tells them. “You are entitled to hire counsel. Likewise, company counsel may represent you and you can ask someone from the company to come with you if you choose to do so.”

Implementing protocols

Jobes says, companies should implement protocols and train reps about potential investigations at least twice a year at regional meetings, national sales meetings, or other venues.

In addition, Jobes also conducts annual training for her Adolor’s senior management. She says that includes senior vice presidents all the way up to the CEO. This training is designed to show them what recent corporate integrity agreements (CIA) are requiring, as well as the latest risk areas highlighted by the OIG, she explains. “Again, the message, if delivered appropriately, is not scary,” she says. “It is informative.”

In large part, she says, the goal is simply to inform senior management what is taking place in the industry in a way in a way they understand. For example, she notes that Synthes, a medical device company currently under heavy government scrutiny, happens to be right down the street from Adolor. The prosecution and imprisonment of several Synthes executives is something that anyone who is a responsible corporate officer should know about, she says.

One of the other benefits of this type of training, says Levy, is that management does not like surprises. “It is much better to do this in the absence of a grand jury subpoena and the initial frenzy of a government investigation,” he says. Effective training sensitizes people about not only the individual risks created by the Park Doctrine, but also what these investigations typically look like and what the costs will likely be, he explains.

First steps

According to Jobes, one of the first decisions that must be made upon receiving a subpoena or a CID is whether to contact Main Justice or the respective U.S. Attorney’s Office. Jobes says she would never advise doing so prior to consulting counsel, which makes selection of counsel one of the first tasks.

CIDs are becoming key enforcement tool, says attorney

Joshua Levy says that for years grand jury subpoenas were the only tool used by prosecutors to request documents at the outset of an investigation. That changed when the HIPAA amendments in 1997 provided for new types of administrative subpoenas. More recently, he says, the Fraud Enforcement and Recovery Act of 2009 (FERA) modified the rules surrounding Civil Investigative Demands (CID), making them much easier to use.

“CIDs have a lot of advantages for the government compared to grand jury subpoenas or HIPAA subpoenas,” says Levy. For example, unlike subpoenas, a CID allows the government to ask for testimony from witnesses, as well as interrogatories from companies.

In addition, he says, there are fewer restrictions on what the government is allowed to do with information obtained through a CID. For example, DOJ can now share that information with both the Civil Division and the Criminal Division. Documents obtained by a CID can also be shared with relators, he points out, which can have the effect of arming relator’s counsel about the facts underlying an investigation. This can weaken a company’s effort to dismiss complaints because they do not meet the particularity requirements of Rule 9(b) of the Federal Rules of Civil Procedure if a *qui tam* claim reaches stage, he explains. CIDs have also accelerated the investigative process, says Levy, because it eliminates the necessity of the grand jury process.

The use of CIDs also allows for more document discovery, testimony, and interrogatories, before the government has to make an intervention decision, says Levy. “It used to be they could only get that information through the grand jury,” he says, “but this allows for greater access and easier access.”

Another important change under FERA, says Levy, is that the designation of a CID has dropped from the Attorney General level to the Attorney General’s designee. This allows prosecutors in DOJ’s Civil Division to authorize CIDs. U.S. Attorneys are now allowed to issue CIDs as well, he points out. ■

“The first thing I am going to do is call my outside counsel,” she says. As surprising as it may sound, she says, companies sometimes talk to prosecutors after the initial contact without first speaking to their lawyer. But when they engage in what they think is a casual conversation, she says, they often wind up inadvertently volunteering information.

In selecting counsel, Jobes says, it is important to understand that former prosecutors know how to “talk the talk” even in instances where there has been a “changing of the guard” in a particular office. In short, she says, former prosecutors have a familiarity with the process that is invaluable. “Any of you who have dealt with attorneys who were former prosecutors will see it right away,” she says. “They recognize tactics. They can map out strategy.”

Levy takes a similar view. In fact, he says, companies should do some due diligence in terms of who they are going to hire, because that can have a significant impact on their relationship with the prosecutors who are running the investigation, as well as the reputation of the company within the U.S. Attorney’s Office. In a worst-case scenario, he says, companies may wind up hiring somebody who turns into a liability. “I have seen that happen,” he says.

“Everyone is at some risk”

According to Levy, it is important to understand that the risk individuals currently face is not limited to the application of the Park Doctrine, which targets senior executives. The government is scrutinizing both the sales force and headquarters, as well, he cautions. This puts lawyers “in the crosshairs” because they play a role in approving promotional practices and various operating plans, says Levy. “Everyone is at some risk in terms of government scrutiny,” he says, which is another reason to be cautious when the first subpoena arrives.

Selecting a firm

According to Jobes, many companies often deal with a single large law firm. But it is not uncommon to select someone who is not part of that firm to handle an investigation. “That does not hurt you in any way,” she says. “White Collar defense is a totally different genre and you should not be afraid, if necessary, to go outside your comfort zone for selection of a White Collar defense attorney.”

Levy says he is a firm believer in getting off on the right foot with prosecutors by getting on the phone and establishing credibility. That means

getting documents out the door as quickly as possible, he says. “These cases tend to be huge,” he explains. It is easy to be overwhelmed by the process of loading documents on review platforms. Moreover, there are often delays in that process and the government can become frustrated if it issues a subpoena and 30 days later they still do not have documents, he cautions.

Getting organized

Jobes points out that companies are already prepared for an FDA audit. “They are ready for FDA to walk in the door,” she says. “Those are the people who can help you and be your partner should documents be demanded from an outside agency.”

It may sound rudimentary, she says, but having all the sales training documents stored electronically in one place is critical. “You would be shocked to learn that many companies store them in each therapeutic area or let each business keep these documents separately,” she says. “That really isn’t going to help you in terms of gathering records quickly and easily.”

One of the most important steps is to get organized at the outset, says Levy. “There will be a flurry of activity and it will feel like a crisis,” he says. “You have to get organized right out of the box.” Levy says that means getting people involved who can start creating a tracking sheet and marking exactly what is done in response to each document request. “Time will go by and you will forget if you don’t keep a record of what you are doing to respond,” he warns.

It is also important to have a system to code the documents, says Levy. Typically, the head of investigations at the company will have a constant need for information, he says. “You need to amass a huge amount of information for the government,” he says. “You also need to get through it pretty

As surprising as it may sound, companies sometimes respond to government inquiries before they speak with their outside counsel, says Adolor’s Chief Compliance Officer, Elizabeth Jobes.

quickly. That requires a system and a review team in place to code the documents, and establish a “hot docs” review process, he says.

Jobes says counsel should be involved in selection of “hot docs” to maintain privilege. Companies must also establish a means to deal with discussions of privilege, which is complicated by the way compliance and legal functions are typically separated under recent CIAs, adds Levy.

Narrowing the request

It is also important to determine at the outset which requests will be too burdensome for the company to comply with, says Levy. The date range may be problematic, he says, or it may be that the product was promoted by a company that was acquired for which the information is not immediately available. It is useful to communicate with the prosecutor about the scope of the request, Levy explains, because prosecutors may actually be more interested in a certain time period.

Rather than asking prosecutors to modify the subpoena, he says, it is typically more productive to ask prosecutors to leave the request for the earlier period open. “Ninety-nine times out of a hundred you never hear from them again about the earlier time period,” he says, “because they are overwhelmed by the material they are getting.”

One important issue that is often confronted, says Levy, is whether contract attorneys at law firms should do the first level review. That can save a significant amount of money for the company being investigated, he says, but it also raises questions in terms of quality control.

Jobes says she prefers to have someone employed by the firm for anything that involves the day-to-day dealings of the company. “I always want someone with skin in the game,” she says. “Contract attorneys are very useful for routine work,” she says, “but I still like someone who is employed by the firm. Hopefully they will represent us as if it were their company, and that’s what you want.”

In addition, Jobes says, it is important for in-house counsel to meet every lawyer on the team, including the first-year associates who do much of the day-to-day work. “I am still shocked by how many people are not doing this,” she says. ■

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■ **Joshua Levy**, Ropes & Gray, Boston, MA, joshua.levy@ropesgray.com

Polaris names Scallon partner

Polaris Management Partners, a management consulting firm that focuses on the compliance needs of the life sciences industry, announced the promotion of **Mark Scallon** to partner. Scallon joined Polaris in 2006 and has been instrumental in the firm’s rapid growth over the last five years.

Scallon leads Polaris’ State Law Reporting and Aggregate Spend Practice and has overseen the provision of over 30 aggregate spend projects to Polaris’ client base. He also advises life sciences companies on general compliance issues, including auditing and monitoring, policy development, risk assessments and process efficiency. In addition, he works with companies under investigation and has successfully completed seven IRO projects for companies who have signed a CIA with the government.

With over 12 years of experience, Scallon often speaks at conferences and has published several articles related to off-label monitoring, risk assessment methodology, and aggregate spend capture and reporting.

He is currently leading Polaris’ initiative to establish the firm’s west coast office. He can be reached at: mscalton@polarismanagement.com

Norris joins Potomac River Partners

Joel Norris, who has been working in the pharmaceutical industry since 2004, recently joined Potomac River Partners. Norris, who has worked with a range of drug and biotech companies, gained extensive aggregate spend experience with King Pharmaceuticals both before and after its integration with Pfizer. He successfully designed, implemented and managed the aggregate spend and state law reporting solution for King from 2007 to 2011.

In addition to being a subject matter expert in aggregate spend and state law reporting, he has broad experience in compliance auditing and monitoring, and payments to HCPs. He has spoken at several pharmaceutical conferences, including a case study on “How to Build an Aggregate Spend Program at a Small or Mid-Size Pharmaceutical” the First National Disclosure Summit four years ago.

He can be reached at: jnorris@potomacrivertpartners.com

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- Developing a Balance Between Internal Audit and the Compliance Functions
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- Maintaining, Training, and Motivating Employees to Retain Internal Audit Talent
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December 12, 2011 - December 13, 2011
Kempinski Hotel Bristol Berlin, Berlin

4th Annual Risk Evaluation and Mitigation Strategies

January 19, 2012 - January 20, 2012
Westin Arlington Gateway, Arlington, VA
Early Prices Expire on December 9, 2011

European Medical Affairs & KOL Best Practices Summit

February 9, 2012 - February 10, 2012
Hotel Fira Palace Barcelona, Barcelona
Early Prices Expire on January 6, 2012

2nd Annual Maximizing Relationships with Nurse Practitioners and Physician Assistants Summit

February 23, 2012 - February 24, 2012
Hyatt at The Bellevue, Philadelphia, PA
Early Prices Expire on January 13, 2012

6th Annual Clinical Billing & Research Compliance

March 4, 2012 - March 6, 2012
The Westin Casuarina Las Vegas Hotel, Casino & Spa, Las Vegas, Nevada
Early Prices Expire on January 6, 2012

4th Digital Pharma Europe

March 5, 2012 - March 6, 2012
Swissôtel Berlin, Berlin

3rd Annual Proactive GCP Compliance

April 2, 2012 - April 4, 2012
Washington, DC

10th MSL Best Practices Summit

April 12, 2012 - April 13, 2012
New Jersey
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3rd Digital Pharma West

June 25, 2012 - June 28, 2012
San Francisco, CA



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