VOL. V, ISSUE 11/OCTOBER 4, 2006

RX COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

Schering-Plough settles wide-raging best price, off-label, and kickback allegations for $435 million

Federal prosecutors announced August 29 that Schering-Plough Corporation has agreed to pay a total of $435 million to resolve criminal charges and civil liabilities associated with Best Price violations, illegal off-label promotion, and kickbacks to physicians. When Schering-Plough settled its case two years ago with the U.S. Attorney's Office in the District of Philadelphia, it was widely understood the case in Boston was well underway. By all accounts, this settlement puts the company's fraud and abuse liabilities behind it but at a significant cost.

Under the terms of the wide-ranging agreement, Schering-Plough Corporation will pay a $180 million criminal fine and, together with its subsidiary company, Schering Sales Corporation, another $225 million to settle civil liabilities.

"Everything under the sun is in there and they admit to a lot of the behavior," says one former high-ranking government attorney, after reviewing the settlement. "It reminded me of the Neurontin case, with everything from forging documents to destroying documents, to paying off doctors, to fraudulent advisory boards." ▶ *Cont. on page 2*

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Schering Settlement, Gleason Arrest: A New Era in Off-Label Enforcement

Wednesday, October 18, 2006, 1-2:30 P.M. (EST)
http://www.hcmarketplace.com/prod-4757.html

How can you reduce liability in the new era of off-label enforcement? Listen to a detailed analysis from two industry experts as they explore two landmark off-label cases — the Schering-Plough settlement and the Dr. Peter Gleason indictment — and the significant impact they have left on pharmaceutical sales promotions.

- **David Adams,** Partner, Venable, Washington, DC
- **Wayne Pines,** President, Regulatory Services and Healthcare, APCO Worldwide, Washington, DC

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For more information, see page 3.

▶ *Cont. from page 1*

Schering-Plough settles wide-raging best price, off-label, and kickback allegations for $435 million

To resolve the criminal charges, Schering-Sales Corporation agreed to plead guilty to one count of criminal conspiracy to make false statements to both the Food and Drug Administration (FDA) regarding its improper drug promotional activity and to the Health Care Financing Administration (HCFA), now the Centers for Medicare and Medicaid (CMS), regarding its Best Price for certain drugs.

Unlike many pharma companies that have settled charges while maintaining no wrongdoing, the new management team at Schering-Plough opted to acknowledge that its past behavior was sometimes inappropriate, and to focus on its new culture of compliance. Undoubtedly, part of the impetus for the corporation to adopt this position is because the U.S. Attorney's office in Boston is widely regarded as the most aggressive in the country and has demonstrated its willingness to bring criminal charges and prosecute individuals.

"Since April 2003, when new management joined Schering-Plough and launched its Action Agenda to transform the company, we have made great progress in building an organization that puts business integrity at the center of its work," said **Brent Saunders,** senior vice president, Global Compliance and Business Practices, Schering-Plough Corporation. "With this agreement, we are putting issues from the past behind us. It is another step as we transform Schering-Plough into a high-performance competitor for the long term."

OIG excludes Schering Sales Corp.

As a result of its criminal conviction, Schering Sales will be excluded permanently from participation in all federal health care programs.

According to a source, there are three relators in the Schering-Plough case. However, they are not yet public, he says, in part due to some relator-share contentions.

Note: See the next issue of *Rx Compliance Report* for more on the OIG's latest statements regarding exclusion.

The case against Schering-Plough

Under the agreement, Schering Sales will plead guilty to charges that it conspired with others to give free Claritin Redi-Tabs to a major HMO to disguise a new lower price being offered to the HMO to obtain its business.

Drug companies, notes DOJ, are required to report their best price on drugs provided to certain commercial customers, including HMOs, to CMS and to pay quarterly rebates to the Medicaid program. "From April 1998 through 1999," charges DOJ, "Schering Sales reported a false best price to [CMS], which failed to include the new low price of Claritin Redi-Tabs provided to the HMO, to avoid paying millions of dollars in additional rebates to the Medicaid program."

"It reminded me of the Neurontin case, with everything from forging documents to destroying documents, to paying off doctors, to fraudulent advisory boards," says one former high-ranking government attorney

In addition, Schering Sales will plead guilty to charges that it conspired with others to make false statements to the FDA in response to the FDA's inquiry regarding certain illegal promotional activities by company sales reps at a national medical conference for oncologists.

"Those false statements were designed to reassure the FDA that the promotional activities were isolated and not directed by [the] home office, when, in fact, the activities were widespread and part of a national marketing plan," according to DOJ. "In addition, the [c]ompany sought to falsely lull the FDA into believing that it had taken appropriate steps to reinforce the message with its representatives that such promotional activities were prohibited, when in fact, the [c]ompany knew and expected that those activities would continue."

The civil settlement

Schering-Plough agreed to settle its civil False Claims Act liabilities and liabilities under the Food, Drug,

and Cosmetic Act for a total of $255,025,000. Specifically, the company will pa y $159,502,000, plus interest, to the United States in civil damages for losses suffered by the Medicare program, the federal portion of the Medicaid program, the Veteran's Administration, the Department of Defense, and the Federal Employees Health Benefits program as a result of the company's "improper drug promotion and marketing misconduct, and Medicaid rebate fraud," according to DOJ.

Schering-Plough will also pay a total of $91,602,000, plus interest, to settle its civil liabilities to the 50 states and the District of Columbia for losses the state Medicaid programs suffered.

The civil settlement resolves allegations that Schering-Plough and Schering Sales knowingly caused the submission of false and/or fraudulent claims for Schering's drugs that were not eligible for reimbursement.

These included the government's claims that:

1) Schering misreported its best price to CMS on Claritin RediTabs to evade Medicaid rebate liability,

2) Schering misreported its best price on private-labeled K-Dur to CMS to evade Medicaid rebate liability,

3) Schering overcharged public health service entities because of its misreporting of best price to CMS,

4) Schering induced physicians to start patients on Intron A for Hepatitis C by paying them remuneration through three marketing programs,

5) Schering induced physicians to use Tenodar for certain patients with brain tumors and brain metastases and to use Intron A for certain patients with superficial bladder cancer through improper preceptorships, sham advisory boards, lavish entertainment, and improper placement of clinical trials; and

6) Schering knowingly promoted off-label uses of Temodar for certain brain tumors and brain metastases and Intron A for superficial bladder cancer despite not having FDA approval. ■

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Listen to a detailed analysis from David Adams and Wayne Pines as they explore two landmark off-label cases, Schering-Plough settlement and the Dr. Peter Gleason indictment, and the significant impacts they have left on pharmaceutical sales promotions.

AGENDA

I. Settlements under the False Claims Act and changes to the off-label promotion landscape

II. Analysis of Schering-Plough settlement
  A. Who is in charge of regulating off-label issues?
  B. Factors that trigger legal liability
  C. Factors that trigger the government's interest in enforcement action
  D. Schering's response to an FDA letter: Implication of false statements

III. Dr. Peter Gleason Indictment
  A. Facts of the indictment
  B. Implications: Physician needs to be concerned about off-label information
    i. Training
    ii. How to avoid legal action
  C. FDA pursuing companies for off-label promotions

IV. Key take-away points from Schering settlement and Gleason indictment

V. Live Q & A

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MEET OUR SPEAKERS

David Adams a partner at Venable, practices in the areas of pharma Advertising, Marketing and New Media, Food and Drug, International Trade.

Wayne Pines is president, regulatory services and healthcare, APCO Worldwide, provides strategic counsel to clients facing crises or media, legislative, regulatory or marketing problems.

Former high-ranking government attorney cites lessons of Schering-Plough settlement

According to one former high-ranking government attorney, the Schering-Plough settlement has several noteworthy features.

I. Massive settlement dollars

First, notes the attorney, the amount of money Schering-Plough has paid the government to resolve various fraud allegations is "truly amazing." Combined with the settlement it reached with the Eastern District of Pennsylvania in 2004, Schering-Plough has now paid nearly $800 million to resolve drug marketing fraud cases. "That's a lot of money," she says.

II. "A prosecutor's dream"

According to the attorney, Schering-Plough's behavior, as outlined by the government, was both egregious and blatant. This is similar to the Neurontin case, she points out, which has become the "poster-child" for pharma marketing fraud. "You can't be paying $500 to doctors to have them switch to your drug," she says. "That's a no-brainer. You can't destroy documents. That's another no-brainer."

When you have the type of conduct noted above, says the attorney, federal prosecutors can heap on every allegation they have because the company will likely be forced to settle.

In addition to allegations of illegal off-label promotion, the Schering-Plough case involved traditional pricing allegations, she notes. "That is something the U.S. Attorney's Office and the Civil Fraud section at Justice love because you can tie it into reimbursement and reach these huge settlements."

"That's what everyone on the prosecution's side wants," she explains. "They want off-label promotion cases along with a claim that the government would not have paid for it." On top of that, she adds, the government charges that Schering was not accurately reporting its prices. In other words, she says, not only should the government not have paid, but where it did pay it was paying too much, she says.

III. A novel scheme

The attorney notes that, according to the information, Schering was obtaining advice from outside counsel about a drug sampling program. "It appears they were trying to give free samples to an HMO, basically saying, 'We will give you these but you have to buy a certain number at a certain price,'" she says. ""What it was really doing was giving the HMOs the product for a lower price and disguising it as free samples plus product at another price."

"This is the first time I have seen that as an allegation and the fact they got legal advice to do it is also interesting," she says. "Clearly, what they were trying to do, if the allegations are true, is use outside counsel to bless this program."

According to the attorney, it is not clear from the documents if they were withholding information from their counsel and trying to get their counsel to render opinions based on facts that were not true.

IV. Will individuals be prosecuted?

According to the attorney, it does not sound as if the outside counsel or other individuals in this case will be prosecuted. "But it is not clear," she adds. She points out that in the TAP case, which was also handled by federal prosecutors Michael Loucks and Susan Winkler, the U.S. Attorney's Office in Boston office deposed several lawyers who had advised the company. According to the attorney, it was almost unprecedented for prosecutors to depose lawyers to reveal the advice they were giving their client. "They are the most aggressive office in the country," she says. Ultimately, they were not able to successfully prosecute the individuals in the TAP case. "They were furious," she says, "and I wonder whether they are able to put together a better case against individuals in this case." ■

"That's what everyone on the prosecution's side wants," says a former high-ranking government attorney. "They want off-label promotion cases along with a claim that the government would not have paid for it."

Prosecutor says Schering has changed culture and practices

"Schering has been prosecuted several times and has paid more than a billion dollars," First U.S. Attorney Michael Loucks noted last week. However, he added, during the course of the recently concluded investigation, the U.S. Attorney's Office in Boston concluded that Schering had dramatically revamped both its business practices and its corporate culture. In short, he said, prosecutors determined "that Schering had, in fact, changed."

"In the course of doing an investigation we became convinced, and genuinely believe, that Schering had changed [and] had made an effort to change its culture, its practices, and its policies," said Loucks, who supervised the investigation. "The business that is there today is not the same business… that was engaged in all the activities that were announced in the prosecution two weeks ago, but really took place a number of years ago."

"If there is an indication or a demonstration of change, that is important from our perspective," Loucks added. "People can reform. Corporations can reform [and] change their behavior."

"It takes a lot of work and it takes sometimes dramatic changes in corporate compliance cultures and ethics," Loucks concluded. ■

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Medicare Congress Office, 7790 Barberry Ave., Yucca Valley CA USA 92284

If you have any questions regarding these discounts, please call 760/365-0837 or email registration@hcconferences.com.

Critics blast off-label component of Schering-Plough's global settlement

Washington Legal Foundation chief counsel says prosecutors ignore legal precedent

There is no shortage of views concerning Schering-Plough's global settlement announced August 29. Not surprisingly, the most controversial aspect is the government's prosecution of the company's allegedly illegal off-label promotion. "I am outraged by the 'improper promotion' part of the case," says **Richard Samp,** chief counsel at the Washington Legal Foundation (WLF) in Washington, DC.

Samp notes that a senior FDA official is quoted as saying, "The FDA takes seriously its responsibilities to protect consumers from products that are promoted for unapproved uses." According to Samp, that sort of thinking has the potential to cause "serious harm" to health care delivery in this country," argues Samp. "Does the government really believe that off-label uses of approved drugs are a bad thing?" he asks. "No responsible medical official feels that way."

"I trust that FDA and the HHS OIG will recognize this is a serious legal and policy challenge," says **John Kamp,** executive director of the Coalition for Healthcare Communications in New York. "It deserves a direct substantive response, not evasive procedural tricks."

Scientific evidence

According to Samp, the questions that ought to be asked are: (1) is there reliable scientific evidence that Temodar is effective in treating brain tumors; and (2) is there reliable scientific evidence that Intron A is effective in treating superficial bladder cancer? "The U.S. Attorney apparently doesn't care about the answer to those questions," says Samp. "He thinks he is protecting consumers by silencing speech about those issues, regardless how truthful."

As WLF established in litigation against FDA, notes Samp, there is a First Amendment right to speak truthfully on such issues. "To the extent that the U.S. Attorney is relying on evidence that Schering distributed peer-reviewed journal articles about its products, he is in contempt of a federal court injunction," he says.

Estimating damages

"Absurdly, in quantifying the amount of gain Schering derived from its improper promotion, the U.S. Attorney cites the estimated dollar volume of off-label sales," he argues. According to Samp, that figure assumes that there would have been no such sales but for Schering's promotion. To the extent that there is valid scientific information regarding off-label uses, he adds, "one would hope and expect that there would be substantial sales regardless of the promotional activity of which the U.S. Attorney complains."

"Absurdly, in quantifying the amount of gain Schering derived from its improper promotion, the U.S. Attorney cites the estimated dollar volume of off-label sales," says WLF's Chief Counsel Richard Samp

Samp maintains that if such sales decrease as a result of this prosecution despite valid evidence that the off-label uses are effective, the U.S. Attorney is directly responsible for harming health care delivery. If such sales do not decrease, then what possible valid reason can the U.S. Attorney have had for going after Schering?" he asks.

"Perhaps realizing that he is on shaky ground," says Samp, "the U.S. Attorney couched the prosecution in terms of a false statement to FDA in response to a 2001 FDA Warning Letter." However, Samp maintains the allegedly false statements were sufficiently vague (e.g., the promotional activity cited by FDA was an "isolated incident") that it is hard to believe that FDA could ever have obtained a criminal conviction. "I can only surmise that Schering agreed to the plea deal because it determined that the negative publicity of an indictment and trial, and the risk that it might be debarred from federal programs, would be intolerable," he says.

However, if the government is going after Schering for making a false statement to government officials, he says, it should not be allowed to get away with telling the public that Schering is being sanctioned for engaging in improper promotion of its products.

The bottom line, Samp concludes, is that government officials should be asked if they believe that there is substantial evidence that Intron A is effective in treating superficial bladder cancer and Temodar is effective in treating brain tumors."

"If the response is, as I suspect it would be, that they don't know the answer, then the federal government is being highly irresponsible in engaging in the practice of medicine, something normally deemed outside the purview of federal officials, and in depriving consumers of health care information that federal officials have no reason to suspect is not truthful," he says. "How can such conduct be deemed to constitute "protect[ing] consumers?" ■

■ **John Kamp,** Executive Director, Coalition for Healthcare Communications, New York, NY, jkamp@cohealthcom.org

■ **Richard Samp,** Chief Counsel, Washington Legal Foundation, Washington, DC, rsamp@wlf.org

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Former FDA Associate Chief Counsel outlines key aspects of Schering-Plough settlement

According to **David Adams,** a partner with Venable in Washington, DC, there are several notable aspects to the Schering-Plough agreement. First, he says, it is further evidence of a trend toward regulating promotion of off-label use through prosecutions and plea agreements based on both violations of the Food, Drug, and Cosmetic Act and false claims and anti-kickback statutes related to reimbursement. "Drugs with big state and federal outlays for reimbursement, and with significant off-label uses, are obvious targets," he says.

"In these circumstances, the federal and state prosecutors are able to shake down companies for huge fines and civil assessments and impose onerous corporate integrity agreements," he says.

The second important thing about this agreement, says Adams, is that it introduces a somewhat frightening new angle on liability related to violations of the Food, Drug, and Cosmetic act. The complaint predicates liability on the company's response to an untitled letter from FDA's Division of Drug Marketing, Advertising, and Communications involving a booth at a medical meeting, he notes. Because the company's response to the letter indicated that the incident was isolated and that the company would address the agency's concern over off-label promotion, the indictment alleges a conspiracy involving false statements to FDA–statements deemed false based on the company's broader array of activities involving dissemination on off-label use, he explains.

Companies should note the particular activities deemed to establish the conspiracy to promote off-label use, including compensation related to sales goals and substantial budgets for advisory boards, speakers, entertainment, and preceptorships, he warns.

"Companies must recognize that the combination of large levels of federal and state reimbursement and large budgets for disseminating information on off-label use can place them in a precarious position," he concludes.

■ **David Adams,** Patrner, Venable, Washington, DC, DGAdams@venable.com

Off-label promotion

Schering-Plough CIA adds new enforcement provisions in off-label arena

As part of its global resolution with the government, Schering-Plough will be subject to an amendment to its existing corporate integrity agreement (CIA). This was anticipated when the company settled its case with the Eastern District of Pennsylvania two years ago and certain expected features of the CIA were noticeably absent.

According to **John Rah** of Epstein, Becker & Green in Washington, D.C., the pricing components included in the Schering-Plough CIA are fairly common. However, the addendum also cites various integrity obligations regarding the monitoring of off-label promotional activities.

The two most significant CIAs that can be used as benchmarks are the Serono CIA and Pfizer CIA, the latter resulting from the Neurontin investigation, which Rah and his colleague, **Lynn Snyder,** helped craft.

Rah says the integrity obligations and the review provisions included in the Serono and Pfizer CIAs with respect to off-label promotional activities, largely focus on the medical department and/or the medical information department and the processes these companies' medical information departments use to monitor against what could be considered solicited requests for medical information. Specifically, the Pfizer and Serono CIAs both address the processes in place for responding to requests for medical information and the auditing and monitoring of those processes.

Monitoring detailing sessions

Apart from a focus on the medical information department, he adds, the Serono and Pfizer CIAs also have a component for monitoring activities during detailing sessions between sales representatives and health care professionals, which Rah says is a "verbatim review" of third-party documents. The Pfizer, Serono, and Schering CIAs all require that the companies obtain third-party records to assess whether potential off-label promotional activities occurred in the field, specifically, between a sales rep and a health care professional. "The OIG wanted to see if there are third-party records that these companies could obtain to see if there is potential off-label promotional activity taking place in the field," he explains. In the Schering CIA, the provision is referred to as the Message Recall Monitoring Program, he reports.

In the Schering CIA, however, the OIG adds one additional requirement in an effort to assess what occurs during a detailing session. According to Rah, the new component included in the Schering-Plough addendum is the Schering-Plough Specialty Field Sales Force Promotion Monitoring Program (see next page). "This seems to be another piece where the OIG is trying to get their arms around what is going on in terms of promotional activities in the field and whether there is potential off-label promotion taking place," he says.

"The OIG is going beyond just getting the third-party records that purport to reflect what happens during a detailing session," says attorney John Rah

Rah says the addendum requires Schering-Plough to implement a monitoring program that requires company personnel to join the reps on their sales calls. The addendum, he points out, requires the company to conduct "a minimum of 30 full-day, direct inspections and observations of the messages and materials delivered by Schering-Plough Specialty Field Sales Force Representatives to HCPs." These "inspections" will consist of "directly observing all meetings between Schering-Plough Specialty Field Sales Force Representatives and HCPs during that workday," he explains.

"The OIG is going beyond just getting the third-party records that purport to reflect what happens during a detailing session by having people from the compliance group at Schering-Plough actually attend some of these detailing sessions to see for themselves if potential off-label promotional activity is occurring," says Rah. "That seems to be [the most significant] addition in the Schering-Plough CIA that does not exist in the Serono and Pfizer CIA." ■

■ **John Rah,** Epstein, Becker & Green, Washington, DC, JRah@ebglaw.com

Schering-Plough Specialty Field Sales Force Promotion Monitoring Program

Here is the section of the HHS OIG's addendum to Schering-Plough's corporate integrity agreement that deals with some of the off-label promotion requirements:

Schering-Plough shall implement a Field Sales Force Promotion Monitoring System that will consist of a formalized process designed to identify potential off-label promotional activities, by Schering-Plough's Specialty Field Sales Forces*, through observations of the interactions of the Schering-Plough Field Force with Health Care Professionals (HCPs) by members of Schering-Plough's Global Compliance and Business Practices ("GCBP") group familiar with product labeling and appropriate product messages. During each Addendum Reporting Period, GCBP will conduct a minimum of 30 full-day, direct inspections and observations of the messages and materials delivered by Schering-Plough Specialty Field Sales Force Representatives to HCPs. (These inspections and observations shall be known as "Inspections.") Each Inspection day will consist of directly observing all meetings between Schering-Plough Specialty Field Sales Force Representatives and HCPs during that workday. The Inspections shall be scheduled throughout the Reporting Period, and shall be scheduled throughout the Reporting Period, and shall be randomly selected by GCBP. The number of Inspections conducted for each Specialty Sales Force shall be proportional in number to the size of each Specialty Field Sales Force, and shall be conducted in all regions across the United States.

At the completion of each Inspection day, GCBP personnel shall complete an Inspection Report, which shall include: 1) the identity of the Specialty Sales Force Representative; 2) the identity of the GCBP professional; 3) the date and duration of the Inspection; 4) the products promoted during the Inspection; 5) identification of any potential of-label promotional activity by the Specialty Sales Force Representative.

In the event that a GCBP Inspection identifies potential off-label promotion, Schering-Plough shall investigate the incident consistent with Schering-Plough's established investigation protocol. If the investigation determines that there was off-label promotion by a Specialty Field Sales Force Representative, Schering-Plough shall notify the OIG pursuant to Section III.I of the CIA. As part of each Annual Report, Schering-Plough shall provide the OIG with copies of the Inspection Reports in any instances in which it was determined that there was off-label promotion during the Inspections and a description of the action(s), if any, Schering-Plough took as a result of such determinations. Schering-Plough shall make Inspection Reports for all other Inspections available to the OIG upon request.

Monitoring and Review of Requests for Off-Label Information

Schering-Plough has in place, and shall continue to maintain, policies addressing the discussion and dissemination of information about non-FDA approved uses of products (off-label information). These policies provide, among other things, that Covered Persons may not directly or indirectly solicit, encourage, or promote unapproved uses of a product to HCPs. Schering-Plough's policies require that when Covered Persons receive inquires about unapproved uses of products, Covered Persons shall direct such inquiries to headquarters personnel rather than responding to the inquiries themselves. Specifically, Schering-Plough has established a Global Drug Information Services (GDIS) unit to undertake various functions, including responding to requests for off-label information about Schering-Plough products.

Schering-Plough documents and records all inquiries submitted by field personnel to GDIS on behalf of customers, including requests relating to off-label information. On a quarterly basis, Schering-Plough conducts a field force submitted off-label inquiry Analysis (Off-Label Inquiry Analysis) as described below).

In order to conduct its Off-Label Inquiry Analysis, GDIS compiles and provides information to the GCBP group and others within Schering-

Plough about all requests submitted to GDIS about Schering-Plough products. The request[ed] information is separated by therapy area and/or product (e.g., Primary Care, Hepatitis, Temodar, Inron A, PEG Intron, etc.), and analyzed to identify those field personnel with the highest number of requests for information. For each therapy area, the requests are further analyzed and reviewed to determine whether the requests are for off-label information. In addition, all information related to the GDIS requests for the top 10 requests in the therapy area is reviewed by a compliance manager for each business unit. The compliance manager completes a summary detailing any findings. In the event that the analysis and review indicates that an individual may have inappropriately caused the dissemination of off-label information or engaged in off-label promotion, Schering-Plough conducts a formal investigation of the situation and undertakes disciplinary action where appropriate.

Schering-Plough shall conduct the Quarterly Off-Label Inquiry Analyses, substantially in the form described in the Addendum, through the term of the Addendum. If incidents of off-label promotion are discovered, the Compliance Officer shall implement effective responses, including disclosing Reportable Events pursuant to Section III.I (Reporting), as appropriate. As part of each Annual Report, Schering-Plough shall submit to the OIG a description of the Off-Label Inquiry Analyses conducted during the Addendum Reporting Period and a summary of the findings of the Analyses.

Message Recall Monitoring Program

Schering-Plough shall implement a Message Recall Monitoring Program designed to identify potential off-label promotional activities by Schering-Plough's Specialty Field Sales Forces through the analysis of commercially available, non-Schering-Plough studies generated by an independent entity concerning physician recall of the marketing messages delivered by those Sales Forces (Message Recall Studies) during the Addendum Reporting Period. During each Addendum Reporting Period, Schering-Plough shall obtain Message Recall Studies relating to two Schering-Plough products that have been selected by the OIG for that period (Covered Products). At its option, Schering may obtain other Message Recall Studies relating to the Covered Products or to other products. Schering-Plough shall analyze the results of all Message Recall Studies to determine whether they reveal any indicators of potential off-label promotional activities.

At the end of each Addendum Reporting Period, Schering-Plough shall complete a Message Recall Monitoring Report that shall consist of; 1) the initiation and completion dates of all Message Recall Studies conducted during that period; 2) the content and scope of those Message Recall Studies; 3) a description of any indicators of potential off-label promotional activities revealed by the Studies; and 4) a description of the action(s). if any, taken by Schering-Plough as a result of learning of such indicators. The Message Recall Monitoring Report shall be submitted to the OIG as part of each Annual Report.

Schering-Plough shall implement a Message Recall Monitoring Program designed to identify potential off-label promotional activities by Schering-Plough's Specialty Field Sales Forces through the analysis of commercially available, non-Schering-Plough studies generated by an independent entity

Prior to the start of the Second Addendum Reporting Period and every Addendum Reporting Period thereafter, the OIG shall select up to two Schering-Plough products to be Covered Persons for the purposes of this Section III.M. The OIG shall notify Schering-Plough which Covered Products have been selected for each Addendum Reporting Period. The Parties have already selected the Covered Products for the first Addendum Reporting Period. ■

Government outlines off-label promotion case against Schering-Plough

Here is the government's off-label promotion case against Schering-Plough Corporation as outlined by Michael Sullivan, US Attorney for the District of Massachusetts, and Assistant U.S Attorneys Susan Winkler and Jeremy Sternberg:

False Statements Concerning Schering's Off-label Marketing of Oncology Drugs

On or about June 29, 2002, SS and various co-conspirators received a copy of, or learned of, an untitled letter dated June 28, 2001, that Schering received from the Division of Drug Marketing, Advertising, and Communications ("DDMAC") of the FDA concerning a May 2001 commercial exhibit hall booth that Schering maintained and staffed with representatives of the [oncology and biotechnology business unit] ("hereafter OBBU") sales force at he 37th American Society of Clinical Oncology ("ASCO") Annual Meeting, held in San Francisco, California. The letter notified Schering that DDMAC had "identified promotional activities that [were] in violation of the Federal Food Drug and Cosmetic Act (Act) and its implementing regulations," and explained that Schering gave "false or misleading efficacy information about Temodar to visitors at the commercial exhibit hall booth" at the ASCO meeting and that "Schering had also promoted Temodar for the unapproved use in first line therapy or anaplastic astrocytoma." DDMAC requested that Schering "immediately cease making such violative statements and any other promotional activities or materials for Temodar that make the same or similar presentations." The letter requested Schering submit a written response to the FDA on or before July 13, 2001, and provide the date on which "this and other similarly violative materials were discontinued.

At the time of the receipt of the FDA letter, Schering Sales and its co-conspirators knew and understood, the OBBU sales force, at the direction of home office, was engaged in the widespread marketing of Intron A for superficial bladder cancer and Temodar for conditions other than refractory anaplastic astrocytoma. Among other actions taken by Schering's home office to ensure that the OBBU sales force aggressively pursued sales of Intron A and Temodar for unapproved uses were the following:

- the sales force was trained to seek off-label sales through training classes, ride-alongs with managers, district meetings, teleconferences, and sales meetings;
- the marketing department provided the sales force a plan of action that targeted off-label sales;
- the sales force was provided with clean copies of "for your information only" scientific articles and abstracts from headquarters to use with physicians;
- the sales force was required to create business plans that emphasized detailed promotional goals to obtain off-label sales;
- the sales force was evaluated and richly compensated, in large measure, by their success in achieving sales in unapproved uses;
- the sales force was provided with substantial budgets for advisory boards, speakers, entertainment, and preceptorships to assist in obtaining off-label sales.

"Schering Sales and its co-conspirators knew and understood the sales representatives would be done with their week's work "at noon on Monday" if they did not promote Temodar and Intron A for unapproved uses."

Schering Sales and its co-conspirators knew and understood the sales representatives would be done with their week's work "at noon on Monday" if they did not promote Temodar and Intron A for unapproved uses.

On or about June 29, 2001, certain employees of Schering Sales met to determine how top respond to the FDA's untitled letter of June 2, 2001.

On or about July 12, 2001, Schering Sales and its co-conspirators knowingly and willfully caused a written response to be submitted to the FDA that falsely stated that the statements identified in the FDA's letter were "an isolated incident" and "certainly inconsistent with the direction provided by the home office," despite the fact that Schering Sales and its co-conspirators knew and were directing the OBBU sales force to engage in widespread off-label marketing of Intron A for superficial bladder cancer and Temodar for conditions other than refractory anaplastic astrocytoma.

No later than on or about July 12, 2001, Schering Sales and its co-conspirators caused to be included in the written response to the FDA false assurances designed to lull the FDA into believing that effective remedial action had been taken in order to avoid further FDA scrutiny of Schering's promotional activity. Among other things, Schering Sales and various co-conspirators caused Schering to falsely state in writing to the FDA that Schering and its employees would only market Temodar according to its labeled indications and that an electronic message was that day being sent to all Schering Temodar sales representatives regarding the "importance of appropriate and accurate promotion" and that the sales force was being "reminded that they may only discuss the approved indication for this product." At the time, Schering Sales and its co-conspirators well knew that the electronic message was not designed to deter such discussions because it would be substantially overridden by the training, incentives, and support to promote off-label uses of the drug.

As a result of the false representations in the July 12, 2001 letter, Schering Sales and its co-conspirators caused the FDA, on or about August 2, 2001, to issue a letter that stated that the FDA considered the matter closed in light of the following affirmations contained in Schering's July 12, 2001 letter:

- "The statements made by your representatives in this matter are an isolated incident and are not consistent with the direction provided by the Schering home office."
- "Schering sent an electronic mail message on July 12, 2001, to all Schering Temodar sales representatives to reinforce the importance of appropriate and accurate promotion and highlight issues discussed in DDMAC's June 28, 2001, untitled letter, and instruct them that they may only discuss the approved indication for Temodar."

As a result of the false statements to the FDA to avoid scrutiny of the ongoing off-label promotional activities directed by home office, Schering Sales and its co-conspirators caused Schering to obtain, between July 2001 and December 2003, approximately $124,179,000 in before-tax profits to which it was not entitled.

All in violation of Title 18, United States Code, Section 371. ■

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The program also includes a panel of five judges.

Government outlines the Best Price case against Schering-Plough

Here is the government's Best Price case against Schering-Plough Corporation as outlined by Michael Sullivan, US Attorney for the District of Massachusetts, and Assistant U.S Attorneys Susan Winkler and Jeremy Sternberg:

THE CONSPIRACY

From in or about early 1998 through in or about August 2001, the exact dates unknown, in the District of Massachusetts, and elsewhere throughout the United States,, the defendant Schering Sales Corporation together with others know and unknown to the U.S. Attorney, did knowingly and willfully combine, conspire and agree to knowingly and willfully make materially false, fictitious and fraudulent statements and representations in matters occurring within the jurisdiction of the executive branch of the United States government in violation of 18 U.S.C. $ 1001.

MANNER AND MEANS

It was part of this conspiracy that Schering Sales and its co-conspirators knowingly and willfully made material false statements to HCFA regarding the Best Price of Claritin Reditabs by concealing the fact that Schering was providing to an HMO free drugs contingent on purchases of the drugs from Schering, thereby allowing Schering to retain approximately $4,392,000 in monies which were owed in rebates to the state Medicaid programs and to which Schering was not entitled; and

It was further part of the conspiracy that Schering Sales and its co-conspirators knowingly and willfully made material false statements to the FDA in order to avoid scrutiny by the FDA of Schering's off-label promotional activities regarding Temodar and Intron A, thereby allowing Schering to obtain approximately $124,179,000 in before-tax profits which it otherwise would not have obtained.

OVERT ACTS

In furtherance of the conspiracy, and to effect the objects thereof, in the District of Massachusetts and elsewhere, Schering Sales and its co-conspirators, committed the following overt acts, among others:

False Statements Concerning The Claritin Reditabs "Sampling" Program

In or about January 1998, an employee of Schering Sales met with a representative of a particular large HMO that maintained a widely known formulary and replaced it with a less expensive non-sedating antihistamine. As a result of this meeting, Schering Sales learned that the HMO was willing to reestablish Claritin RediTabs on its formulary if the price was reduced to $1.10 per Claritin RediTab, a price that Schering Sales knew and understood would set a new Best Price for the drug and would require Schering to pay increased Medicaid rebates to the state Medicaid programs.

In February 1998, Schering Sales and certain of its employees discussed several different proposals to provide the $1.10 price for Claritin RediTabs to the HMO, all of which were designed to avoid reporting the new low price to HCFA and incurring the corresponding obligation to pay increased rebates to the state Medicaid programs. One of the proposals discussed was to ship sufficient trade size packages of Claritin RediTabs to the HMO for free as "samples" so that the blended price between the drug purchased by the HMO and the drug provided for free was $1.10 per RediTab.

On or about February 18, 1998, Schering Sales obtained legal advice from outside counsel that a proposed Claritin RediTab "sampling" program to the HMO would not affect Schering's Best Price reporting obligations. In obtaining legal advice, Schering Sales failed to disclose the material fact that the "samples" of free drug provided would be contingent on the amount of drug purchased to reach a blended price of $1.10 per RediTab.

In or about April, 1998, Schering Sales and its co-conspirators caused a sufficient quantity of free trade size packages of Claritin RediTabs to be shipped to the HMO so that, when combined with the Claritin Redi[T]abs purchased by the HMO, the blended price was $1.10 per RediTab.

From in or about March 1998 through in or about September 1999, Schering Sales and its co-conspirators caused false documentation to be created that indicated that the free goods shipped to the HMO were samples requested by the HMO, despite the fact that Schering Sales and its co-conspirators knew and understood that the HMO did not allow its physicians to receive samples except in very limited quantities; that the HMO refused to sign any agreement for free drug that contained the words "samples"; that Schering shipped full trade packs of Claritin RediTabs to the HMO; that Schering shipped the free drug to the same HMO warehouses as it shipped the purchased drug, that the HMO distributed the free drug to the same HMO warehouses as it shipped the purchased drug; that the physicians did not receive the free drug for use as "samples" despite the fact that certain physicians at the HMO signed "sample request forms" prepared by Schering, each of which requested several thousand samples to be sent to the HMO warehouse; and that the HMO entered the blended price of $1.10 per RediTab into its accounting systems for all Claritin RediTabs whether purchased from Schering or provided by Schering to the HMO for free.

From at least February 1999 through in or about July 1999, Schering Sales and its co-conspirators prevented an internal audit team at Schering from auditing the "sampling" at the HMO in accord with Schering's normal audit procedures by frustrating the schedule of an on-site visit to determine how the "samples were handled by the customer. In or about August 1999, the internal audit team raised concerns about the "sampling" program to management.

In or about September 1999, after a decision was made to terminate the program, Schering Sales and its co-conspirators caused a final calculation to be made of the amount of free drug required to be provided to the HMO contingent on the amount of drug purchased by the HMO to reach the blended $1.10 price for Claritin RediTabs for the remainder of 1999 for each of the HMO's regions of operations, and caused a final shipment of free drug to be made to each of the HMO's regional warehouses.

In or about October 1999, after the "sampling" program was terminated, Schering Sales obtained a written legal opinion from outside counsel that confirmed the earlier legal conclusion provided that the "sampling" program did not impact Schering's best price reporting obligations "because the provisions of these drug samples to [the HMO] by the Company [was] not contingent on any purchase requirements," although as Schering Sales knew and understood, the free drug was in fact provided contingent on purchase requirements to obtain the $1.10 blended price. This written legal opinion, finalized in October 1999, bore a date of February 18, 1998, thereby falsely indicating that the legal analysis contained therein was provided to Schering Sales before the free goods were shipped to the HMO, despite that fact that the opinion referenced a letter to the HMO not written until March 1998, incorporated by reference a kickback analysis from a compliance binder that was not completed before the fall of 1998, and purported to be authored by two attorneys, one of whom did not even join the law firm until months later.

In each quarter from second quarter 1998 through fourth quarter 1999, inclusive, Schering Sales and its co-conspirators caused materially false statements to be submitted to HCFA regarding the Best Price for Claritin RediTabs that failed to include the $1.10 price for Claritin RediTabs that was being provided to the HMO in the calculation of Best Price.

In each quarter from second quarter 1998 through fourth quarter 1999, inclusive, Schering Sales and its co-conspirators caused Schering to underpay rebates owed to the state Medicaid programs and retain approximately $4,392,000 in monies to which it was not entitled, in that Schering failed to include the $1.10 price for Claritin RediTabs in they calculation of the Best Price that was being utilized to determine the amount of rebate owed. ■

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Rx Compliance Report is published 24 times a year. Subscription price is $597 per year.

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