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RX COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

FDA chief outlines new enforcement mechanisms; leading FDA attorneys say new emphasis on enforcement is already evident

New FDA Commissioner puts spotlight on misbranding and false advertising

FDA Commissioner, Margaret Hamburg, outlined a series of six new mechanisms last month designed to promote "swift" and "aggressive" enforcement of the agency's regulations. Hamburg said "unreasonable delays" have left serious violations—including incidences of misbranding, misleading labeling, and false advertising—unaddressed "far too long." Some of the measures she outlined during her August 6 address—ranging from a speedier process for warning letters to a formal "close-out" process once violations are addressed—are already being implemented.

Leading FDA attorney, **Robert Brady**, says that while Hamburg's blueprint for enforcement is not surprising, it is, nevertheless, very noteworthy. "Everybody has been anticipating an increase in enforcement," he explains. "She is putting an exclamation point on that." According to Brady, who co-chairs Hogan & Hartson's FDA practice, it is highly unusual for an FDA Commissioner to dedicate an address solely to the subject of enforcement. Moreover, he says, Hamburg's remarks were clearly aimed at the agency, as well as the industry. "Obviously, she wants to send a message not only to industry but to her own troops, as well," he says.

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Pfizer finalizes record $2.3 billion fraud settlement

Last week, the Department of Justice (DOJ) announced a wide-ranging settlement to resolve investigations into Pfizer's promotion of Bextra and other drugs. As part of the agreement, Pfizer will pay DOJ and other agencies a total of $2.3 billion in criminal penalties and civil payments, making it the largest heatlthcare fraud settlement in history.

When Pfizer disclosed the preliminary agreement in January on the heels of Eli Lilly's $1.4 billion Zyprexa settlement, it was immediately tagged "the Bextra settlement." However, it has been clear for some time that the settlement would include a lengthy list of additional drugs. Nevertheless, the lion's share of the settlement unveiled last week is for Pfizer's alleged improper off-label marketing of Bextra. The company is paying $502 million to settle civil charges in addition to a $1.3 billion criminal fine, both relating to Bextra marketing.

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FDA chief outlines new enforcement mechanisms; leading FDA attorneys say new emphasis on enforcement is already evident

Daniel Kracov, who heads the FDA and healthcare practice at Arnold & Porter, takes a similar view. The agency's enforcement initiative is not simply designed to "get their numbers up," says Kracov. Rather, he says, it is designed to give enforcement more punch, from a public health perspective, by establishing a defined process that has a strong deterrent effect.

Moreover, both Brady and Kracov say the FDA's enforcement shift is already being felt. "We are seeing a lot more enforcement action," reports Brady, a seven-year veteran of the FDA. "DDMAC is a lot more energized," he says. This is reflected not only in an uptick in warning letters but in DDMAC's informal communications, as well, he points out.

Nor is the FDA's enhanced enforcement likely to be limited to warning letters, says Brady. For example, he points to considerable discussion about expediting debarment and disqualification of clinical investigators.

According to Kracov, recent FDA actions—from press releases to product seizures—are already taking place much faster than in the past. The lesson for industry, he says, is that companies must reevaluate their preparedness from an FDA perspective, not only in terms of compliance, but also in terms of response. Companies should be prepared for the agency to move very quickly, he says, especially with regard to safety issues. They should also be ready to match—or exceed—the intensity of the agency when responding, he says.

Hamburg concedes regulatory ambiguity

According to Hamburg, who has been in her new post only a few months, "visible and clearly-explained" enforcement actions will help maintain "a level playing field" for the industry. "Making sure that offenders are held legally accountable prevents companies from having to choose between doing the right thing and staying competitive," she maintains.

Notably, however, she also concedes a lack of clarity regarding many of the agency's existing rules and regulations. "You certainly don't need to tell me about the complexity, and often the opaqueness, of aspects of food and drug law," Hamburg said in response to a question pointing to recent court rulings that highlighted the complexities of the Food Drug and Cosmetic Act (FDCA).

"The issue in those cases has not been that the FDA's rules and regulations are unclear," FDA attorney **John Fleder**, of Hyman Phelps in Washington, D.C. told Hamburg, "but rather [that] there are no rules and regulations and what the statutory terms mean is not clearly defined by Congress or by the FDA."

Hamburg responded that said she is committed to making FDA "more transparent" and its rules "more explicit." She specifically cited the need for "a new clarity" in agency policy. "It is complex territory," she said, "and I think not all of it is put into plain language and not all of it is as straightforward as we might want it to be."

"We are seeing a lot more enforcement action," reports Hogan & Hartson's Robert Brady. "DDMAC is a lot more energized."

Hamburg said "a more open and collaborative" relationship with industry will enable the agency to better explain its standards and expectations. The FDA's transparency initiative is one step in that process, she said. But moving in a more timely fashion is also important, she added. In fact, "routinely accepted" internal timelines at the FDA "boggle the mind" of an outsider, such as herself, she said. "Some of these timeframes just don't seem acceptable," she stated.

Here are some of the other key points addressed by Hamburg:

More effective enforcement tools needed. Hamburg said FDA is fortunate to have received significant funding increases for the next fiscal year. Some of these funds will be devoted to additional inspection and compliance activities. But additional steps are needed, said Hamburg.

Likewise, while the broad framework of the changes she outlined can be implemented under FDA's existing authority, the agency must seek more effective enforcement tools from Congress, she said.

Internal and external cooperation. According to Hamburg, while the agency already works closely with its state and local partners domestically, international cooperation and coordination are also on the rise. "We live in an increasingly globalized world," she explained. "The importance of working with sister regulatory agencies around the globe is increasingly important."

Hamburg noted that she has already traveled abroad to meet with the agency's counterparts in the European Union to discuss improved cooperation and "increasingly harmonized standards" and practices.

The solution: A strong compliance program. The FDA—like regulated industry—faces no shortage of challenges, said Hamburg. "The solution is a commitment to compliance backed by a strong compliance program," she concluded. Every company should take the time to examine whether they have such an effort in place, she said, and reassess the adequacy of their program.

FDA's new emphasis seen as "additive"

Nobody expects the FDA's new emphasis on enforcement to diminish the efforts of state and federal agencies that have added a whole new dimension to enforcement over the past decade. Rather, says Kracov, FDA's renewed focus on enforcement should be seen as "additive." The intensity of FDA's actions will likely make things easier for the governmental entities and private parties that stepped into the breach when FDA enforcement was not as vigorous.

According to **William Vodra**, Senior Counsel with Arnold & Porter, in Washington, D.C., Hamburg's address makes a telling point with respect to off-label enforcement. In all likelihood, he says, her promise that FDA will seek closer cooperation with the agency's regulatory partners to develop enforcement strategies means that when other agencies have powers that enable the agency to move faster or be more effective, it will seek their assistance.

The reality, says Vodra, is that FDA criminal penalties are never going to break the billion dollar mark, making a settlement such as Lilly's $1.4 billon Zyprexa settlement impossible if FDA attempted to go it alone. "I do not see that happening," he says, "because FDA does not want to reduce the incentive to comply with the law." Moreover, he adds, the Administration wants all the revenue it can get.

The FDA's six-pronged approach to bolster enforcement

In her August 6 address to the Food and Drug Law Institute, FDA Commissioner, Margaret Hamburg, noted that, in recent years, the General Accountability Office and others have pointed to "a steep decline" in the agency's enforcement activity. Many of the FDA's enforcement actions have been hampered by "unreasonable delays," she maintains, because "the pathway to enforcement actions can be too long and arduous."

Here are the six steps she outlined to improve the effectiveness and timeliness of the agency's regulatory and enforcement system:

1. **Set post-inspection deadlines.** First, said Hamburg, the FDA will establish a clear timeline for regulated industry to respond to significant FDA inspection findings. Once the agency identifies a serious problem, she said, companies will generally have no more than 15 working days to correct the issue before the FDA moves ahead with a warning letter or an enforcement action. "This will help FDA issue warning letters on a timely basis and facilitate prompt corrective action," said Hamburg.

2. **Take responsible steps to speed the warning letter process.** Second, she said, the FDA will speed the issuance of warning letters. To accomplish this, Hamburg announced a new policy limiting the review of warning letters by the FDA's Office of Chief Counsel to "significant" legal issues. This approach, which will create "a more streamlined process," she argued, is "consistent with the FDA's longstanding historical practice."

3. **Work more closely with FDA's regulatory partners.** Third, said Hamburg, the FDA will seek to work more closely with the agency's regulatory partners to develop effective risk controls and enforcement strategies.

(continued next page)

A complex landscape

According to Fleder, a former Director of the Department of Justice's (DOJ) Office of Consumer Litigation and a twenty-year veteran of that office, an accurate picture of the new enforcement landscape will take some time to emerge. For one thing, the cases that surface will primarily be cases that were initiated prior to the new Administration, while new cases may take years to materialize. "You may just get signals in the short-term," he predicts.

Vodra says Eli Lilly's Evista settlement in December 2006 is an example of just how long these cases can take to develop. He points out this came more than six years after an injunction against Lilly for precisely the same behavior covering the same time period (although the government alleged that Lilly continued the conduct after the injunction).

Finally, says Fleder, the relationship between the FDA DOJ regarding FDA enforcement is "extremely complex." Not only does it involve a lot of people and a lot of policies, he says, but a lot of new people who were not in their current positions eight months ago, not to mention some that have yet to be named, including a permanent FDA Chief Counsel.

However, Vodra maintains that while there is always a complex interaction between FDA and DOJ, it often has more to do with routine interactions rather than highly visible cases of special interest to the political leadership.

According to Vodra, history shows that the political leadership can move quickly to alter the direction of FDA enforcement. He says that former FDA Commissioner David Kessler's efforts to show that FDA was back in the enforcement business after the passivity of the Reagan years and the struggles over Laetrile in the 1970s demonstrate that when the FDA Commissioner stakes out an issue, that person can demand attention from the political counterparts at DOJ. ■

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(continued from page 3)

4. **Prioritize follow-up on warning letters and other enforcement actions.** Fourth, she said, the FDA will prioritize enforcement follow-up. After a warning letter is issued or a major product recall occurs, she explained, the agency will make it a priority to follow-up promptly with appropriate actions to determine if the company has made the required changes.

5. **Be prepared to take immediate action in response to public health risks.** Fifth, said Hamburg, the agency will be prepared to act swiftly and aggressively regarding public health issues. "The FDA will no longer issue multiple warning letters to non-compliant firms before taking enforcement action," she warned.

   If speed is essential to addressing significant health concerns or egregious violations, she added, the FDA will consider immediate action, even before a formal warning letter is issued.

   According to Hamburg, these five procedural changes will help to ensure that violations are taken seriously, that warning letters and enforcement actions occur in a timely manner, and that steps are taken to protect consumers in cases where immediate enforcement action is not possible.

6. **Develop and implement a formal warning letter "close-out" process."** The final step outlined by Hamburg relates to the agency's response to firms that have taken the necessary corrective actions. If the FDA can determine that a firm has fully corrected violations raised in a warning letter, she said, the agency will issue an official "close-out" notice and post this information on the FDA website.

   Not every type of warning letter will be eligible for a close-out letter, she added, but for ongoing violations, it could play "an important motivating role" in spurring corrective actions.

FCPA enforcement

SEC announces blueprint for increased FCPA enforcement

"There appears to be little end in sight to the government's laser-focus on enforcement of the Foreign Corrupt Practices Act (FCPA)," says **Joseph Tompkins**, a former Deputy Chief of the Fraud Section at the Department of Justice (DOJ). To the contrary, says Tompkins, a partner with Sidley Austin in Washington, D.C., the incoming Administration appears to be accelerating this trend.

Last month, **Robert Khuzami**, Director of the Division of Enforcement at the Securities and Exchange Commission (SEC), announced the creation of a special unit dedicated exclusively to FCPA enforcement. The special unit, he says, will focus on "new and proactive approaches" to identify violations of the FCPA.

The SEC is not alone. **Kirk Ogrosky**, Deputy Chief of the Fraud Section at DOJ, recently indicated that Main Justice will be rolling out "a number of initiatives" in the FCPA arena over the next year in areas where it has original jurisdiction.

SEC: "More is needed"

While the Commission is already active in this area, Khuzami told the New York City Bar last month, "more needs to be done, including being more proactive in investigations, working more closely with our foreign counterparts, and taking a more global approach to these violations."

In addition to establishing a unit dedicated to FCPA enforcement, Khuzami also outlined several significant changes in the structure and operation of the SEC's Division of Enforcement. While these changes are not specifically directed at the FCPA, says Tompkins, they could have implications on the Commission's enforcement of the Act. For example, Khuzami announced that the SEC's Division of Enforcement would streamline decision making authority by granting supervisors the power to open a formal investigation. "This means that if defense counsel resist the voluntary production of documents or witnesses, or fail to be complete and timely in responses or engage in dilatory tactics, there will very likely be a subpoena on your desk the next morning," he warned.

In addition, Khuzami said that SEC investigations will proceed more quickly. Going forward, he announced, approval by the Division Director will be required for all tolling agreements. "Tolling agreements have become far too common," he explained. "In some instances, they impose a significant cost of delay." In the future, these agreements will represent the exception rather than the rule, he said.

Likewise, internal memoranda to the Commission recommending specific enforcement actions will be shorter and will be subject to fewer reviews and require quicker turnaround times, he said.

These initiatives are designed to achieve one goal, said Khuzami: "To move our cases more quickly and to free up time and resources to take on new matters with greater urgency and impact."

SEC role increasing

According to **Paul Gerlach**, a partner with Sidley Austin in Washington, D.C., Khuzami's remarks highlight the important role that the SEC plays in FCPA enforcement, especially with respect to the Act's accounting standards provisions—including the books and records provisions—which are often overshadowed by the Act's anti-bribery provisions. The SEC prosecutes, through civil and administrative actions, the accounting standards provisions of the FCPA and may obtain profit disgorgement from issuers that violate the FCPA, he explains. "In recent years," he says, "the government has increased its enforcement of the Act's accounting standards provisions, especially when it does not have sufficient evidence to prove violations of the anti-bribery provisions."

The SEC's Khuzami's says the agency will work more closely with its foreign counterparts to investigate and prosecute FCPA violations.

Also significant, says Gerlach, is Khuzami's express acknowledgement that the SEC will work

more closely with its foreign counterparts to investigate and prosecute FCPA violations.

Increased cooperation

Cooperation between the U.S. and foreign governments in enforcing the FCPA has been a consistent theme at the SEC, says Tompkins. In February, he points out, SEC Chairman Mary Schapiro indicated the Commission is "working vigorously across borders to detect and punish such illicit conduct." Shortly thereafter, he says, then-Director of the Division of Enforcement, Linda Thomsen, noted "the close and cooperative working relationships" that have developed in FCPA investigations among the SEC, DOJ, and foreign law enforcement agencies and securities regulators."

Increased cooperation between U.S. and foreign governments in fighting corruption not only makes U.S. prosecutions of the FCPA more likely, says Tompkins, but also further exposes companies to potential liability in foreign jurisdictions.

"With the addition of an FCPA unit and the implementation of new structural and operational initiatives," says Tompkins, "the SEC appears to be gearing up for increased and quicker-paced enforcement." Companies should bear these changes in mind when assessing their risk under the Act, he warns. ■

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FCPA compliance

Developing and implementing effective third-party due diligence and oversight

By Keith M. Korenchuk, Arnold & Porter, LLP

At the top of any risk assessment of pharmaceutical companies confronting Foreign Corrupt Practice Act (FCPA) exposure is the potential liability created by third-parties who act on behalf of the company. To manage this risk, companies must develop and operate a robust third-party due diligence and oversight program. Third-parties, who are engaged to act on behalf of a company, must not make improper payments that seek to influence purchasing decisions of government officials, or to create an improper advantage. If a company knows, or should have known, that a third-party is making such an improper payment, a company will have liability under the FCPA for the actions of the third-party acting on its behalf.

In light of the current regulatory enforcement environment and the increasing use of third-parties in an outsourced world, most pharmaceutical companies are currently reviewing or revising their approach to enhance their oversight of third-parties. While each company must evaluate its third-party relationships in the context of its own operations and compliance program, a basic framework to undertake this review is appropriate for all who engage third-parties outside the United States.

These steps in this roadmap include:

Initial scoping of the types of activities engaged in by third-parties. A company must decide what activities create sufficient risk to require further due diligence. These third-parties can range from travel agencies to distributors who provide an exclusive service in a given company. The real questions are whether the third-party is acting on its behalf and whether there is interaction with government officials (including healthcare practitioners).

"Effective compliance requires ongoing oversight with respect to third-party activities."

Risk Tiering. Many companies have hundreds, if not thousands, of third-parties who provide services. To ensure that resources are dedicated to those third-parties and countries where there is the greatest risk, many companies utilize a risk-tiering process to evaluate the activity and country in question. Higher risk scores require greater scrutiny.

Questionnaire/internal due diligence. When the determination is made that a third-party should be subject to greater scrutiny, basic information should be obtained from that third-party and those responses should be verified through internal company review and evaluation. This process obtains basic information concerning the company and seeks to verify that information through internal company research.

Risk Assessment. When basic information is obtained concerning a third-party, a risk assessment must be undertaken to evaluate the risk of doing business with that third-party. Generally, this assessment must be made by qualified individuals and subject to an escalation process in the event that certain red flags arise during the due diligence process. This escalation could include more intensive due diligence conducted by a third-party and consultation with more senior management within compliance and legal.

Remediation. Depending on the results of the risk assessment, a decision might be made to look at other third-parties or to require a third-party to undergo certain remediation activities. These activities could include putting compliance controls in place, requiring a new code of conduct, or specifying other actions prohibiting certain interactions with government officials.

Contractual protections. If the decision is made to proceed with a contract with the third-party, contractual provisions should be required as part of the formal agreement with the third-party. These provisions typically require compliance with the FCPA, notification to a company of any potential violations, the ability of a company to terminate a relationship should any bribery occur, and the ability of a company to audit the activities of a third party to evaluate ongoing compliance

Training. A critical element of third-party compliance is to require a third-party to ensure that its sales force and other key personnel who interact with government officials are appropriately trained. This training can be conducted by the company or internally by a third-party

Ongoing oversight. Effective compliance requires ongoing oversight with respect to third-party activities. This oversight includes auditing of the third party and a requirement on renewal and on an annual basis that the party has maintained its compliance with the FCPA and other anti-bribery laws.

Without question, effective oversight on third-parties for many global companies is a daunting process, requiring significant resources, personnel, and a commitment to work with the business to efficiently run this oversight process. Many FCPA fines and settlements revolve around third-party misconduct. In an increasingly outsourced world, significantly more resources will be required to enhance this third-party oversight in order to manage and mitigate those risks. ■

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False Claims Act

Correcting False Claims about the New False Claims Act Legislation

Regardless of what the supporters of the Fraud Enforcement and Recovery Act of 2009 (FERA) might have intended, S. 386, which was passed by Congress on May 18 and signed into law by President Barack Obama on May 20, 2009, unnecessarily expands the ability of individuals acting as private attorneys general to sue—supposedly on behalf of the government—defendants who have allegedly submitted false claims for money or property, two legal scholars recently argued.

According to **Hans von Spakovsky** and **Brian Walsh** of The Heritage Foundation:

> FERA's amendments to the False Claims Act dispense with even the aspects of this balance that recent Supreme Court decisions clarifying the False Claims Act's language helped to achieve. The act's changes throw open the door to new classes of frivolous and unscrupulous litigation for personal gain, ostensibly for the benefit of the government but controlled by individual plaintiffs and trial lawyers.

Below is an excerpt of a recent analysis by the two legal scholars on the likely impact of the new law:

Using the Law Enforcement Power of DOJ to Benefit Private Parties

In order to give the government the ability to investigate a possible fraud, the False Claims Act grants the attorney general the ability to serve a "civil investigative demand" on anyone who "may be in possession, custody, or control of any documentary material or information relevant to a false claims law investigation." Previously, the attorney general could not delegate this law enforcement authority, and information and documentation obtained as fruits of the Justice Department's exercise of this authority could not be shared with *qui tam* plaintiffs and their counsel unless "consent is given by the person from whom the discovery was obtained."

However, the new law, as amended by S. 386, gives the attorney general the authority to delegate this law enforcement investigative power and to share any information obtained "with any *qui tam* relator." This exceedingly plaintiff-friendly amendment will allow the attorney general or his designee within the Justice Department to give private individuals and private trial lawyers documents and information obtained using the law enforcement authority of the federal government. The amendment places the U.S. government in the position of helping one private party in litigation against another, instead of conducting its own objective, impartial investigation to try to ascertain the truth of whether a violation of the law actually occurred.■

To read the complete analysis, visit: www.heritage.org/Research/LegalIssues/lm0042.cfm

Hans A. von Spakovsky is a Legal Scholar, and Brian W. Walsh is Senior Legal Research Fellow, in the Center for Legal and Judicial Studies at The Heritage Foundation in Washington, D.C.

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Margaret Hamburg, MD, Commissioner

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Janet Woodcock, MD, Director, Center for Drug Evaluation and Research

THE IMPACT OF COMPARATIVE EFFECTIVENESS ON THE FDA

Robert Temple, MD, Associate Director for Medical Policy, Center for Drug Evaluation and Research

AN UPDATE ON FDA DRUG ADVERTISING ENFORCEMENT AND NEW GUIDANCE

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FDA'S DEVICE APPROVAL AND SAFETY INITIATIVES

Jonathan Sackner Bernstein, MD, Associate Center Director, Post Market Operations, Center for Devices and Radiological Health,

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NEW TRENDS IN SOCIAL MEDIA
Sanjay J. Koyani, MPH, Director, FDA Web Communications, Office of Public Affairs

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Pfizer finalizes record $2.3 billion fraud settlement

According to **Michael Loucks**, acting U.S. Attorney for the District of Massachusetts, the size and seriousness of the resolution, including the massive $1.3 billion criminal fine, reflect "the seriousness and scope of Pfizer's crimes." Loucks says Pfizer violated the law over an extensive time period. "Furthermore," he says, "at the very same time Pfizer was in our office negotiating and resolving the allegations of criminal conduct by its then newly-acquired subsidiary, Warner-Lambert, Pfizer was itself in its other operations violating those very same laws."

The enormous fine imposed on Pfizer demonstrates that "such blatant and continued disregard of the law" will not be tolerated, said Loucks. His characterization of Pfizer's conduct in this instance stands in stark contrast to the credit he has sometimes given drug companies settling large fraud cases. For example, when Schering-Plough settled its third major fraud case with the Boston Office three years ago, Loucks noted the dramatic change that had taken place in the culture of that organization in the interim.

"Apparently, the conduct surrounding Bextra really irked the prosecutors," says **Patrick Burns**, of Taxpayers Against Fraud.

A record settlement

Pharmacia & Upjohn Company agreed to plead guilty to a felony violation of the Food, Drug and Cosmetic Act (FDCA) for misbranding Bextra with the intent to defraud or mislead. According to DOJ, Pfizer promoted the sale of Bextra for several uses and dosages that the FDA specifically declined to approve due to safety concerns. The company will pay a criminal fine of nearly $1.2 billion, the largest criminal fine ever imposed in the United States for any matter. Pharmacia & Upjohn will also forfeit $105 million, for a total criminal resolution of $1.3 billion.

In addition, Pfizer has agreed to pay $1 billion to resolve allegations under the civil False Claims Act that the company illegally promoted four drugs – Bextra; Geodon, an anti-psychotic drug; Zyvox, an antibiotic; and Lyrica, an anti-epileptic drug – and caused false claims to be submitted to government healthcare programs for uses that were not medically accepted indications and therefore not covered by those programs. The civil settlement also resolves allegations that Pfizer paid kickbacks to healthcare providers to induce them to prescribe these, as well as other drugs.

The federal share of the civil settlement is roughly $668 million and the state Medicaid share of the civil settlement is $331 million. This is the largest civil fraud settlement in history against a pharmaceutical company.

Pfizer will pay a criminal fine of nearly $1.2 billion, the largest criminal fine ever imposed in the United States for any matter.

Bextra: 11-year veteran triggers investigation

The decision by a Pfizer sales representative in Florida to file a *qui tam* suit in 2003 kicked off the federal and state investigations that led to the record-breaking settlement. Ironically, the whistleblower, John Kopchinski, was personally hired as a sales representative in 1992 by Edward Pratt, the chairman and chief executive officer of Pfizer at that time, after Kopchinski began corresponding with Pratt while serving as an Army officer in the Gulf War. Kopchinski worked for Pfizer for 11 years.

As noted above, $1.8 billion of the $2.3 billion settlement is solely due to Pfizer's improper off-labeling marketing of Bextra. Pfizer is paying $502 million to settle civil charges in addition to the $1.3 billion criminal fine both relating to Bextra marketing.

The FDA approved Bextra to treat arthritis as well as menstrual pain in very limited doses. Kopchinski's suit alleged that Pfizer promoted Bextra for uses and in doses that far exceeded what the FDA had approved, putting patients at risk for serious health problems such as heart attack, stroke, and pulmonary embolism. The suit also alleged that Pfizer paid kickbacks to doctors to influence them to prescribe and endorse Bextra for these off-label uses.

See the next issue of Rx Compliance Report for details of the the off-label scheme and an excerpt of the complaint.

According to **Erika Kelton**, a partner with Phillips & Cohen in Washington, D.C., who represented Kopchinski, there are several reasons the Bextra settlement carries such a staggering price tag. The first, she says, is that the off-label treatments that Pfizer was promoting improperly were indications the company unsuccessfully sought to have approved. "In essence," she says, "Pfizer arrogated to itself the decision on approval by basically disregarding the FDA's denial and going ahead and marketing it anyway."

Federal prosecutor Michael Loucks says Pfizer violated the law in connection with Bextra at the very same time it was resolving the Neurontin investigation.

A second reason the settlement has real teeth, says Kelton, is that Pfizer's marketing of Bextra allegedly put patients at serious risk. "The safety profile of this drug is such that people were put at risk through unecessary off-label prescriptions," she says.

Finally, Kelton points out, Pfizer was already subject to a corporate integrity agreement from a series of settlements relating to other drugs.

Geodon's $300 million resolution

As part of the record settlement, Pfizer also agreed to pay $300 million to resolve allegations that it engaged in off-label marketing of its blockbuster atypical anti-psychotic Geodon, which generated over $1 billion dollars in sales in 2008. The allegations were first made in a *qui tam* lawsuit filed by **Brian Kenney** and **Tavy Deming** of Kenney Egan McCafferty & Young in Plymouth Meeting, PA on behalf of Stefan Kruszewski, a psychiatrist.

Geodon was approved by the FDA only to treat patients ages 18-65 diagnosed with schizophrenia or acute manic or mixed episodes associated with bipolar disorder. According to Kruszewski, however, Pfizer promoted the drug for a variety of off-label conditions, including depression, bipolar maintenance, mood disorder, anxiety, aggression, dementia, attention deficit hyperactivity disorder, obsessive compulsive disorder, autism, posttraumatic stress disorder, and for pediatric, adolescent and geriatric patients.

Kenney says the reason the U.S. Attorney's Office in Philadelphia Office was able to achieve such a substantial settlement for Geodon was largely twofold. First, he says, Pfizer focused on "vulnerable" populations, namely adolescents and the elderly, for which there was no approved indication. In addition, he maintains, Pfizer misrepresented the drug's safety profile.

"It is those two things combination," says Kenney. "They were aggressive in going outside the approved patient population," he says, "and they focused on symptoms as opposed to the actual disease state for which it had been approved."

"Pfizer targeted pediatrics and adolescents to expand off-label use and maintained on its payroll an army of more than 250 child psychiatrists nationwide," says Kenney. He says the company regularly paid generous speaking fees to these child psychiatrists to give what amounted to promotional lectures about the benefits of Geodon to their peers. Kenney says the purpose of paying so many child psychiatrists was to gain a foothold within the fastest growing market for antipsychotics: children.

According to Deming, less than five percent of the U.S. population is diagnosed with schizophrenia or bipolar disorder. However, in 2008, Geodon surpassed the blockbuster benchmark of $1 billion in sales. Deming maintains that if Pfizer had limited its Geodon marketing to on-label uses, it would never have achieved anywhere near the more than $1 billion sales that occurred in 2008.

Zyvox's $100 million resolution

Kenney and Deming also served as co-counsel to whistleblower Ronald Rainero, a former Pfizer sales manager who brought a *qui tam* lawsuit against Pfizer for unlawful marketing practices relating to the antibiotic Zyvox. As part of the overall settlement, Pfizer agreed to pay $100 million to resolve allegations that it engaged in the marketing of Zyvox for a variety of off-label conditions beyond the methicillin-resistent Staphylococcus aureus (MRSA) infections for which Zyvox was FDA-approved. Rainero's complaint alleges that Pfizer made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Zyvox in order to further the off-label campaigns.

According to **Stephen Sheller**, of Sheller, P.C. co-counsel in Zyvox case, Pfizer ignored a 2005 FDA warning letter to stop promoting its antibiotic Zyvox as clinically superior to the significantly less

expensive, generic vancomycin when its own FDA-approved label indicated otherwise.

In its July 2005 warning letter, the FDA stated that Pfizer's ad misbranded Zyvox, made misleading and unsubstantiated implied superiority claims, and omitted important safety information. According to Sheller, although Pfizer paid lip service to the FDA in response to the letter, it continued to make claims to physicians that Zyvox was superior to vancomycin. Zyvox costs approximately ten times as much as the generic vancomycin.

A sweeping CIA

As part of the settlement, Pfizer also agreed to enter into an expansive corporate integrity agreement (CIA) with the HHS Office of Inspector General. "This historic settlement emphasizes the government's commitment to corporate and individual accountability and to transparency throughout the pharmaceutical industry," said HHS Inspector General Daniel Levinson. "The corporate integrity agreement requires senior Pfizer executives and board members to complete annual compliance certifications and opens Pfizer to more public scrutiny by requiring it to make detailed disclosures on its web site," he said.

Pfizer points out that the CIA memorializes many actions it has voluntarily initiated, such as the plan it announced in February to disclose its financial relationships with physicians, medical organizations and patient advocacy groups, including investigators who conduct clinical research. Notably, that makes Pfizer the first pharma company to commit to reporting payments for conducting Phase I-IV clinical trials, in addition to disclosing payments for speaking and consulting.

The next issue of Rx Compliance Report will examine the novel elements included in the CIA.

No end in sight

The *qui tam* attoneys highlighted the central role of federal prosecutors Sara Bloom of the Boston Office and Marilyn May of the Philadephia Office, among others, in resolving the investigation. They also promised no end in sight for similar settlements.

"This case took six years," says Kelton. "There are many cases in the pipeline that are not yet public." Needless to say, she adds, there are new cases being filed all the time. "It has been our experience that fraud schemes evolve," she says. "This is going to continue for some time."

Pfizer responds

In response to Pfizer's landmark settlement, Pfizer Senior Vice President and President, Worldwide Pharmaceutical Operations. and **Ian Read** and General Counsel **Amy Schulman** sent employees an internal notice regarding the settlememt. "These are serious issues that represent a significant cost for our company," the pair told their colleagues.

Here is an excerpt of the notice:

Overview of the Settlements. The settlements involve many allegations made by the DOJ and state governments. While the details vary, the allegations center on claims that certain medicines were promoted for unapproved uses. These medicines include Bextra (which Pfizer voluntarily withdrew from the market in 2005), Geodon, Zyvox and Lyrica. In addition, our final agreement with the DOJ covers allegations of inappropriate payments to certain health care professionals involving these and nine other Pfizer medicines — Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft and Zyrtec. It is important to note that the safety of these medicines, when used as directed for approved indications, was not questioned.

Pfizer denies these allegations of wrongdoing, except in two important instances. Our subsidiary, Pharmacia & Upjohn Company, Inc., is pleading guilty to violating the U.S. Food, Drug, and Cosmetic Act for off-label promotion of Bextra. This is a criminal violation, and it is the only guilty plea we entered. In addition, with respect to the civil portion of the settlement, we are acknowledging that our sales force was not appropriately trained and made improper comparisons between Zyvox and another medicine.

Focus on Compliance. These actions occured in the past but they affect our reputation today, and the economic impact is enormous.

Over the past several years, we have continued to broaden and upgrade our companywide compliance program, refining policies and increasing training, monitoring, auditing and other measures to identify and resolve potential compliance issues early on.

While we need to learn from our mistakes, we want to emphasize that the vast majority of our colleagues are people of integrity who want to do the right thing. ■

Only two weeks away!

4th Annual Forum on Educational Grants for the Bio/Pharmaceutical Industry

September 14-15, 2009
Philadelphia, PA
www.cbinet.com/grantseast

CBI's Annual East Coast Forum continues to provide executives with the most productive discussion on the evolving regulatory environment for educational grants. With the increased scrutiny, proposed legislation, new regulations and guidelines for industry executives; it is critical to hear updates on the current challenges within the bio/pharmaceutical and medical device industry. Don't miss out on this networking opportunity to discuss hot topics and political issues surrounding commercial support for medical education programs.

Topics to being research for 2009 include:

- Request for proposals
- Updates on legislation
- The evolving environment for CME
- ACCME proposals
- Advocacy and transparency
- Educational design
- Grant review committees
- Innovative tools for grants
- Outcomes data

Also… mark your calendars for these important events!

5th Annual Pharma/Biotech Enterprise Governance, Risk and Controls Congress

September 23-24, 2009
Philadelphia, PA
www.cbinet.com/erm

Leadership Summit on Global Interactions with Healthcare Providers

October 20-21, 2009
Arlington, VA
www.cbinet.com/globalcompliance

11th Annual Guidelines for Disseminating Off-Label Information

October 22-23, 2009
Arlington, VA
www.cbinet.com/offlabel

Rx COMPLIANCE REPORT
EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

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Rx Compliance Report offers $800 discount for the Fourth Annual Regulatory Symposium

September 30-October 2, 2009
Renaissance Hotel, Washington, DC
www.fdasymposium.com

The following *Rx Compliance Report* discounts are now available for the Fourth FDA Regulatory Symposium, www.FDASymposium.com, Sept. 31-Oct. 2, 2009, at the Renaissance Hotel in Washington, D.C. The Symposium will be offered both onsite and online (both live and archived for 6 months).

Rx Compliance Report subscribers may register for the following discounted rates: $995 for onsite attendance and $795 for online attendance.

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Pahrump, NV 89048

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