

Rx COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL
SALES AND MARKETING COMPLIANCE

Siemens pays \$800 million to settle FCPA violations

Coordinated enforcement actions by DOJ, SEC and German authorities result in massive penalties

Siemens AG, a German corporation, and three of its subsidiaries this month pleaded guilty to violations of the Foreign Corrupt Practices Act (FCPA). As part of the plea agreements, Siemens and its subsidiaries agreed to pay a combined criminal fine of \$450 million. Siemens also reached a settlement of a related civil complaint filed by the U.S. Securities and Exchange Commission (SEC), charging the company with violating the FCPA's anti-bribery, books and records, and internal controls provisions in connection with many of its international operations. Siemens agreed to pay \$350 million in disgorgement of profits relating to those violations. While the alleged violations spanned a broad array of industries worldwide, the company was specifically charged with bribing officials to sell medical devices in China, Russia, and Vietnam.

"The Siemens resolution is striking in its global reach and level of cooperation among law enforcement agencies," says former Department of Justice attorney **Larry Freedman**. "It breaks the sound barrier." At the same time, Freedman says that DOJ's recognition of, and reward for, the company's internal investigation and compliance efforts, and its interest in not debarring Siemens, should be directly applicable to health care FCPA matters. ▶ *Cont. on page 2*

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Waxman puts spotlight on DTC advertising and off-label promotion

Never has there been any doubt about Rep. Henry Waxman's (D-CA) views regarding drug marketing. But just for good measure, he laid down a marker for the pharmaceutical industry this month in one of his first major statements as the newly-minted Chairman of the House Committee on Commerce. "If people want to know how I am going to behave as Chairman of the Committee," said Waxman, "all you have to do is to look at how we handled things when I was Chairman of the [Oversight and Government Reform] Subcommittee."

By his own assessment (and that of nearly all others), Waxman used his leadership position to put a relentless spotlight on what he sees as longstanding problems of fraud and abuse in the industry and the mismanagement of government programs and regulatory agencies. Changes are in store, he told attendees during a lively address to The Prescription Project's conference in Washington, D.C. ▶ *Cont. on page 9*

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Siemens pays \$450 million to settle FCPA violations

According to **Linda Chatman Thomsen**, director of the SEC's Division of Enforcement, the scope of Siemens' bribery was "unprecedented in scale and geographic reach," involving more than \$1.4 billion in bribes to government officials in Asia, Africa, Europe, the Middle East, and the Americas.

But if Siemens is the poster child for fraudulent activity related to the FCPA, it is also the poster child for effective corrective action. "To its credit, Siemens has taken extraordinary steps to reveal its long-standing, systemic criminal conduct and it has fundamentally restructured its operations to make them transparent and honest going forward," said U.S. Attorney for the District of Columbia **Jeffrey Taylor**.

According to the government, the resolution of the U.S. criminal investigation of Siemens and its subsidiaries reflects, in large part, the actions of the company and its audit committee in disclosing potential FCPA violations to the U.S. Department of Justice (DOJ) after the Munich Public Prosecutor's Office initiated searches of multiple Siemens offices and homes of Siemens employees. Siemens and its subsidiaries disclosed the violations after initiating what the government calls "an internal FCPA investigation of unprecedented scope."

Siemens shared the results of that investigation with DOJ and took appropriate disciplinary action against individual wrongdoers, including senior management with involvement in, or knowledge of, the violations, says the government. The company also took remedial action, including the implementation of a sophisticated compliance program and organization.

Compliance monitor imposed

Under the terms of the plea agreement, Siemens agreed to retain an independent compliance monitor for a four-year period to oversee the continued implementation and maintenance of a robust compliance program and to make reports to the company and the DOJ. Siemens also agreed to continue fully cooperating with the Justice Department in ongoing investigations of corrupt payments by company employees and agents.

See related story, next page. ■

Ernst & Young Expert Paints Daunting Global Landscape

The Siemens investigation represents a large complex case that has taken years to resolve, notes **Ted Acosta** of Ernst & Young. The portion of the case dealing with medical devices appears to have grown out of a larger case involving other facets of the company, he says. What is relevant to drug and device companies about the case, says Acosta, is that they now face a Department of Justice and a Securities and Exchange Commission that is well-versed in their business model, especially the medical device sector.

"You are now dealing with a much more knowledgeable FCPA prosecution team in both agencies," he says. That will likely make both agencies more inclined to take these types of cases now that they understand them, he predicts.

International fraud cases proliferate

According to Acosta, 2008 witnessed a greater number of enforcement actions, in general, not only in the United States, but overseas by foreign prosecuting bodies than ever before. He says the combination of a focus on corporate governance and corruption and fragile health care budgets are leading countries to exercise more scrutiny of how business is done by drug and device companies. "We are seeing a lot more activity abroad, both formally and informally," he reports.

Moreover, there appears to be no discernable pattern to the fraud cases overseas, says Acosta. "I haven't seen any patterns such as emerging markets versus mature markets or big countries versus small countries," he says. Sometimes, investigations are triggered by the local government. Other times, it is a U.S. government inquiry. Yet other times, it is a source inside the company, he says.

In short, the only discernable trend is increased scrutiny worldwide, he concludes.

■ **Ted Acosta**, Ernst & Young, New York, NY, ted.acosta@ey.com

FCPA enforcement is on the rise worldwide, says Morgan Lewis attorney

The new Administration in Washington will likely bring a new set of priorities to healthcare fraud enforcement. But one thing that is not likely to change is the government's current focus on Foreign Corrupt Practice Act (FCPA) enforcement, says **Glenn Lammi**, director of legal studies at the Washington Legal Foundation in Washington, D.C. In fact, he points out, both the Department of Justice and the U.S. Securities and Exchange Commission (SEC) have publicly proclaimed that FCPA enforcement will continue to be significant in terms of their individual and collective resources. The SEC, he noted during a WLF webinar on this subject this month, is on record predicting that the dollar amounts that will be announced related to future cases will dwarf disgorgement and penalty amounts that have been obtained in private cases.

Mark Srere, a partner in the litigation practice of Morgan Lewis in Washington, D.C., takes a similar view. In the seven years since 9/11, white collar enforcement has gone down in almost every category except FCPA, he points out. DOJ has added new attorneys to enforce the Act, he notes, while the FBI has added an entirely new unit dedicated to investigating FCPA violations.

The government has already demonstrated its success in this area, says Srere. There is not likely to be any move to limit the expanding scope of prosecutions for FCPA violations, he predicts. "We don't believe there will be any slow down under the new Administration," he says. "This is one of those issues both sides of the aisle can agree on."

Srere says top DOJ officials cite several reasons for this trend. One is the Sarbanes-Oxley Act, which has made companies more aware of their responsibilities. Another is greater cooperation between U.S. officials and foreign officials. It is easier to bring

cases when the two sides are trading information on a real-time basis, he explains, as opposed to going through arcane, and often cumbersome, mutual legal assistance treaties.

According to Srere, the result of these trends is that there are reportedly approximately 80 cases under active government investigation.

The government's heavy hammer

Large fines in this area have already become the norm—and they are getting larger, says Srere. "But it's not just the money you pay out of pocket," he adds. For example, many of these cases result in compliance monitors, he points out. In addition to being quite expensive, this can be quite intrusive, says Srere. "Imagine having someone outside your company monitor everything you do for three years in terms of the FCPA," he says.

The government is also seeking jail time, says Srere. This is not an accident, he says. Rather, the government has stated that it is looking to put executives in jail for the deterrent effect.

The global reach

FCPA cases are unfolding all over the world, says Srere. In short, the government is looking to bring these cases wherever it can find them.

"These are easy cases to investigate," he says. That is because once the government finds one company bribing officials in a specific industry in a foreign country, it can examine other companies doing business in that industry in the same country. "They know that if one company has to pay a bribe to get the contract that other companies have to pay bribes as well," he explains. That makes it an easy pattern to follow, says Srere. "Once they get one thread they can pull on, they can start looking for other ones."

In addition, says Srere, the Organisation for Economic Co-operation in Development's Convention on Combating Bribery now has 37 signatories. That demonstrates that this is a problem that not only U.S. enforcement authorities are going after but foreign enforcement authorities as well, he cautions. ■

■ **Mark Srere**, Partner, Morgan Lewis, Washington, DC, mssrere@morganlewis.com

"There is not likely to be any move to limit the expanding scope of prosecutions for FCPA violations," says Mark Srere of Morgan Lewis.

Attorney cites seven steps to ensure best practices for FCPA compliance

“Best practices are universal when it comes to the FCPA,” says **Brian Privor**, an associate with Morgan Lewis in Washington, D.C. He recommends that companies base their FCPA compliance around several key questions and considerations.

I. Know your business partners, agents, and consultants.

According to Privor, the first thing for companies to understand is who they are doing business with overseas. “Know your business partners,” he says. “Know who you are doing business with. Know what your contracts mean and understand exactly what kind of services you are providing and receiving in return.”

II. Know your exposure to, or contacts with, foreign government officials (including employees of state-owned businesses).

In terms of FCPA enforcement, Privor says, it is critical to know if the company is state-owned and whether any of the employees are government officials. “You have to know right out of the box, ‘Are they state-owned?’” he says. Under the U.S. enforcement regime, if companies are state-owned, state ownership seems to be enough, he says. However, if they are operating abroad, some countries use ownership as a factor but focus more heavily on whether the service in question is a public function. “For FCPA purposes, government ownership is probably enough,” he explains. In fact, U.S. prosecutors have brought criminal FCPA charges for making improper payments to doctors employed by government-owned hospitals.

Companies must also know whether the person they are dealing with is an employee of the government entity, says Privor. Employees of government entities are state foreign officials under the FCPA, he explains. “Once you find that state ownership, you should treat everyone you are working with as an employee of the government,” he says.

According to Privor, the consistent message from senior DOJ attorneys in this area is, “When you don’t know, treat them as a government official until you can prove otherwise.” That is a very

conservative approach, he says. “But you are better off taking a conservative approach than finding yourself in hot water, because it is going to be a lot more expensive to get out of it later.”

III. Know what you are paying for and understand the services that will be provided and how the payments will be made.

The key to FCPA compliance is ensuring that payments are not being made to foreign government officials for purposes of obtaining or retaining business or to secure an improper advantage, says Privor. Thus, he says, it is imperative that companies make payments only for *bona fide* business services. Likewise, companies that use overseas agents or intermediaries must make sure that their counterparty is providing legitimate services, not undefined “consulting” services or, worse yet, buying “access.” Payments should be made directly with receipts and a paper trail, he says. “Be suspicious of cash payments or payments that are routed through third countries or use unusual structures,” he adds.

IV. Follow the kind and type of foreign government investment in each of your business partners.

Given the current global financial crisis, Privor emphasizes the importance of maintaining an up-to-date understanding of the current scope of government ownership and control of all business partners. Particularly in the financial sector, he has witnessed numerous government bailouts and takeovers of public companies, which may transform those companies into government instrumentalities for FCPA purposes. “This means that you must be vigilant to determine whether the financial institutions with which you do business are now considered government entities,” says Privor. “Whether a bank is your lender or a partner in an overseas development project, your dealings with employees of those entities can trigger the FCPA if the institution is government-owned.”

The lessons of the financial industry apply equally to pharmaceutical companies, says Privor. If a pharmaceutical company obtains substantial assistance from or is taken over by the government,

it may be considered a foreign government instrumentality. Thus, he recommends that companies develop a list of financial institutions and other business partners with which they are doing business and have a process in place to keep that list updated.

V. Determine your relationship with each business partner.

Privor says it is important for companies to understand what type of arrangement they are entering into. "Is it a financial institution?" he asks. "Are they just extending you credit? Or are they a client? Are you selling them something? Is this an arm's-length transaction?"

Conversely, he says, the entity could be an investment partner and the arrangement could constitute a joint venture. "A lot of the biggest FCPA cases involve joint ventures with foreign entities," says Privor. Each one of these relationships may dictate a different process, he says, but it is important to keep your FCPA compliance "up to snuff."

"When you are dealing arm's-length, continue to deal arm's-length," he says. Likewise, there is nothing wrong with selling goods and doing business with a foreign government. "What's wrong is paying a bribe with the corrupt intent to attain or retain business."

VI. Ensure that your current FCPA policies are up-to-date and enforced.

Companies must also ensure that their FCPA policies are up-to-date and enforced, says Privor. The traditional FCPA policies that come into play most often, he says, are going to be things like gifts, travel, and entertainment. Promotional expenses have also been a big target of FCPA enforcement, he says. DOJ has recently issued opinions dealing with this subject, he points out.

"A particularly nettlesome area for companies overseas is the payment of finder's fees and commissions and special preferences," warns Privor. If companies are doing business with a particular organization that has government support, he says, it is important to know who is receiving the commissions and the finder's fees to put the deal together. "Those things need to be looked at very carefully," he says.

Privor says it is safe to assume these policies apply to an overseas partner, unless it can be

determined that they are not government controlled. He recommends a conservative approach when dealing with entities for which the ownership has not been determined.

VII. Conduct due diligence and follow through with training and compliance.

"The name of the game is due diligence," Privor concludes. "You obviously need to keep good records," he says, "and you need to demonstrate, above all, good faith."

"Make sure you know who you are dealing with," says Privor. Sometimes that can be as easy as doing an Internet search or checking with consultants, he says. Local officials and local embassies can also be helpful. "There are any number of ways to identify who you are working with," says Privor. While it is not an easy process, he says, it is an important step in the process of FCPA compliance.

"It is not enough to have policies in name only," he adds. "You should train employees so they understand the law and company policy."

It is also important to have "tone from the top" to show that management, and the company as a whole, are serious about compliance, says Privor. "You should maintain records to

back that up," he adds. When companies do this, they can sometimes avoid a potential enforcement action altogether, he says. Alternatively, they may receive a lighter penalty if they can demonstrate to the government that they went to great lengths to get it right.

The government recognizes that companies will not have "perfect compliance," says Privor. "You are not expected to get it right 100 percent of the time," he explains. "But you are expected to make the effort 100 percent of the time." In other words, he says, "If you do get it wrong, you better have made a concerted effort to get it right." ■

■ **Brian Privor**, Morgan Lewis, Washington, DC, bprivor@morganlewis.com

"You are not expected to get it right 100 percent of the time," says Privor. "But you are expected to make the effort 100 percent of the time."

Government outlines Siemens' bribery of officials in Vietnam, China and Russia

Below is the information provided by the U.S. Department of Justice regarding Siemens' bribes in relation to sales in the medical device sector:

Medical Devices in Vietnam

Siemens MED paid \$183,000 in early 2005 and \$200,000 in early 2006 in connection with the sale of approximately \$6 million of medical devices on two projects involving the Vietnamese Ministry of Health. After learning that bribe payments were required in Vietnam, Siemens MED sought the name of the business consultant entrusted by Siemens TS to conduct business in that market, including making its bribe payments. Siemens MED then entered into an agreement with an affiliate of the group of Hong Kong-based business consultants used by Siemens TS to act as Siemens MED's payment intermediary. The payments were routed through a U.S. correspondent bank and then to Singapore bank accounts of the Hong Kong business consultant. The amounts were then withdrawn in cash and transported to Vietnam. Project calculation sheets connected to the sales describe the payment to the intermediary as relating to "room preparation." A number of Siemens' senior managers, including the then-CFO of Siemens' business in Vietnam, admitted that the purpose of the payments was to bribe government officials.

With regard to the \$183,000 payment that was made in early 2005, the former CFO of Siemens Limited Vietnam ("SLV") described how he and the then-CEO of Siemens SLV picked up an envelope with \$183,000 cash at a hotel in Singapore "from a Hong Kong businessman" and flew to the Hanoi Airport where the money was left with the then-head of Siemens MED in Vietnam, who had primary responsibility for contract negotiations with officials at the Vietnamese Ministry of Health.

Medical Devices in China

Between 2003 and 2007, Siemens MED paid approximately \$14.4 million in bribes to the same intermediary described above in connection with \$295 million in sales of medical equipment to five Chinese-owned hospitals, as well as to fund lavish trips for Chinese doctors. The former controller of Siemens oversaw the business relationship between

Siemens and the affiliate of the Hong Kong-based intermediary that it used to pay the bribes. A majority of the sales on which the intermediary received a payment involved a bribe to a government official. The same intermediary was used by Siemens TS to pay bribes in China and by Siemens MED to pay bribes in Vietnam.

For example, Siemens paid \$64,800 in May 2006 in connection with the sale of a \$1.5 million MRI system to the Songyuan City Central Hospital in China. The payment was sent to a U.S. bank account, and later routed to a Singapore bank account in the name of the intermediary. A project calculation sheet signed by the then-CFO of Siemens Limited China, a regional company, described the payment as relating

to "expenses (commissions);" however, no services were provided by the intermediary aside from acting as a vehicle for the transfer of bribe payments. In or around March 2008, Songyuan Hospital's deputy director and head of the radiology department was convicted in China of corruption charges, including a charge for accepting a \$60,000 bribe from a Siemens

salesperson in connection with the sale of the MRI system and sentenced to fourteen years in prison.

Siemens also used the Hong Kong intermediary to pay \$9 million in travel costs for "study trips" taken by doctors who worked at government-owned hospitals in China. The study trips, which included lavish trips to Las Vegas, Miami, and other vacation spots in the United States, were connected to at least 231 separate sales to hospitals awarded to Siemens with revenue of approximately \$235 million. The former CFO of Siemens MED in China used the

Between 2003 and 2007, Siemens MED paid approximately \$14.4 million in bribes in connection with \$295 million in sales of medical equipment to five Chinese-owned hospitals.

intermediary to pay for study trips because of concerns about the lavishness and “non-scientific content” of the trips, which were taken by doctors who were in a position to award business to Siemens.

Bribes were also paid to secure sales of medical equipment to hospitals in China on behalf of two Siemens U.S.-based subsidiaries, Oncology Care Solutions (“OCS”) in California and Molecular Imaging (“MI”) in Illinois. For OCS, Siemens developed a scheme to minimize the risk of anti-bribery prosecution in the United States for these transactions by routing the approval of business consulting agreements and the payment of business consultants through Siemens’ headquarters in Germany rather than in the United States. Between 1998 and 2004, this scheme was used to approve improper payments of approximately \$650,000 to Chinese business consultants in connection with the U.S.-related sales. A senior manager at Siemens MED in Germany and officials of the U.S.-based subsidiaries, including the CFOs of OCS and MI were aware of the business consultant payments and facilitated the scheme by verifying the amounts to be paid and that the payments were due and owing. At one point, after approving twenty-six such payments, the senior manager at Siemens MED refused to continue the payment scheme, citing concern for the welfare of his family if he were sent to prison. The CFO of [Siemens] MED attempted to pressure the senior manager to keep the payment scheme going, but without success.

In 2005, these officials also verified that “clean-up” payments totaling over \$500,000 were owed to Siemens’ Hong Kong-based intermediary in connection with sales by OCS and MI in China. The outstanding payments were for bribes owed to third-parties on behalf of Siemens. After receiving

confirmation from OCS and MI that the payments were outstanding, the former controller of Siemens MED authorized three “clean-up” payments in 2005 for \$377,400, \$140,000, and \$44,000.

Medical Devices in Russia

Between 2000 and 2007, Siemens MED made improper payments of over \$55 million to a Dubai-based business consultant in connection with sales of medical equipment in Russia. The business consultant was used as a payment intermediary for bribes to

government-owned customers in Russia. The former CFO of Siemens MED knew of, and approved, the payments. Senior Siemens officials estimated that up to 80% of Siemens’ MED business in Russia involved illicit payments. On one such transaction in 2006, Siemens made payments of approximately \$287,914, some of which was used for bribes, in connection with the \$2.5 million sale of a computer tomography system to a public hospital in Ekaterinburg. On this contract, the bribes were routed through the Dubai-based business consultant, as well as a second business consultant that was registered in Des Moines, Iowa. ■

Between 2000 and 2007, Siemens MED made improper payments of over \$55 million to a Dubai-based business consultant in connection with sales of medical equipment in Russia.

DTC advertising

PhRMA’s revised DTC guidelines not likely to deter Congressional critics

The Pharmaceutical Research and Manufacturers of America (PhRMA) Board of Directors this month adopted measures to strengthen its voluntary guidance on Direct-to-Consumer advertising. Not surprisingly, Congressional critics gave the revisions a lukewarm response. “On one hand, PhRMA has taken our

committee’s concerns seriously by revising parts of their DTC code,” says House Oversight and Investigations Chairman Bart Stupak (D-MI). “On the other hand, some of these changes are merely a rewording of prior policy that does nothing to increase consumer protection.”

PhRMA’s voluntary Guiding Principles, which

originally went into effect in January 2006, provide guidance to companies on ways to ensure that DTC communications provide accurate, accessible and useful information to patients and consumers.

According to **Adonis Hoffman**, senior vice president at the American Association of Advertising Agencies in Washington, D.C., says the industry is damned if it does and damned if it doesn't. "The impression I get is that any action the industry takes on its own accord is seen as an effort to stop legislative action that could be more far-reaching," he says.

However, Hoffman says, it is both important and commendable for PhRMA to continue reviewing its own guidelines with a view toward making them better and more relevant to the marketplace. "You have to take them at face value," he says, "and it's a move in the right direction." Moreover, legislation may or may not be passed, he points out, making it important for the industry to do what it thinks is responsible and proactive.

PhRMA maintains that numerous studies and surveys demonstrate that DTC advertising plays a key role in educating patients and fostering strong relationships between patients and their healthcare providers. Critics counter that it increases utilization of new drugs before the potential risks of those drugs are fully known.

New principles

The revised principles address aspects of DTC ranging from healthcare professionals and celebrities featured in advertisements, to presentation of balanced benefit and risk information, to the appropriate timing and placement of advertisements with adult-oriented content.

The revised principles, which take effect March 2, 2009, include the following enhancements:

- ▶ A new principle states that DTC product advertisements featuring actors in the roles of healthcare professionals should identify that actors are being used. If actual healthcare professionals are featured and are compensated for their appearance, the advertisement should acknowledge the compensation.
- ▶ An added principle provides that DTC television or print advertisements featuring a celebrity endorser should accurately reflect the opinions, findings, beliefs or experience of the endorser. Companies

should maintain verification of the basis of any actual or implied endorsement, including whether the endorser is or has been a user of the product.

- ▶ A new principle highlights the legal requirement that DTC print advertisements should include FDA's MedWatch number for reporting of potential adverse events and DTC television advertisements should include the company's toll-free number or refer patients to a print advertisement that contains the MedWatch number.
- ▶ An existing principle regarding education of health professionals prior to a DTC campaign for a new medicine or indication is expanded to add that companies should consider individually setting specific periods of time for education before launching a branded DTC campaign.
- ▶ A revised principle includes language strengthening guidance related to the content and placement of DTC advertisements with adult-oriented content. Specifically, the new version states that DTC television or print advertisements "containing content that may be inappropriate for children" should be placed in programs or publications "reasonably expected to draw an audience of approximately 90 percent adults (18 years or older)."

"Some of these changes are merely a rewording of prior policy that does nothing to increase consumer protection," says Rep. Bart Stupak.

- ▶ An existing requirement addressing risk-benefit balance in DTC advertising is strengthened to specify that risks and safety information, including the substance of relevant boxed warnings, should be "presented with reasonably comparable prominence to the benefit information, in a clear, conspicuous and neutral manner, and without distraction from the content."

The new principles provide that company CEOs and compliance officers will certify each year they have processes in place to comply with the principles. ■

► *Cont. from page 1*

Waxman puts spotlight on DTC advertising and off-label promotion

“It is a time of big change for me,” said Waxman. Last month, in a move that surprised more than a few Washington insiders, he successfully challenged and dethroned Rep. John Dingell (D-MI) as head of the House Commerce Committee. As Waxman was quick to point out, that committee has sweeping jurisdiction over healthcare, which has been “a primary interest” of his since he was elected to Congress 34 years ago.

Waxman was also quick to point out what he has been able to accomplish in the FDA arena in various leadership positions over the last two decades. As Chairman of the Health and Environment Subcommittee from 1979 through 1994, for example, he managed to help pass a broad spectrum of health legislation from the Waxman-Hatch legislation to the Orphan Drug Act.

“That’s what I intend to continue,” said Waxman. “But that doesn’t mean we aren’t going to look at oversight,” he quickly added. “We are certainly going to have a very strong oversight presence” because oversight “informs the legislative process.”

A busy agenda

Waxman made it clear that his overriding mission will be to work with soon-to-be President Barak Obama and his Administration to ensure affordable, accessible healthcare coverage for all Americans. “But there will be a lot more on our agenda,” he said. This includes providing clear and effective legislative authority to bring generic biologics to the market and restoring the effectiveness of the FDA and other public health agencies, which have been starved for resources.

Waxman then underlined his long-standing interest in drug marketing, especially the marketing of new drugs, which must be viewed in the prism of drug safety, he said. The “inconvenient truth” facing Americans, said Waxman, is that, even with the new authorities granted to the FDA under the FDA Amendments Act, new drugs reach the market before their risks are fully understood. “Unless we require companies to conduct massive, lengthy, and prohibitively expensive clinical studies in hundreds of thousands of patients before marketing, the full

risks of a drug will not be truly understood in the first few years after a drug goes on the market,” he explained.

Waxman targets DTC advertising...

According to Waxman, it is in these first few years of a drug’s life that drug companies often aggressively market their products and engage in direct-to-consumer advertising. “This increases the number of consumers exposed to safety risks of new products, long before those risks are truly understood,” he charged. “That argues for moving cautiously with new products, particularly when existing drugs are working well.”

Waxman says these factors explain his support for legislation that would grant FDA the authority to restrict DTC advertising for new drugs on a case-by-case basis. “I think that concept makes a great deal of sense and could provide FDA an important tool to protect the public health,” he said.

... and off-label promotion

But it doesn’t stop there, said Waxman. “We have also got to be concerned about how drugs are advertised to physicians, not just to consumers,” he said. “After all, physicians are the ones who prescribe the drugs.”

“We know that it is inside the doctors’ offices where the most persuasive and effective advertising really goes on,” he charged. According to Waxman, drug companies have “exploited the unseen nature of this marketing to physicians to engage in so-called ‘off label marketing’.”

Given that many of these unapproved uses lack scientific support, off-label marketing can lead to the unsafe use of drugs and devices, said Waxman. The fundamental principle of the Food Drug and Cosmetic Act is that FDA should review the safety and efficacy for a drug or device before it is marketed, he said. As a result, Congress must ensure that companies have the proper incentives to test

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new drug uses, just as they have incentives to test new drugs, he argued.

Distorting clinical information

Waxman also pointed to repeated examples of drug companies “cherry-picking” the information they give to physicians. In some cases, he says, that includes companies distorting “vital information” about the safety and efficacy of their drugs. “This is a grave disservice to physicians and patients, undermining the scientific basis of drug prescribing,” he charged.

The FDA Amendments Act will, for the first time, require drug companies to register their clinical trials they are conducting and to make the results of

those studies public when they are completed, he pointed out. Waxman said he plans to “closely monitor” how this is working.

Academic detailing

That information still needs to get into the hands of the physicians, said Waxman. For too long, he argued, “most of the information physicians receive to make prescribing decisions has come from the marketing representative—and only from the marketing representative—of the drug companies.” What is needed, he concluded, is “a balance” of information. That, he said, explains his support for legislation proposing an academic detailing program, which he is working on with Senator Kohl (D-WI). ■

Key congressional aide blasts FDA’s draft off-label guidance

If Rep. Henry Waxman’s aide, **Ann Witt**, has her way, FDA’s draft guidance on medical reprints will never see the light of day in its current form. And as the key staffer for the powerful California Democrat on FDA-related issues, Witt’s views should not be taken lightly.

Witt told attendees at FDLI’s recent drug advertising and promotion conference in Washington, D.C., that even the cynicism that comes from 20 years of watching drug advertising up close left her unequipped for the continued wave of stories about the excesses of Merck’s marketing of Vioxx, which included the alleged manipulation of study results and the omission of serious adverse effects. “To find that this kind of really irresponsible marketing and distortion of the scientific record was so pervasive there is truly troubling,” says Witt, who spent a dozen years at the FDA. These revelations should lead all sides to question whether substituting peer review for FDA review and approval is really a good way for doctors to learn about new uses of drugs, she argues.

The point she was trying to make, Witt tells *Rx Compliance Report*, is that allowing drug companies to choose which peer-reviewed studies are given to doctors (when they can manipulate study results and cherry-pick only positive studies) may not be the best way to educate them about new uses. That does not mean that she questions the value of peer-reviewed literature as a whole or as a source of good information for doctors, says Witt, who headed FDA’s Division of Drug Marketing, Advertising, and Communications (DDMAC) in 1992.

Moreover, she adds, nobody is suggesting (as she said FDA Deputy Chief Counsel Jeffrey Senger, who preceded her talk with a cautious recitation of the debate to date, might have been suggesting) that critics of the draft guidance are opposed to off-label use or to providing doctors with sound scientific evidence about those uses. “There are many cases where off-label use is appropriate,” she says, adding that oncology is probably the best example.

Rather, she says, the concern is that allowing companies to decide which scientific evidence gets to the doctors is “very questionable and probably quite risky for the patients to whom the drug will be prescribed on the basis of that very selective science.”

It has been “repeatedly established,” Witt maintains, that company-sponsored studies reach favorable results about their products far more than

independently-funded studies. It is also the case, she says, that company-sponsored studies now make up the majority of the studies in the physicians’ literature.

“If we permit companies to promote on the basis of preliminary evidence, that’s all we’ll have —preliminary evidence,” says Waxman aide Ann Witt.

FDA's draft guidance

According to Witt, it is useful to compare the regime for the dissemination of reprints established by the Food and Drug Modernization Act (FDAMA) with FDA's draft guidance. Prior to the Bush Administration, she says, the FDA viewed dissemination of reprints as potential threat to the incentive companies have to get drugs approved for new uses, which the agency deemed critical to the enhancement of evidence-based medicine. The fear, she says, was that if companies were allowed to promote off-label on the basis of preliminary evidence, that would eliminate their incentive to conduct the rigorous and expensive studies necessary for FDA approval.

Witt says the requirement that drug companies conduct such studies has resulted in "far more well-supported medical decisions" within the medical community, because it provides the necessary evidence to compare the safety and effectiveness of drug products. "If we permit companies to promote on the basis of preliminary evidence, that's all we'll have— preliminary evidence," she argues.

Absent that evidence, she says, the likelihood is that some companies would continue to conduct rigorous studies for a period of time while others would not. "Companies would be under tremendous financial pressure to compete in the marketplace," she contends. "What you would see is a real lowering of the standard of evidence available on products."

According to Witt, the FDA opposed the FDAMA provisions on dissemination of reprints in their original form until conditions were added to protect patients from prescribing based on misleading evidence as well as the drug approval process itself. Those conditions included the requirement that companies were either seeking approval for the use they were promoting (or that they promised to do so) and that the reprints to be disseminated would be reviewed by FDA, says Witt. "I think those were absolutely critical requirements to protect the central goals of the drug approval process," she argues.

In addition, says Witt, the legislation and implementing regulations required companies disseminate copies of studies that reached different conclusions, if the reprint did not represent a balanced view of the data that existed on the product.

"It certainly wasn't a cure-all," she says, given the potential that companies could "cherry pick" positive data to present. "But at least it was a step in that direction."

Shortcomings in FDA's draft guidance cited

The guidance that FDA put out last February includes none of those protections, says Witt. "There is no reason it couldn't have," she adds. "It is guidance. It establishes conditions under which companies safely know that their dissemination won't be the subject of an enforcement action."

Instead, she says, the guidance adopted some of the conditions established by the FDAMA regime, but omitted many of the most important conditions.

According to Witt, FDA's draft guidance does not require companies to seek approval for the use at any point. "It does not provide any mechanism for FDA review of the reprints before they are disseminated," she adds. And while it has some provisions prohibiting the disseminating of false or misleading reprints, it does not require companies to disseminate contrary articles.

"Instead," she says, "in a gesture to that idea, FDA's draft guidance says that companies must submit a bibliography of articles."

According to Witt, most people familiar with pharmaceutical detailing and physicians' workloads understand that it is one thing to hand a physician a reprint along with data that do not support what the reprints says. It is another thing, she says, to hand them a bibliography that does not even highlight studies that are inconsistent with the reprint and expect them to dig up those studies. "It's completely unrealistic," she argues.

"It seems somewhat misguided to attack FDA for failing to include all the FDAMA provisions in their guidance, when Congress allowed that law to lapse," argues Wiley Rein's Bill McGrath.

FDA guidance could stifle enforcement

Another troubling aspect of the guidance, says Witt, is what it would potentially do to the efforts of the Department of Justice and state Attorney Generals who are trying to recoup the losses for Medicaid and Medicare from off-label promotion.

WLF case revisited

According to Witt, the court in the Washington Legal Foundation (WLF) case made it clear that FDA retains the authority to use reprint dissemination as evidence of intended use in enforcement actions. “That is,” she says, “as evidence of illegal marketing.”

Witt says the WLF Court indicated that companies could challenge decisions by FDA on a case-by-case basis under the First Amendment. “But it certainly didn’t say that FDA would lose those challenges or that it lacked the authority to use reprints to establish ‘intended use.’” If FDA establishes that a company “intends” a drug for a new use, the company may be violating statutory requirements that it obtain approval of the use and provide adequate directions for that use, she adds. “FDAMA made that clear as well,” she says. “But the guidance does not.”

Unlike FDAMA, says Witt, FDA’s draft guidance says, “Here is your safe harbor. If you follow these conditions, rest assured we won’t use your dissemination as evidence of intended use... Nowhere does it suggest that if you go outside the limits of the guidance that FDA cannot do anything about it.”

Witt predicts this is going to cause problems for state Attorneys General seeking to bring cases based on clear rules about what is acceptable promotion and what is not.

In addition, because it does not require FDA review of the reprints, the guidance is virtually unenforceable for FDA, she contends.

An impossible task for FDA

Witt maintains that it has always been “incredibly difficult” for FDA to police the detailing activities of the drug industry. “It happens behind closed doors,” she says. “There are probably ten times as many sales representatives as there are FDA employees overall. The idea that FDA is going to be out there somehow figuring out what reprints have been disseminated to companies and whether they meet the terms of this guidance is laughable.”

Although the guidance does include some useful conditions, says Witt, “I really don’t understand how it is that FDA imagines it is going to enforce them, even if it had the enforcement authority to do so, which the guidance really doesn’t say that it does.”

For all these reasons, says Witt, Rep. Waxman is “extremely concerned” about the draft guidance and has launched an investigation into its genesis. Some internal documents have been received from FDA, she reports, but many of her office’s questions have yet to be answered. ■

WLF chief counsel takes dissenting view

Not surprisingly, Waxman aide Ann Witt’s statements regarding FDA’s draft guidance found its fair share of detractors. “With regard to the WLF decision, she has it all wrong,” says Washington Legal Foundation’s (WLF) Chief Counsel **Richard Samp**. He takes particular exception with Witt’s assertion that the court in the WLF case made it clear that FDA retains the authority to use reprint dissemination as evidence of intended use in enforcement actions. “The court said no such thing, and I challenge her to find a single sentence in the opinion on which she could possibly base her claim,” says Samp.

Rather, he maintains, what the D.C. Circuit said was that it was dismissing FDA’s appeal from the District Court decision—and vacating as moot that portion of the injunction that addressed FDAMA—because FDA had abandoned its District Court position that FDAMA included prohibitions against inappropriate reprint dissemination. As a result, the District Court decision stands, he says.

Wiley Rein’s **Bill McGrath** takes a similar view. “It seems somewhat misguided to attack FDA for failing to include all the FDAMA provisions in their guidance, when Congress allowed that law to lapse,” he says. ■

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OID Senior Attorney cites emerging best practices for day-to-day compliance activities

Senior OIG attorney Mary Riordan says drug and device companies should consider “radical” steps to regain public confidence

Senior OIG attorney **Mary Riordan** has been at the agency since the onset of the current scrutiny of drug marketing. During that time, she has negotiated most of the major corporate integrity agreements (CIA) with pharmaceutical manufacturers.

Below is a rundown of advice she offered attendees at the recent Pharmaceutical Compliance Congress in Washington, D.C. regarding proactive measures that companies can take to improve their day-to-day compliance activities. Riordan says this should include some fairly “radical ideas” such as eliminating incentive compensation and the budget for sales reps to provide gifts and meals for physicians.

Coordinate compliance across the organization.

Riordan says companies should coordinate their compliance efforts across the organization as a means of enhancing their compliance efforts. Specific controls are important, she says. But it is also important to periodically take a step back from the day-to-day activities to think about “big picture” items such as identifying those drugs that carry the greatest risk of illegal off-label promotion.

Once companies identify the high-risk drugs, Riordan says, they should “look strategically across the company” to determine how they are “marrying the compliance message with the business message.” In other words, she says, it is important to imbed compliance into the business operations on a day-to-day basis.

According to Riordan, this can include looking at sales quotas, marketing plans, sales and marketing meeting materials, and call lists, as well as strategic decisions such as whether the company is going to seek a supplemental new drug application. “You really need to look at whether there is an inconsistency between the compliance message you are trying so hard to convey for your compliance program and the actual business practices,” she explains.

Ideally, says Riordan, the company’s business practices and compliance practices will line up. But where there are inconsistencies, she says, the compliance function must remedy the inconsistencies. It is equally important to identify and

eliminate inconsistencies between the compliance message that is talked about during training and what actually happens in the field when sales reps are knocking on doors, she adds.

Riordan says companies should use field monitoring activities, such as ride alongs, to help foster relationships between compliance and sales reps. She says that relationship will likely reduce the number of anonymous calls to the hotline and increase direct

contact between the two groups, thereby making compliance more consistent with good business practices.

Complete an annual needs assessment.

Riordan says every company should complete an annual needs assessment to evaluate, for example, how many speakers and consultants will be needed. “Then stick as close as you can to the plan that you have established at the beginning of the year,” she says. According to Riordan, there may be legitimate reasons to deviate from the plan. For example, a product launch may not work as expected. “But having a plan at the beginning of the year regarding how many consultants, ad boards, and speakers you will need will help everybody stay on track with the compliance goals,” she maintains.

Examine incentives. According to Riordan, one significant reason sales reps may deviate from the company’s compliance practices is inappropriate incentives. In other words, she says, what incentives has the company given them to go off-message or to engage in improper promotion?

To remedy this, Riordan says companies should consider changing the basis for compensation. “Look at your base salary and look at the incentive

The OIG’s Mary Riordan says putting caps on the aggregate amounts that any one healthcare provider can receive is “a great idea.”

compensation,” she says. “Should you do away with incentive compensation?”

While that may be “a radical idea,” she says, it is worth thinking about in today’s “new environment.”

Likewise, if companies maintain incentive compensation, they might wish to base it on something other than sales or sales goals, she says. For example, it may be possible to develop a new metric to assess whether sales reps “stay on message” or to base incentive compensation on the achievement of compliance goals. These are the type of challenging questions companies should be considering, she says.

To the extent that companies maintain incentive compensation, they must ensure it does not promote off-label promotion, says Riordan. “Look at whether the sales goals that are set can only be achieved by promoting off-label,” says Riordan. “If that is the case, you have a huge problem.” While companies must examine how they establish incentive compensation for every product, the focus should be on those where there is a high risk of off-label promotion, she says.

Establish strict controls. After working on “the incentive problem,” Riordan says, companies should examine the arsenal of tools sales reps have at their disposal. First, she says, companies should minimize the mechanisms that sales reps have to put money or other items or services of value into the hands of physicians. Reducing the overall number of consulting arrangements or speaker programs goes back to that needs assessment, she explains. “This is another way to get a business benefit out of compliance,” she adds.

For those mechanisms, such as speaker programs and advisory boards, that are deemed necessary, Riordan says, companies must establish and enforce strict controls around those programs and examine the kind of approval process they have in place. For example, she says, putting caps on the aggregate amounts that any one healthcare provider can receive is “a great idea.”

Riordan says companies must ensure that payments to healthcare providers comport with fair market value and that written contracts are in place. They must also ensure that speakers are complying with relevant policies and procedures regarding off-label promotion, she adds.

Riordan also recommends moving the authority for certain functions out of the hands of the sales force and into other areas of the company where it

might be more appropriate. She points out that when the OIG’s compliance guidance for pharmaceutical manufacturers recommended separating the grant function from the sales and marketing function six years ago, that was considered “a very radical idea.” Yet, most companies have now taken that step, she points out. “I would encourage you to think about other places where it might be appropriate to separate other functions from the sales function,” she says.

Centralize sample distribution. Riordan also recommends that companies consider centralizing the distribution of samples to ensure that samples are only distributed in response to written requests from healthcare providers and to increase the likelihood that sampling is consistent with labeled indications.

Focus on off-label promotion. It is no secret that off-label promotion is one of the biggest risks that all manufacturers face right now, says Riordan. While there is no silver bullet in this area, she says, companies should channel all questions about off-label issues to the medical information or medical affairs department to ensure they are answered by a well-trained and well-controlled group of individuals. “I urge you to think about what you are having your sales reps do in terms of answering questions about off-label issues,” she says.

Likewise, Riordan says, companies should examine which personnel should be distributing information about the non-approved uses. “Do you want your sales reps handing out journal articles?” she asks. “Or is that something that should be more controlled and be done by the medical affairs department?”

Another “fairly radical idea,” she says, would be to eliminate the budget for sales reps to provide gifts and meals to physicians. “Maybe this is the time to change the expectation doctors have that sales reps will always come bearing gifts,” she says.

“I suspect eventually this is where the industry will move,” she concludes. ■

Riordan says the time has come for “radical ideas” such as the elimination of incentive payments to sales reps.

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