

# Rx COMPLIANCE REPORT

EXCLUSIVELY DEVOTED TO PHARMACEUTICAL SALES AND MARKETING COMPLIANCE

## HHS OIG says trend toward transparency on many fronts is “a positive development”

*OIG’s Riordan says transparency is one of the big changes “coming down the road”*

Improper influence in the relationships between drug and device companies and prescribers and researchers lies at the core of many governmental, Congressional, and public concerns about the two industries, the OIG’s **Mary Riordan** told the Ninth Annual Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum in Washington, D.C. last month. To address that concern, Riordan says, she envisions “a trend towards transparency on many fronts.”

“It seems to be the general view that transparency is one of the big changes coming down the road,” says Riordan. In the two weeks since she delivered that message, a key Congressional advisory body and a leading Democratic Senator took steps that bear out that prediction (*see related story below*). ▶ *Cont. on page 2*

### IN THIS ISSUE

- ▶ **DISCLOSURE.** HHS OIG says trend toward disclosure on many fronts is “a positive development” (p. 1)
- ▶ **DISCLOSURE.** MedPAC approves broad disclosure recommendations; Senator Baucus includes disclosure in reform agenda (p. 1)
- ▶ **CORPORATE INTEGRITY AGREEMENTS.** OIG puts spotlight on novel features of Cephalon CIA (p. 4)
- ▶ **STATE ENFORCEMENT.** Pfizer’s \$60 million settlement with state AGs continues important trend toward state enforcement (p. 10)
  - ▶ State AGs resolve five-year investigation into Pfizer’s marketing of Bextra/Celebrex (p. 11)
- ▶ **IN THE STATES.** DC finalizes regulations imposing novel licensing requirements on pharma, Wisconsin Medical Society Board passes new physician gift policy, University of Minnesota considers sweeping conflict-of-interest policy (p. 14)

## MedPAC approves broad disclosure recommendations; Baucus includes disclosure in health reform agenda

On November 6, the Medicare Payment Advisory Commission (MedPAC) unanimously approved recommendations for a strong set of public disclosure requirements regarding financial relationships between drug and medical device companies and physicians, as well as a variety of other entities. Last week, Senate Finance Committee Chairman Max Baucus (D-MT) unveiled a health care agenda that endorses MedPAC’s approach.

The Baucus plan links an earlier but similar version of MedPAC’s recommendations for disclosure to the need for “stronger enforcement” aimed at blunting inappropriate industry influence on healthcare practitioners. ▶ *Cont. on page 7*

## First National Summit on Disclosure & Transparency Set for March 5–6 in D.C.

The First National Disclosure & Transparency Summit will be held March 5-6, 2008, in Washington, D.C. *See p. 6 for details.*

► *Cont. from page 1*

## **HHS OIG says trend toward transparency on many fronts is “a positive development”**

Riordan points out that proposed federal legislation—the Physician Payments Sunshine Act—and the idea of transparency more generally, have been endorsed by a sizable list of industry groups, including PhRMA, AdvaMed, the AMA, and a number of individual companies. “I think all of those are positive developments,” she says.

Riordan says she expects to see federal transparency legislation enacted sometime next year. The OIG supports legislative and other efforts to increase transparency in the relationships between both drug and device manufacturers and healthcare providers, she says.

Riordan says she is also encouraged to see individual drug manufacturers announcing plans to begin affirmatively reporting payments they are making to doctors. “I expect that we will see more of those kinds of announcements in the near future,” she predicts.

### **Conflict-of-interest: Grant funding**

A corollary to the OIG’s concern about relationships between manufacturers and prescribers is concern about the improper influence that manufacturers may exert on scientific and medical researchers, says Riordan.

An illustration of this, she says, is recent action with regard to conflicts of interest in grant funding. For example, the National Institutes of Health (NIH) recently froze grant funds that had been issued to Emory University because an Emory professor of psychiatry allegedly failed to properly disclose thousands of dollars he received from a drug company while leading a government-funded research project studying one of the company’s drugs.

That is only the latest development in an ongoing investigation by the Senate Finance Committee into whether money paid by drug companies to doctors and academics compromises medical research and scholarship funded by federal grants, she points out.

Last year, NIH awarded more than \$23 billion in grants to more than 325,000 researchers at more than 3,000 universities, notes Riordan, making it an

area of significant interest for the OIG. Given the sheer number of grants and universities involved, NIH must rely on the universities to oversee the grants in a detailed way, she explains.

In its January 2008 report on conflicts of interest, which covered 2004 through 2006, the OIG found that NIH was unable to provide all of the required conflicts of interest reports it had received from the grantee institutions, notes Riordan. It also found a lack of follow-up on reported conflicts of interest, she adds.

### **Clinical trials disclosure**

Riordan also points to increasing concern about the industry’s failure to properly disclose information about clinical trial research, both to the FDA and to the public. A recent example, she says, are allegations reported in *The Wall Street Journal* that Pfizer mishandled information about studies of Neurontin. The company is alleged to have delayed the publication of certain study information to make it look more favorable or to downplay the negative effects of the drug.

---

**“It seems to be the general view that the transparency is one of the big changes coming down the road,” says the OIG’s Mary Riordan**

---

“This is not an isolated incident,” says Riordan, who points to a *Journal of American Medical Association* (JAMA) article earlier this year in which researchers concluded that clinical trial information related to Vioxx had been selectively reported to minimize the appearance of any mortality risk.

In addition to the issue of selective publication of research trials and research results, law enforcement is scrutinizing the issue of ghost writing and guest authorship, says Riordan. To illustrate the issue, she cites an article published in *JAMA* earlier this year, which found that Vioxx clinical trial manuscripts authored by Merck employees often attributed first authorship to academically-affiliated investigators who did not always disclose the industry financial support.

The OIG is facing “a whole world of issues involving research disclosure,” says Riordan.

## Medical device industry

Another broad area of concern involves the medical device industry, says Riordan. The problems outlined above “are certainly not limited to the drug side” of the industry, she says. In fact, on the day of her talk, she points out, the *Chicago Tribune* ran a story about the inherent conflicts of interest in the financial relationships between device manufacturers and physicians. The article concluded that despite last year’s \$311 million settlement involving five major device makers, money from device manufacturers is still flowing.

Here too, Congress has been active, notes Riordan. For example, just last month, Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) sent a letter to the Cardiovascular Research Foundation and to Columbia asking them about funds they received from device manufacturers. This follows hearings earlier this year by Kohl’s Special Committee on Aging, which examined the financial interactions between medical device companies and surgeons, which often involve substantial payments in the form of consultant fees, educational grants, royalties, funding for clinical trials, travel, and grants.

## STATE ACTIVITIES

The states have become very active on a number of fronts, according to Riordan.

Here are several areas that warrant attention, she says:

**State laws regulating behavior.** States continue to implement a variety of laws designed to address the growing concerns about relationships between drug and device makers and healthcare practitioners, says Riordan. Two of the more recent initiatives that should be on the radar screen of drug and devices companies, she says, are the Massachusetts law passed last summer and a statute recently enacted in the District of Columbia.

The comprehensive Massachusetts law requires both drug and device manufacturers to establish comprehensive compliance programs. Notably, it also requires manufacturers to begin posting information about payments to physicians, hospitals, nursing homes, pharmacists, and other providers who have authority to prescribe and dispense drugs next summer. “Massachusetts is just one more of those states that you now have to contend with in terms of reporting payment information,” she says.

“This is really just a part of the wave toward transparency.”

The District of Columbia took a different approach in the SafeRx Amendment Act, which establishes pharmaceutical detailing as a health occupation to be regulated by the Board of Pharmacy. The District is the first jurisdiction to take this step, notes Riordan. The law requires individuals who detail providers in the District to become licensed by April of next year. The license, in turn, requires training or a waiver.

Notably, says Riordan, the new D.C. law also requires healthcare professionals who are prescribing a drug for an off-label use to explain to patients that the drug is not being prescribed for an FDA-approved use. The prescriber must also provide the patient with information about possible risks and side effects associated with that off-label use. This is the first jurisdictional law “that also addresses the whole issue of off-label promotion” with prescribers, she says.

---

*The OIG is facing “a whole world of issues involving research disclosure,” says Riordan.*

---

### **AWP pricing cases.**

Meanwhile, there are a series of ongoing state lawsuits against manufacturers for AWP and other pricing fraud. Last month, for example, Kansas Attorney General Steve Six announced that he was filing suit against 13 drug companies in connection with AWP and wholesale pricing fraud issues.

**Consumer protection actions.** The states have also been very active in pursuing consumer protection actions against manufacturers, says Riordan. Last month, Pfizer announced a \$60 million settlement with 33 states and the District of Columbia to resolve claims related to its Cox-2 products. That follows Eli Lilly’s \$62 million settlement to resolve a multi-state investigation relating to Zyprexa under the consumer protection statutes with 32 states and the District of Columbia.

“The states have really taken the whole issue of off-label promotion and begun to look at it very closely under the microscope of their consumer protection laws,” says Riordan. “These consumer protection actions are certainly proceeding full-steam ahead.”

**State False Claims Acts.** Riordan also points out that the Deficit Reduction Act of 2005 created an incentive for the states to adopt their own False Claims Act laws that are modeled on the federal law. The OIG, working in conjunction with DOJ, determines whether the state law meets the necessary criteria. If so, the state is eligible to receive enhanced amounts in settlements.

To date, the OIG has approved 12 such state laws, Riordan reports. “You should certainly expect to see more state false claims act actions initiated by the states,” she warns.

## OIG ENFORCEMENT WORK

Riordan says the OIG continues to work very closely with its law enforcement partners, namely the Department of Justice and the National Association of Medicaid Fraud Control Units, in a variety of areas that have been the focus of attention in the drug and device industry for many years. “I suspect that we will continue to see these types of allegations brought by relators for a long time to come,” she predicts.

Here are several examples cited by Riordan:

**AWP pricing cases.** Average Wholesale Pricing (AWP) cases have been around for a long time at both the state and federal level, notes Riordan. The United States has intervened in two actions and filed suit against Abbott Labs, Dey Labs and Roxanne, she adds. “We are at the discovery stage of those cases and those cases are proceeding,” she reports. “At the same time, the United States is continuing to investigate a few other manufacturers who are named as defendants by the relators in those cases.”

**Medicaid drug rebate issues.** “We continue to see Medicaid drug rebate issues,” says Riordan, pointing

## OIG puts spotlight on novel features of Cephalon CIA

According to Riordan, the OIG’s corporate integrity agreement (CIA) for Cephalon, which was imposed as part of the company’s \$425 million global resolution to settle off-label promotion allegations, includes several unique requirements that deserve attention. “It is useful to understand our rationale,” she says, “because we are going to continue using these ideas in future CIAs where it is appropriate to do so.”

to a pair of settlements with Merck this year to resolve allegations about so-called nominal price discounting programs that carried a total \$649 million price tag.

“The numbers of Medicaid rebate cases are significantly smaller than the other types of cases,” she says. “But we do have a number of such cases and I expect these cases to continue.”

### Kickback cases.

“Kickback issues have been a longstanding concern of the OIG and continue to be so,” says Riordan. For example, in January, the OIG and DOJ entered a \$1.5 million settlement with a

doctor who was

alleged in the False Claims Act action to have accepted kickbacks from medical device manufacturers.

Notably, the OIG has also brought kickback cases under its own administrative authorities, says Riordan.

“There are plenty of situations where a U.S. Attorneys’ Office or Main Justice might not have the resources” to pursue a kickback case against a doctor or manufacturer and the OIG may pursue the matter, she explains. “I think we will continue to see more cases like that,” she predicts.

**Off-label promotion cases.** The largest set of False Claims Act cases continues to be off-label promotion cases, says Riordan. These settlements range in size from the OIG’s March settlement with Otsuka Pharmaceuticals for \$3.9 million to the recent \$375 million settlement with Cephalon, which was part of a larger global resolution of \$425 million. ■

Riordan says the Cephalon CIA includes several provisions specifically designed to increase accountability for compliance and transparency in the company’s business practices.

For example:

**Board of directors’ certification.** The Cephalon CIA continues a trend of encouraging Boards of Directors to play an active role in the oversight of a

---

*The largest set of False Claims Act cases continues to be off-label promotion cases, says Riordan.*

---

company's compliance program, says Riordan. Under the CIA, the Board (or a Committee of the Board) is required to meet at least quarterly to review the company's compliance program. It is also required to pass an annual resolution indicating that it reviewed the compliance program and concluded the program is effective. "If the Board is not able to certify or indicate in the resolution that the compliance program is effective, the Board needs to explain why that is," she explains.

Riordan says this requirement is consistent with the message the OIG has been conveying for years, namely, that in order for compliance programs to be effective, they must have the buy-in from the Board of Directors and the top-level management.

**Certification from management team.** The second unique provision included in the Cephalon CIA is a requirement for certifications from various members of the management team who are involved in key risk areas, such as sales, marketing, and medical affairs. Requiring those managers to certify compliance will engage them in the process and give the compliance officer some additional assistance in trying to promote compliance throughout the organization, she says.

According to Riordan, this requirement illustrates the OIG's recognition that compliance cannot solely be the responsibility of the compliance officer. "Everybody in the organization must be devoted to compliance," she says. "When you have an organization of thousands of people, there is no way that the compliance officer can be the only one bearing that responsibility."

**Notification of HCPs.** The Cephalon CIA also requires the company to send out letters to all healthcare providers who are currently detailed by the company. The rationale for this is two-fold, says Riordan. The OIG wants the company not only to notify those healthcare providers about the settlement, but also to alert them to the fact that there is a mechanism at their disposal to report questionable conduct by the sales reps.

According to Riordan, the reports may be made either to the company through an e-mail or phone call to the compliance department or directly to the FDA. "We think this requirement will further sensitize both the sales reps and the physicians to the whole issue of off-label promotion," says Riordan. Such notifications may "ultimately turn out to be

another tool that the compliance officers can use to figure out exactly what is going on out in the field," she adds.

**Posting of Payment information.** Another significant change in the Cephalon CIA, says Riordan, is the requirement that Cephalon post information about the payments it makes to physicians. This information must be posted on Cephalon's website and must include information about payments for speaking, consulting, and other activities.

According to Riordan, the OIG engaged Cephalon in extensive dialog regarding the logistics required to aggregate this information and then post it. "The OIG ultimately agreed that we would permit a two-phased reporting process" with the company reporting initial information in January 2010 and more comprehensive information by 2011," she explains. "What we intend is that the comprehensive

reporting that comes into play in 2011 will largely mirror the reporting that is contemplated by the language of the Physician Payments Sunshine Act." While the OIG is cognizant of the pending federal legislation, she says, it also believes that transparency is important. "We wanted to get it started sooner rather than later," she says.

### **Enhancement of CIA requirements**

Riordan says the OIG continues to consider new and enhanced provisions to CIAs. "We are thinking more critically about situations where it is appropriate" to include such provisions, she says. Three types of situations warrant this examination, according to Riordan. The first is cases that involve a criminal plea. If the conduct "is serious enough that the Department of Justice feels it is appropriate to charge this conduct as criminal conduct," the OIG

---

*The OIG's Riordan says the Cephalon CIA includes several provisions specifically designed to increase accountability for compliance and transparency in the company's business practices.*

---

believes additional safeguards are necessary “before we are amenable to allowing that company to

---

**The OIG is closely following the use of independent monitors and “thinking about whether those might be appropriate in CIAs,” says Riordan.**

---

continue to do business with Federal healthcare programs,” she explains.

The second scenario involves a second or third resolution between the government and a particular company, says Riordan. “These repeat offender situations certainly must be evaluated on their own merits,” she says. “But it does raise a concern when we have a second or

third time situation with a manufacturer, whether the OIG should waive exclusion.”

Finally, Riordan says, the OIG would think “long and hard” about adding new provisions in a particular CIA if egregious or injurious conduct is involved. Often, that goes hand-in-hand with the criminal plea, she says.

### **Possible use of monitors**

Riordan also notes that the deferred prosecution agreements the New Jersey U.S. Attorneys’ Office entered into with four device manufacturers last year included a requirement for an independent monitor. “We are certainly watching the implementation of those provisions and thinking about whether those might be appropriate in CIAs,” she says.

“We are also paying close attention to the provisions that have been included in some of the recent consumer protection actions,” she adds. ■

## **State and federal prosecutors to discuss recent landmark settlements**

*Rx Compliance Report* is co-sponsoring two important pharma audioconferences next month. Each event includes an all-star line-up of state and federal prosecutors who handled these ground-breaking cases, as well as several of the *qui tam* attorneys, defense counsel, and other outside experts.

A special discount offer of \$575 for both audioconferences is available. Please visit: [www.pharmaaudioconferences.com](http://www.pharmaaudioconferences.com).

### **The Lessons of Cephalon’s \$425 Million Off-Label Settlement: A New Model for Off-label Enforcement**

**Thursday, December 4, 2008**  
**1:00 pm - 2:30 pm (EST)**

**Peter Chatfield, Esq.**  
Partner, Phillips and Cohen, Washington, DC

**C. William Gambrell, Jr., Esq.**  
Assistant Deputy Attorney General, Director, SC Medicaid Fraud Control Unit, South Carolina Attorney General, Columbia, SC

**Mark Jensen, Esq.**  
Partner, King & Spalding, Washington, DC

**Marilyn May, Esq.**  
Assistant U.S. Attorney, Eastern District of Pennsylvania, Philadelphia, PA

**Eric Sitarchuk, Esq.**  
Partner, Morgan Lewis, Philadelphia, PA

### **How State Attorneys General Are Reshaping Pharmaceutical Marketing and Compliance through Fraud Investigations and Settlements**

**Wednesday, December 17, 2008**  
**1:00 pm - 2:45 pm (EST)**

**David Hart, Esq.**  
Assistant Attorney General, Oregon Department of Justice, Salem, OR

**James D. Kole, Esq.**  
Senior Assistant Attorney General, Chicago Consumer Fraud Bureau, Illinois Attorney General’s Office, Springfield, IL

**Meredith Manning, Esq.**  
Partner, Hogan & Hartson, Former Assistant US Attorney, Civil Division for the US Attorney’s Office, Former Associate Chief Counsel, Food and Drug Administration, Washington DC

**Arnold I. Friede, Esq.**  
Counsel, McDermott Will & Emery LLP, Former Associate Chief Counsel, Food and Drug Administration, Washington, DC (Moderator)

# First Annual Summit On Disclosure And Transparency For Drug, Device And Biotech Companies

*The Leading Forum on Disclosure, Transparency and Aggregate Spend for Drug, Device and Biotech Companies*

## A Pharma Congress Conference

March 5-6, 2009

ONSITE, Renaissance Hotel Washington DC

[www.disclosuresummit.com](http://www.disclosuresummit.com)

**OR... In your own office or home line via the Internet with 24/7 access for six months**

The National Disclosure Summit is the first event that brings together the state and federal legislators and enforcers who are driving disclosure requirements with the industry leaders and outside experts who are crafting the programs to comply with this rapidly growing trend.

To view a list of the roughly 30 confirmed speakers, visit: [www.disclosuresummit.com](http://www.disclosuresummit.com).

Here are some of the featured sessions:

### **DAY I: THE PERFECT STORM: DISCLOSURE GRIPS THE DRUG AND DEVICE INDUSTRIES**

- How Disclosure and Transparency are Reshaping Pharma and Device Marketing and Compliance
- The Physician Payments Sunshine Act: Prospects for Federal Disclosure Law - The Republican and Democratic Perspectives
- The Role of the OIG
- The Role of State Legislation
- The Role of State Attorneys General In Imposing Disclosure Obligations
- How Recent Settlements Have Changed Pharmaceutical Marketing and Compliance
- The Role of Disclosure in an Overall Regulatory Scheme
- A Dialogue on Whether Disclosure Will Quiet the Industry's Critics?

### Also:

- What to Expect From the New Congress and the New Administration
  - ▶ Key Congressional Initiatives
  - ▶ DTC: The Perennial Target
  - ▶ CME: Under Fire from all Directions

### **DAY II: HOW TO ESTABLISH EFFECTIVE DISCLOSURE PROTOCOLS AND AGGREGATE SPEND PROGRAMS**

- Lessons of the Deferred Prosecution Agreements in the Device Sector: How Has Disclosure Worked in the Device Sector
- Enforcement Panel: How to Avoid Costly Litigation — State and Federal Prosecutors Assess Disclosure as a Compliance Tool
- Case Studies in the Implementation of a Physician Payment Disclosure Initiative
- Analysis of Huron Consulting Aggregate Spend Survey Results: A Gap Assessment of Aggregate Spend Industry Practices
- Case Study: How to Build an Aggregate Spend Program at a Small or Mid-Size Pharmaceutical Company
- Case Study: Planning Aggregate Spend Activities for the Next Three Years
- State Regulatory Panel: Evolving State Laws and Regulations— What to Expect in the Year Ahead
- Evolving Practices in Aggregate Spend: What Does the Future Hold?
- Industry Disclosure Best Practice Roundtable

*Visit [www.disclosuresummit.com](http://www.disclosuresummit.com) for more information on this innovative conference format*

► *Cont. from page 1*

## **MedPAC approves broad disclosure recommendations; Senator Baucus includes disclosure in health reform agenda**

Baucus' proposal scrambles the politics surrounding disclosure for drug companies. Until now, Senators Charles Grassley (R-IA) and Herb Kohl (D-WI) have been driving this issue, largely through the introduction of the Physician Payments Sunshine Act. Baucus had not thrown his weight behind that effort. Now that he has incorporated it into what is, for all practical purposes, his legislation for health care reform proposal, the fate of disclosure may be tied to that issue.

It could also affect the debate over disclosure in another fashion. Baucus addresses industry-physicians disclosure alongside physician self-referrals and other transparency-related issues for physicians. That strikes closer to home for doctors and could result in some push back,

Baucus' proposal, which was not introduced as formal legislation, is premised, in part, on MedPAC's rationale for a disclosure requirement, namely that it may discourage inappropriate arrangements between physician and industry, allow the media to explore potential conflicts of interest, enable payors to examine physician practices that may be influenced by particular relationships, and highlight those physicians who have decided not to take part in inappropriate relationships.

"Unfortunately, data collection alone may not prevent inappropriate relationships," says the Baucus report. "However, once national, system-wide data is available, the extent of industry influence and the wasteful spending that it leads to can be better determined."

"With this information, stronger enforcement can be put into place," the report continues, "so that regardless of provider relationships, we can be sure physicians are recommending and performing medical care based on sound medical science rather than heavy-handed industry influence."

For these reasons, says the report, the Baucus plan would require disclosure of gifts and other transfers of value made by drug and device companies to physicians and other healthcare professionals. "Only with this information can potential bias be known," the report contends.

## **MEDPAC weighs in**

The MedPAC commissioners unanimously approved three specific disclosure recommendations on November 6 designed to discourage inappropriate relationships between industry and prescribers. The good news for drug and device companies is that MedPAC approved a stronger preemption requirement than the one included in the previous set of draft recommendations. The bad news is that it expands the scope of relationships that should be reported. In this regard, MedPAC's recommendation takes a much more expansive position than the Physician Payments Sunshine Act, introduced in the House and Senate last year.

Here is a rundown of MedPAC's specific recommendations:

**A broad set of relationships.** The first recommendation says that Congress should require all manufacturers and distributors of drugs, biologicals, medical devices, and medical supplies, and their subsidiaries, to report to the Secretary of HHS their financial relationships with the following:

- Physicians
- Physician groups, and other prescribers
- Pharmacies and pharmacists
- Health plans, pharmacy benefit managers, and their employees
- Hospitals and medical schools
- Organizations that sponsor continuing medical education
- Patient organizations
- Professional organizations

MedPAC analyst Ariel Winter noted that distributors were added to this recommendation. Physician groups, pharmacies and pharmacists, health plans, PBMs and their employees were also added, he points out.

---

***“Unfortunately, data collection alone may not prevent inappropriate relationships,” says the Baucus report.***

---

**\$100 reporting threshold.** MedPAC retained the \$100 reporting threshold included in the previous draft recommendation. Specifically, it recommends that manufacturers report payments if the total

annual value of payments to a recipient exceeds \$100 (adjusted annually for inflation). Once this threshold is reached, all payment transfers of value to a recipient, regardless of the amount should be disclosed, according to MedPAC.

MedPAC recommends that companies report the following:

- The value, type, and date of each payment;
- The name, specialty, Medicare billing number (if applicable), and address of each recipient; and
- The name of the drug or device (if the payment is related to the marketing, education, or research of a specific drug or device).

“A relatively low aggregate payment threshold would enable the federal government to collect data on most payments,” said Winter.

Notably, under MedPAC’s recommendations, companies would be allowed to exclude the reporting of discounts and rebates.

Companies would also be allowed to delay reporting of payments related to clinical trials until the trial is registered on the NIH website.

**Preemption.** MedPAC’s final recommendation with respect to preemption fell down on the side of industry. Specifically, it says that federal law should preempt state laws that collect data on the same type of payments and recipients, regardless of the state’s dollar threshold for reporting.

For example, if a federal law excluded reporting of discounts and rebates, a state law could require such reporting, says Winter. “A uniform, comprehensive federal law would probably discourage additional states from passing their own laws,” he added.

**Free drug samples.** Free drug samples were excluded from MedPAC’s first recommendation, which addressed public reporting. Instead, MedPAC voted to recommend that drug companies report these data to the Secretary of HHS.

According to Winter, better data on samples would enable researchers to conduct more detailed analyses of their impact on prescribing behavior and overall drug spending. “But in order to link data on samples to claims data, the government would need to obtain the names and Medicare billing numbers of all physicians in the practice, not just the practitioner or physician who signed for the samples,” he told the commissioners.

Even with this information, says Winter, it would still be difficult to examine the use of samples by individual physicians because it would be impossible to determine how many samples each physician used. However, he says, the information could be used to analyze the use of samples at the practice level and the geographic level. Collecting information on physician specialty would allow for analyses by specialty, he adds.

Based on these considerations, MedPAC voted to recommend that Congress require manufacturers and distributors of drugs to report the following information about drug samples to the Secretary of HHS:

- Each recipient’s name and business address;
- The names, specialties, and Medicare billing numbers of each physician (if the recipient is in a physician practice);
- The name, dosage, and number of units of each sample; and
- The date of distribution.

The initial recommendation indicated that the Secretary should make this information available to researchers through data use agreements. However, the reference to researchers was removed prior to the vote.

**Public website.** MedPAC recommends that Congress direct the Secretary to post the information submitted by manufacturers on a public website in a format that is searchable by manufacturer; recipient’s name, location, and specialty, if applicable; type of payment; related drug or device; and year.

MedPAC will include these recommendations in its March report to Congress. But, for all practical purposes, they are now on the table. ■

---

*“The good news for drug and device companies is that MedPAC approved a stronger preemption requirement than the one included in the previous set of draft recommendations.”*

---

# Pfizer's \$60 million Bextra/Celebrex settlement with state AGs continues trend toward state enforcement

**P**fizer's recent \$60 million settlement with thirty-three state Attorneys General to resolve allegations concerning the illegal marketing of Bextra and Celebrex marks the continuation of an important trend that places drug marketing regulation in the hands of state Attorneys General, according to industry experts. Former Department of Justice **John Bentivoglio** says the standards of conduct included in the Pfizer settlement, and several recent settlements that preceded it, are likely to become *de facto* standards for the industry as a whole.

Clearly, this is the aim of the state Attorneys General regarding the settlement announced October 22. "The comprehensive injunctive relief obtained in this case is outstanding and addresses all concerns identified over five years of investigation," said Oregon Attorney General Hardy Myers, who spearheaded the investigation (*see related story, p. 11*).

The Pfizer settlement appears to represent "an unprecedented incursion by the State AGs into FDA's domain," says former Pfizer attorney **Arnie Friede**. He says it appears to be the most comprehensive State AG settlement to date and incorporates elements of recent settlements with Merck and with Lilly. "In this respect, it again shows that the State AGs are the new cops on the beat and that they will remain on patrol for so long as they perceive FDA is not adequately enforcing the law," says Friede, now an attorney with McDermott Will & Emery in Washington, D.C.

Bentivoglio takes a similar view. For example, he says, while the FDA's draft reprint guidance made a big splash earlier this year because it outlined what companies potentially can and cannot do with respect to reprint practices, that is just one of the many issues addressed in the recent state AG settlements.

According to Bentivoglio, a number of other key marketing questions are addressed in the recent state settlements.

For example:

- When can companies answer an unsolicited request?
- How should companies disclose clinical trial results?

- How should medical information professionals interact with healthcare professionals with respect to grants and sales and marketing?

Bentivoglio says it is "highly likely" that the standards imposed by these settlements will be incorporated in some fashion in future state Attorneys General settlements. "These are not, in my view, just one-offs," he told attendees at the recent Ninth Annual Pharmaceutical Regulatory and Compliance Congress in Washington, D.C. Rather, they are early indicators of what are likely to become *de*

*facto* standards for pharma companies because they will almost certainly be the starting point for requirements in subsequent settlements.

According to Bentivoglio, the settlements include a wealth of information that legal, compliance, and medical affairs can use to assess their own practices. "There is just a treasure trove of stuff in these settlements," he says.

Bentivoglio says companies can make this assessment by posing the following questions:

- How do your practices measure up to these requirements?
- If there are substantial variations, or if your policies are silent, is there a best practice that can be identified?
- If there is a variation, have you examined why that is? Is there a good principled reason for doing so?

The settlements include a range of mandates related to DTC advertising, financial disclosure, CME

---

**According to King & Spalding's Bentivoglio, the settlements include a wealth of information that legal, compliance, and medical affairs can use to assess their own practices.**

---

funding, and detailing practices for multiple products, says Bentivoglio.

Here are some of the areas the significant requirements:

**DTC advertising.** The settlements impose a delay regarding when a company can engage in DTC advertising. According to Bentivoglio, the closest similar requirement is found in PhRMA's voluntary guidelines for DTC advertising.

Notably, he points out, this requirements will last eight years while some of the provisions included in the settlements last for nine years. "A lot of things are going to change in the next nine years," he says. "But these requirements, unless they are modified, will remain in place."

**Dissemination of study results.** Bentivoglio says one of the most interesting features of the recent settlements is the considerable detail they include regarding how companies should disclose clinical trial results. For example, they prohibit use of the concept of statistical significance to support a claim that has not been demonstrated to have clinical significance or validity. For many companies, he says, that may already be a standard practice in terms of promotional review. Nevertheless, he says, it demonstrates the level of detail included in the recent settlements with state AGs.

**Continuing medical education activities.** Interestingly, says Bentivoglio, at least one settlement says the company shall not provide funding for CME if it has knowledge that a potential speaker has been a promotional speaker in the past 12 months. This requirement, he says, is aimed at trying to separate speakers who do promotional talks for the company from speakers who may be thought leaders and are active in the CME community.

**Marketing practices and samples.** The settlements also include some noteworthy requirements regarding marketing practices and samples, says Bentivoglio. For example, it says the company shall not market two or more products in a manner that falsely or misleadingly conflates the various properties of the respective products.

Here too, he says, it is notable that the settlement gets down to the level of requirements requiring detailing of more than one product.

## State AGs resolve five-year investigation into Pfizer's marketing of Bextra and Celebrex

On October 22, 33 states and District of Columbia concluded a five-year investigation into Pfizer's allegedly deceptive promotion of the Cox-2 drugs Celebrex and Bextra by announcing a \$60 million settlement that includes injunctive terms that will apply to all Pfizer prescription drugs and biological products.

The 33-state investigation was initiated in 2003 to determine whether Pfizer and Pharmacia, subsequently purchased by Pfizer, misrepresented that their jointly sold Cox-2 drug Celebrex was safer and more effective than traditional non-steroidal anti-inflammatory drugs (NSAIDs) such as Ibuprofen (Advil) and Naproxen (Aleve). As the investigation proceeded, additional concerns were raised about Pfizer's second generation Cox-2 drug Bextra. Ultimately, the investigation concluded that Pfizer engaged in an aggressive, deceptive and unlawful campaign to promote Bextra "off label" for uses that had been expressly rejected by the FDA.

According to the Oregon Attorney General's office, cheap, generically available NSAIDs have been used for many years to treat pain and inflammation. However, NSAIDs have the potential to cause serious side effects such as bleeding and perforations in the gastrointestinal (GI) system. The Cox-2 drugs Celebrex, Vioxx and Bextra were designed to reduce pain and inflammation without the negative GI side effects of traditional NSAIDs.

Despite being significantly more expensive than traditional NSAIDs, the Oregon AG maintains, Cox-2 drugs have not been shown to be more effective in relieving pain than traditional NSAIDs and neither Celebrex nor Bextra have been proven to significantly reduce serious GI adverse events compared to traditional NSAIDs.

Moreover, the Oregon AG cites "significant concerns" that all three Cox-2 drugs increase the risk of serious cardiovascular adverse events such

► *Cont. next page*

The settlements also address samples, Bentivoglio points out. “I think samples [represent] a risk area that not all companies have gotten their arms around from an off-label promotion standpoint,” he cautions.

**Medical education grants.** While the OIG’s compliance guidance calls for separation of sales and marketing related to educational grants, it was not specific about the agency’s expectations, says Bentivoglio. The Pfizer settlement, however, clearly indicates that sales and marketing can have input but may not be involved in the final approval decision.

### Take-aways

The take-away, says Bentivoglio, is not that any or all of the settlement mandates represent best practices or that all companies should adopt them. That said, compliance officers are often “starved for good examples of what safeguards can be put into place,” he says.

Companies often seek to learn what other companies are doing, he adds. “In the absence of guidance, people want to know what everybody else is doing,” he explains. Moreover, pointing to what other companies are doing can sometimes help get management to embrace a newer, stricter compliance standard, he adds.

Likewise, companies often seek to learn whether they will get credit with the OIG or a state agency for adopting a certain practice. The short answer, he says, is that compliance practices and policies are often incorporated in an eventual settlement. “By adopting some standards in advance,” he says, “you can avoid some of the disruption that occurs when a CIA comes down and you have to live with a whole new world of requirements.” ■

■ **John Bentivoglio**, Partner, King & Spalding, Washington, DC, [jbentivoglio@kslaw.com](mailto:jbentivoglio@kslaw.com)

■ **Arnie Friede**, Partner, McDermott Will & Emery, Washington, DC, [Afriede@mwe.com](mailto:Afriede@mwe.com)

---

**“Samples represent a risk area that not all companies have gotten their arms around from an off-label promotion standpoint,” warns Bentivoglio.**

---

as heart attacks and strokes. Bextra also carries a risk of a serious and sometimes lethal skin condition. Due to safety concerns, in 2004 and 2005 respectively, Vioxx and Bextra were withdrawn from the market place and in 2005 FDA required a “black box” safety warning. The toughest FDA warning label, the warning with a black border denotes the serious risk of adverse effects from the drug.

### “A prolonged multi-prong off-label campaign”

In its complaint, the state alleged that despite the significant safety concerns that led FDA to reject a request to market high dose Bextra for acute and surgical pain, Pfizer conducted a systematic, multi-pronged “off-label” promotional campaign for these very indications by:

- Distributing hundreds of thousands of copies of a positive study from the denied application, as well as other positive studies relating to use of high dose Bextra, without distributing or disclosing the negative study that was the basis for FDA’s rejection, or disclosing that FDA had expressly rejected approving Bextra for acute and surgical pain.
- Co-opting influential doctors with paid consultancies and lavish weekends at high end resorts.
- Distributing hundreds of thousands of samples of high dose Bextra to specialties whose only possible use for high dose Bextra was off-label.
- Providing prizes and otherwise encouraging sales representatives to promote Bextra off label.
- Using supposedly non-promotional Continuing Medical Education to promote Bextra off-label.
- Using imagery and language in advertisements that implicitly promoted Bextra off-label.
- Misrepresenting Bextra’s safety.

▶ *Cont. next page*

The complaint also alleged these efforts continued even after Pfizer completed a study that confirmed FDA's reasoning for rejecting acute and surgical pain indications for Bextra. This study ultimately contributed to FDA's decision to withdraw Bextra from the marketplace, even at the low doses that had been previously approved.

### **Injunctive terms**

The judgment contains injunctive terms addressing all concerns raised during the investigation regarding both Celebrex and Bextra and applying to all Pfizer prescription drugs and biological products such as vaccines. Included in the judgment are terms designed to prevent the following:

- Deceptive use of scientific data when marketing to doctors.
- "Ghost writing" of articles and studies.
- Failing to adequately disclose conflicts of interest for Pfizer promotional speakers when these consultants also speak at supposedly independent Continuing Medical Education.
- Distributing samples with the intent to encourage off-label prescribing.
- Distributing information about an off-label use when FDA has rejected the off-label use, unless Pfizer clearly discloses that FDA rejected the use and FDA's reason for rejecting.
- Distributing off-label studies and articles in a promotional manner.
- Providing incentives to sales staff to increase off-label prescribing.
- Promoting drugs off label for inclusion in hospital standing orders and protocols.
- Using "mentorships" to pay physicians for time spent with Pfizer sales reps.
- Using grants to encourage use of Pfizer products.

- Using sales personnel to make grant decisions that are supposedly unrelated to promotion and marketing.
- Using patient testimonials to misrepresent a drug's efficacy.

### **DTC advertising**

In addition, the judgment requires Pfizer to submit all direct-to-consumer (DTC) television drug advertisements to the FDA for approval and comply with any FDA comment before running the advertisement. If FDA does not respond within 45 days, Pfizer may run the advertisement but must still comply with any subsequent FDA comments about the advertisement and must notify the settling states and the District of Columbia that it is running the advertisement without FDA authorization. For any new drug for pain relief, Pfizer must delay DTC advertising for up to 18 months if the FDA recommends such a delay.

Finally, the judgment generally prohibits Pfizer from deceptive and misleading advertising and promotion of any Pfizer drug, requires Pfizer to register all clinical trials, post clinical trial results and ensure that subjects in Pfizer-sponsored clinical trials give adequate informed consent. ■

## **What's Ahead in *Rx Compliance Report...***

- ▶ Assistant U.S. Attorneys Michael Loucks, Ioana Petrou, and others, examine recent trends in pharma fraud cases
- ▶ Delaware Deputy Attorney General Dan Miller explains the new methodology state prosecutors are using to prosecute off-label cases
- ▶ An update on the debate over FDA's draft guidance for medical reprints
- ▶ Pfizer's Cathryn Clary examines the industry's efforts aimed at regaining public trust

## *In the states*

# DC finalizes regulations imposing novel licensing requirements on pharma

**T**he District of Columbia Department of Health recently finalized proposed regulations addressing the licensing requirements for the practice of pharmaceutical detailing mandated by the District's recently enacted SafeRx Amendment Act of 2008. The Act is the first attempt by a jurisdiction to require pharmaceutical sales representatives and other personnel to obtain a license prior to engaging in detailing and other promotional activities in the jurisdiction, notes **Eileen Kahaner**, a partner with Sidley Austin in Washington, D.C.

The final rule, which took effect October 1, 2008, requires individuals subject to the Act to obtain licensure by April 1, 2009. "It makes no changes to the proposed rule published by the District in June 2008," says Kahaner.

The Act and final rule require pharmaceutical sales, marketing, and/or other company personnel engaged in the "practice of pharmaceutical detailing" to obtain a license prior to engaging in detailing activities in the District, says Kahaner. The final rule defines the "practice of pharmaceutical detailing" with the exact same language as the Act, she adds.

Based on the definitions included in the statute and the final rule, the Act would not appear to reach representatives of medical device manufacturers, says Kahaner.

## **Licensing requirements**

To obtain a license, individuals must meet certain educational requirements or the requirements for obtaining a waiver, as specified in the final rule, says Kahaner. To maintain a license, licensees must complete 15 hours of approved continuing education every two years. Under the final rule, the District Board of Pharmacy is authorized to issue a list of approved continuing education requirements. The Board is also authorized to conduct random audits of continuing education credits at the completion of each renewal period.

Licensees must also abide by a Code of Ethics set forth in the final rule, Kahaner points out. A person who practices pharmaceutical detailing in the

District without a license may be fined up to \$10,000 and may be subject to additional fines and/or penalties under other applicable provisions of the SafeRx Amendment Act and the District's Health Occupations Revisions Act.

## **Wisconsin Medical Society Board passes new physician gift policy**

The Wisconsin Medical Society's Board of Directors last month approved a tough ban on gifts to physician. The policy states: "Physicians shall accept no gifts from any provider of products that they prescribe to their patients such as personal items, office supplies, food, travel and time costs, or payment for participation in on-line CME. A complete ban eases the burdens of compliance, biased decision making, and patient distrust."

"This policy is strong and clear," said Society President Steven Bergin, MD. "It leaves no doubt that the Society's physicians want to prevent even the impression that a gift—no matter how small—could get in the way of a physician's decision-making." The Wisconsin Medical Society is the largest association of medical doctors in the state with more than 12,000 members.

## **University of Minnesota considers sweeping conflict-of-interest policy**

"The University of Minnesota Medical School is considering a new conflict-of-interest policy so strict that doctors wouldn't even be able to accept Post-it Notes bearing a drug company's logo," the Minneapolis *Star-Tribune* reports.

According to the *Tribune*, if adopted, the policy would profoundly alter the relationship between industry and the state's largest medical school. "All personal gifts from industry would be banned. Free drug samples would be limited. Industry support for doctors' continuing medical education would be phased out. Doctors' consulting relationships would be disclosed to both patients and the public. Those financial ties would be monitored far more closely." ■

**NATIONAL CME  
AUDIOCONFERENCE:**  
*Advanced Implementation Strategies  
for a Compliant Grant Process*

**Tuesday, December 9, 2008**  
**1:00 pm - 2:30 pm (EST)**  
**[www.cmeaudioconferences.com](http://www.cmeaudioconferences.com)**

**AUDIOCONFERENCE FACULTY:**

**Howard L. Dorfman, Esq.**  
Counsel, Life Sciences Group, Ropes & Gray,  
Former Vice President Assistant General Counsel,  
Bayer Pharmaceuticals, New York, NY

**A. Monica Jonhart**  
Director, Auditing, Bristol-Myers Squibb,  
Plainsboro, NJ

**Tracy Mastro**  
Director, Huron Consulting Group, New York, NY

**Mike Saxton, MEd, FACME**  
Sr. Director, Team Leader, Medical Education  
Group, US External Medical Affairs, Pfizer, Inc.,  
New York, NY

**Mark DeWyngaert, PhD**  
Managing Director, Huron Consulting Group, New  
York, NY (Moderator)

In this 90 minute audio conference, speakers will review the following points and discuss a variety of steps companies can take to develop and implement a compliant grant process.

**Key Risk Areas:**

- Are these payments potential inducements for product selection?
- Could these payments be construed as a “kickback” or part of a “quid pro quo” arrangement?
- Did these payments potentially initiate use of the product inappropriately?
- Does your company have an auditable process?



**Matthew Hay**, Editor & Publisher  
**Jonathan Wilkenfeld**, Senior Writer

1602 Belle View Blvd., No. 840  
Alexandria, VA 22307  
Phone: 703/501-2019  
RxCompliance@aol.com  
[www.rxcompliancereport.com](http://www.rxcompliancereport.com)

**EDITORIAL ADVISORY BOARD**

**Ted Acosta**, Director of Pharma Compliance, Ernst & Young, New York, NY, Former Senior Attorney, HHS Office of Inspector General

**Kenneth Berkowitz**, President, KPB Associates, Pine Brook, NJ, Co-principal, PharMed Staffing

**Marc Farley**, Executive Director, Worldwide Compliance, Medical Devices & Diagnostics, Johnson & Johnson, New Brunswick, NJ, Former Assistant U.S. Attorney, District of New Jersey

**Laurence Freedman**, Partner, Patton Boggs, Washington, DC, Former Assistant Director, Department of Justice's Fraud Section, Commercial Litigation Branch, Civil Division

**John Kamp**, Executive Director, Coalition for Healthcare Communication, New York, NY, Former Director, Office of Congressional & Public Affairs, Federal Communications Commission

**Daniel Kracov**, Chair, Pharmaceutical and Medical Device Practice, Arnold & Porter, Washington, DC,

**Marc Raspanti**, Partner, Pietragallo Gordon Alfano Bosick & Raspanti Philadelphia, PA

**Bill Sarraile**, Partner, Sidley Austin, Washington, DC

**Paul Silver**, Managing Director, Huron Consulting Group, Atlanta, GA

*Rx Compliance Report* is published 24 times a year. Subscription price is \$597 per year. Discount options for multiple subscriptions are available.

Call 703/501-2019 or visit: [www.rxcompliancereport.com/RxComp\\_orderform.pdf](http://www.rxcompliancereport.com/RxComp_orderform.pdf).

**Please note: Photocopying is prohibited by Federal law (including internal use, faxes and other electronic transfers) without written permission.**