

# DRUG & DEVICE Disclosure Update

A SUPPLEMENT TO RX COMPLIANCE REPORT

## OIG Senior Attorney to drug and device companies: “Think about transparency”

The OIG’s **Mary Riordan** recently addressed the issue of effective, proactive compliance for drug and device companies. By most estimates, her strongest message was directed at the issue of transparency. “I would encourage all companies to support and embrace the idea of transparency,” Riordan told attendees at the Pharmaceutical Compliance Congress in Washington, D.C. Riordan predicts that legislation along these lines is “inevitable,” and she said, “drug and device manufacturers have to start taking steps to be able to collect, aggregate, and report payments they are making to healthcare providers.”

“Everybody has to start thinking about it now,” she emphasized. Riordan says this can occur through a corporate integrity agreement or through other means. But one way or another, “transparency is coming,” she says. “You should make efforts now to start talking to your vendors and your healthcare practitioners and internally about how you can collect this information and be able to report it.” ▶ *Cont. on page 2*

## Will Senator Grassley make the Sunshine Act S.1?

Senator Chuck Grassley (R-IA) has long made it clear that he plans to pursue Congressional action on his legislation that would require drug and device companies to publicly report money they give to doctors. To nobody’s surprise, Grassley announced last week that he will reintroduce this legislation, the Physician Payments Sunshine Act, in the new Congress that begins in January. Now, rumor has it that Grassley would like to make the Sunshine Act S. 1, the first bill introduced in the Senate next year.

### IN THIS ISSUE

- ▶ Senior OIG attorney to drug and device companies: Think about transparency (p. 1)
- ▶ Massachusetts proposes broad disclosure requirements (p. 1)
- ▶ Grassley applauds Emory’s steps on conflict of interest policies (p. 2)
- ▶ CBO weighs in on the Physician Payment Sunshine Act (p. 7)
- ▶ Senior Pfizer executive explains Pfizer’s disclosure and transparency initiatives in the face of growing public scrutiny (p. 8)

### Early-bird discount to Disclosure & Transparency Summit expires December 31, 2008

Senator Grassley will be among the keynote speakers at the First Annual Summit on Disclosure & Transparency March 5–6, 2009, in Washington, D.C. Early-bird registration expires December 31, 2008. See p. 14 for details...

## Massachusetts proposes broad disclosure requirements

The Massachusetts Public Health Council released proposed guidelines earlier this month that would mandate broad public disclosure of fees, payments, and other compensation that drug and device companies give healthcare providers. Massachusetts Department of Public Health Commissioner, John Auerbach, says the proposed regulations attempt to promote “broad transparency of financial dealings between the industry and healthcare providers” without compromising the “legitimate research” taking place throughout the state. ▶ *Cont. on page 4*

► *Cont. from page 1*

## **OIG Senior Attorney to drug and device companies: “Think about transparency”**

### **Use of vendors**

One looming issue, says Riordan, is how to deal with vendors, including whether the appropriate controls are in place. To the extent that companies decide to outsource logistical and other functions, they must think about what information vendors are collecting and reporting and whether they can report information to the manufacturers in an electronic format that can be easily aggregated, she says.

### **Focus on healthcare providers**

Riordan says she includes healthcare providers in this equation “because this whole discussion about transparency is going to bring about a change in the relationship that manufacturers have with physicians.”

“Physicians will certainly be reluctant at first to see their names on websites with information about how much money they have received,” says Riordan. This will lead to some uncomfortable discussions between doctors and their patients, she predicts. Nevertheless, Riordan says the trend toward transparency is “inevitable” and that ultimately, it will be “a good thing.” Says Riordan, “It may get us back on a path where patients trust their doctors and are not assuming they are in the pocket of drug or device manufacturers.”

A growing list of pharma companies are already affirmatively committed to making payment information publicly available, she points out. “I would encourage all of you to think about ways that you might be able to begin to do this, if not completely, at least incrementally,” she advised.

### **Research disclosure**

Riordan says it is also important for companies to think about appropriate disclosure of research results. Clinical trials and research will present a “significant challenge” in the future, she says. There are potential fraud issues associated with selective publication of research results or the massaging of clinical trial data, she warns. This undermines the public perception of the industry as well as public health, she says.

“It is important to examine how it is that your companies are disclosing clinical trial information,” says Riordan. “Are you making it completely available?”

To the extent that companies are involved with research, they need to disclose their sponsorship of, and involvement in, those activities, says Riordan. Ghost

writing and funding for conferences are two specific issues under the spotlight, she says. While companies will probably decide to continue funding conferences, they must disclose that funding and make sure they are complying with all the appropriate safeguards in connection with these events, she says.

### **Funding for supplemental and special publications**

Lastly, Riordan highlights the issue of funding for supplemental and other special publications. “Disclosure is the key here,” she said. “Be clear and honest about what is going on behind the scenes.” ■

---

*“I would encourage all companies to support and embrace the idea of transparency,” said the OIG’s Mary Riordan.*

---

## **Grassley applauds Emory’s steps on COI resolution**

Senator Charles Grassley (R-IA) last week applauded Emory University’s decision to improve its disclosure and transparency practices following an internal investigation into allegations of conflicts of interest involving a department chair at its School of Medicine. In 2007, Senator Grassley started looking at the large sums of unreported money going to research doctors from the pharmaceutical and medical device industries. As a result of

his findings in the case at Emory and those at other universities and research institutions, Grassley called on the National Institutes of Health (NIH) to fully exercise its authority to require grantees to manage conflicts of interest.

Last week, Emory announced that Dr. Charles Nemeroff, the long-time chair of the Department of Psychiatry and Behavioral Sciences at the Emory University School of Medicine has agreed to step

down from the departmental leadership post he held for 17 years and to follow new restrictions on his outside activities. In addition, Emory will not submit any NIH or other sponsored grant or contract requests in which he is listed as an investigator or has any other role for a period of at least two years. Nemeroff will remain in the Department as a professor and will focus on clinical care, teaching and other academic pursuits.

The University and Nemeroff have additionally agreed that he will seek review and approval by the dean's office of any and all outside compensated engagements before he accepts them, and will report any and all outside compensation. In addition, he will be limited to accepting payment for ACCME-accredited speaking engagements sponsored by academic institutions or professional societies.

### **Investigation reveals \$800,000 in unreported income**

Grassley alleged earlier this year that Nemeroff had been paid substantial sums over seven years in outside income by pharmaceutical companies without reporting it to Emory as required by NIH and Emory University conflict of interest regulations and policies. Some of these payments, he charged, were provided primarily to deliver talks promoting the sales of particular drugs.

According to the University, the internal investigation conducted by Emory focused on payments from GlaxoSmithKline (GSK), because it was the largest single payer to Nemeroff. GSK cooperated with Emory in making a complete set of records available, said the University. The investigation revealed that Nemeroff received more than \$800,000 in income from GSK for presentations that he did not report to Emory. This represented payments for more than 250 speaking engagements in the period between January 2000 and January 2006, the University reported.

### **No evidence of bias**

The University said its investigation found no evidence that Nemeroff's outside speaking activities affected clinical care for patients or persons enrolled in clinical trials, and no evidence that his activities biased scientific research in which he was engaged. For his part, Nemeroff has contended that his lectures were not product-specific but were limited to general medical topics such as depression and bipolar disorder. A review to date, based on his

speaker slides and on interviews with attendees at presentations, supports that contention, the University reports.

The University also noted that Nemeroff is an internationally recognized leader in psychiatric research, education and clinical practice who has made fundamental contributions to the understanding and treatment of depression and other mood and anxiety disorders over many years.

### **Emory endorses public disclosure**

Fred Sanfilippo, Emory's Executive Vice President for Health Affairs, noted that universities traditionally depend on the integrity and voluntary cooperation of their faculty to meet the public trust. "To strengthen this approach, we strongly support the public reporting by pharmaceutical and medical device companies of all payments to academic physicians and researchers," he said.

"With access to a common set of data, medical schools, lawmakers, and most importantly the general public will have the transparency needed to ensure objectivity and accountability in biomedical research, clinical practice, and educational activities."

In October, Emory created a new University-wide central office to oversee administration and enforcement of conflict of interest policies for sponsored research. In November, President James Wagner appointed an advisory commission to review Emory's management of potential conflicts of interest by faculty and staff members engaged in research and other professional activities.

"Emory's swift and sure-footed response sets an example for other research institutions to follow and for the National Institutes of Health to hold up as the kind of standard it expects from all those receiving federal research dollars," said Grassley. "Accurate disclosure and transparency are fundamental to the integrity of medical research." ■

---

***The investigation revealed that Nemeroff received more than \$800,000 in income from GSK for presentations that he did not report to Emory.***

---

► *Cont. from page 1*

## **Massachusetts proposed rules include broad disclosure requirements**

Auerbach points out that while six states and the District of Columbia have passed similar measures, none of them go as far as what is required under the proposed rules announced December 10. Moreover, he notes, Massachusetts will also be the first state to require disclosure by medical device companies.

Under the proposed regulations, Massachusetts would become the only state to require adoption and compliance with a state-authored Marketing Code of Conduct, which outlines permitted activities under the law. The proposed rules also require manufacturers subject to the new law to report certain information about any fee, payment, subsidy or other economic benefit of \$50 or more provided to certain healthcare providers and organizations (*see box, p. 5*).

### **Marketing Code of Conduct**

According to **Mark Langdon**, a partner with Sidley Austin in Washington, D.C., the Marketing Code of Conduct and disclosure requirements will be familiar to drug companies because the proposed standards are similar to those that have already been implemented in a handful of other states. “Medical device manufacturers, however, will face new code of conduct and reporting requirements not previously applied to the medical device industry if the proposed rules are finalized,” says Langdon.

The Council maintains that it has adopted regulations that are “at least as restrictive” as the AdvaMed Code and the PhRMA Code, notes Langdon. He also points to the Council’s stated attempt to place drug and device companies “on equal footing” even though the two industries differ in a number of ways.

According to Langdon, some of the differences between the two industry codes were eliminated with the recent publication of an updated AdvaMed Code. However, he says, there are still instances in the proposed rules where some of the updated PhRMA Code provisions (effective January 1, 2009) are more restrictive than the newly-published AdvaMed Code restrictions (effective July 1, 2009). “In some of those cases, the more restrictive PhRMA Code provisions would be applicable to

both pharmaceutical and medical device manufacturers, a groundbreaking development for many medical device manufacturers,” he says.

For example, says Langdon, the proposed rules prohibit the provision of, or payment for, meals for healthcare practitioners when the meals are offered, consumed, or provided without an informational session or outside of the healthcare practitioner’s office or hospital setting. “The updated PhRMA Code is generally consistent with this proposed standard,” says Langdon. However, the updated AdvaMed Code continues to permit the provision of occasional meals and refreshments by medical device sales representatives in connection with a sales or promotional discussion, regardless of the location of the discussion as long as the site is conducive to the exchange of information, he adds.

Similarly, says Langdon, like the updated PhRMA Code, the proposed rules prohibit the provision of, or payment for, meals for healthcare practitioners when

the meals are offered directly at continuing medical education (CME) events, third-party scientific or educational conferences, or professional meetings. In contrast, the updated AdvaMed Code permits medical device manufacturers to provide funding to a CME sponsor to support the provision of meals and refreshments to conference attendees if certain requirements are met.

Langdon points out that the proposed rules also prohibit the provision of, or payment for, meals for healthcare practitioners in several other circumstances, including when the meals are either provided in connection with an entertainment or recreational event or provided to a healthcare practitioner’s spouse or other guest. “Both the updated PhRMA and AdvaMed Codes are generally consistent with these proposed standards,” he says.

---

***Under the proposed regulations, Massachusetts would become the only state to require adoption and compliance with a state-authored marketing code of conduct.***

---

## A wide-ranging regulation

According to **Eileen Kahaner**, also a partner in Sidley Austin's Washington, D.C. office, the proposed Massachusetts Code of Conduct standards also reach many other common marketing activities. For example, "tangible items" (including any "complimentary" items such as pens, coffee mugs, gift cards, etc.) would be prohibited unless the items are provided as compensation for *bona fide* services. "This is similar to the restrictions on promotional items such as 'reminder' or logo items set forth in both the updated PhRMA and AdvaMed Codes," she says.

The proposed rules also prohibit the sponsorship of CME that does not meet the Accreditation Council for Continuing Medical Education

---

**The broad disclosure requirements proposed in Massachusetts are likely to be a sign of things to come for drug and device companies, says Sidley Austin's Bill Sarraille.**

---

(ACCME) Standards for Commercial Support, says Kahaner. "The proposed standard is more restrictive than the updated AdvaMed Code," she explains, "which permits medical device manufacturers to provide financial support to nonaccredited CME programs sponsored by national, regional, or specialty associations."

Also prohibited, she says, is the provision of financial

support for the travel or related expenses of non-faculty healthcare practitioners attending any CME event, third-party scientific or educational conference, or professional meetings, whether it is furnished directly to the individuals participating in the event or indirectly to the event's sponsor, except in cases as determined by the Department.

## Key exceptions

According to Langdon, the proposed rule includes certain exceptions to the Code of Conduct.

These include the following:

- The proposed rules expressly permit the provision, distribution, dissemination or receipt

## Massachusetts introduces novel reporting requirements

According to **Bill Sarraille**, a partner with Sidley Austin in Washington, D.C., the broad disclosure requirements proposed by the Massachusetts Public Health Council earlier this month are likely to be a sign of things to come for drug and device companies.

Under the Massachusetts statute, manufacturers must report the value, nature, purpose, and recipient of any fee, payment, subsidy or other economic benefit of \$50 or more that they provide, directly or through their agents, to any "covered recipient."

The term "covered recipient," he points out, is broadly defined in the proposed rule as persons, businesses, or other organizations authorized to prescribe, dispense, or purchase prescription drugs or medical devices in the state. Examples include physicians, hospitals, nursing homes, pharmacists, health benefit plan administrators, and wholesalers licensed to sell or distribute prescription drugs or medical devices to a healthcare practitioner.

Sarraille also points out that a presentation by the Department of Public Health's Deputy General Counsel makes it clear the agency intends to interpret the disclosure requirement broadly. Unlike other states that have implemented similar rules, he says, that will include requiring manufacturers to report drug samples and demonstration or evaluation devices provided to covered recipients.

According to Sarraille, the Department has expressly provided for one exception from the disclosure requirement for reasonable compensation paid to a healthcare practitioner for the substantial professional or consulting services performed in connection with a genuine research project or clinical trial.

Under the proposed rules, the disclosures must be made by July 1 of each year, with the first such disclosure due on July 1, 2010 covering the period between July 1, 2009 and December 31, 2009. A fee of \$2,000 is due on July 1, 2009 and with every annual disclosure report.

■ **Bill Sarraille**, Sidley Austin, Washington, DC, [wsarraille@sidley.com](mailto:wsarraille@sidley.com)

of peer-reviewed academic, scientific or clinical information and the purchase of advertising in peer-reviewed academic, scientific or clinical journals.

- Covered manufacturers are also permitted to provide prescription drugs and medical device demonstration and evaluation units to healthcare practitioners solely and exclusively for use by the healthcare practitioner's patients.
- The proposed rules also permit covered manufacturers to compensate healthcare practitioners for *bona fide* services, which would include the provision of substantial professional or consulting services in connection with a genuine research project or a clinical trial.
- The proposed rules state that payment can be made for reasonable expenses necessary for technical training on the use of a medical device if that expense is part of the vendor's purchase contract for the device.

### Limitations for pharma

Kahaner says the proposed rules also contain certain limitations that apply only to pharmaceutical manufacturers, all of which are consistent with the revised PhRMA Code.

For example:

**Continuing medical education.** The proposed rules would require pharma companies to separate CME grant-making functions from sales and marketing departments, says Kahaner. Moreover, pharma companies may not provide any advice or guidance regarding the content or faculty for any of its funded CME programs, consistent with the recommendations of the updated PhRMA Code, she adds.

**Confidentiality provisions.** According to Kahaner, pharma companies that use "non-patient identified prescriber data" are required to maintain the confidential nature of the data; develop policies regarding the data's use; educate employees and agents about the policies; maintain an internal contact person to handle inquiries regarding the use of the data; identify appropriate disciplinary actions for misuse of the data; and comply with "opt-out" requests that would prevent the use of the requesting

prescriber's data by the company's sales and marketing personnel.

**Disclosure.** The proposed rules stipulate that pharma companies must require any Massachusetts healthcare practitioner who sits on formulary or clinical guideline committee(s) and serves as a speaker or "commercial consultant" for the manufacturer, to disclose to the relevant committee(s) the nature and existence of his or her relationship with the manufacturer, says Kahaner.

This disclosure requirement extends for two years beyond the termination of any speaker or consultant arrangement, says Kahaner, adding that it is unclear why the Department limited certain provisions in the proposed rules to pharma companies.

### Similarities to the Nevada Code

The Massachusetts proposed rules include other compliance program-type obligations that will be familiar to manufacturers that are subject to the Nevada Marketing Code of Conduct Law, says Langdon. For example, like the Nevada Code, the proposed rules

specifically require manufacturers to provide regular code of conduct training to appropriate personnel.

The Massachusetts proposed rules include sales and marketing personnel among the "appropriate employees" who must receive the mandated training, notes Langdon. Moreover, the training program must ensure that all company representatives who call on Massachusetts-licensed healthcare practitioners have "sufficient knowledge" of the Marketing Code of Conduct as well as "general science" (an undefined term under the proposed rules), and product-specific information.

The proposed rules also require manufacturers to regularly assess employees to ensure compliance with the Marketing Code of Conduct and other relevant company policies, he adds.

---

*The proposed rules require manufacturers to regularly assess employees to ensure compliance with the Marketing Code of Conduct and other relevant company policies.*

---

Also similar to the Nevada Marketing Code of Conduct Law, says Langdon, the Massachusetts proposed rules specifically require manufacturers to:

- Conduct annual audits to assess compliance with the Marketing Code of Conduct;
- Adopt policies and procedures that describe how the company will investigate noncompliance reports and what corrective actions the company will take in response to noncompliance; and
- Adopt policies and procedures that require the company to report instances of noncompliance to “appropriate state authorities.”

Finally, he says, the Massachusetts proposed rules require Covered Manufacturers to identify a compliance officer responsible for “operating, monitoring, and enforcing” the Marketing Code of Conduct.

### Annual compliance reporting

Consistent with the Massachusetts statute, says Kahaner, the proposed rules require manufacturers to annually file the following information by July 1:

- A description of the company’s code of conduct training program;
- A description of the investigation and noncompliance reporting policies and procedures;
- The compliance officer’s name, title, address, telephone number, and e-mail address; and
- A certification that the company has conducted its annual audit and is in compliance with the Marketing Code of Conduct.

Under the proposed rules, the first compliance certification is due by July 1, 2010.

### Stiff penalties proposed

The state’s new compliance law is applicable to medical device and pharmaceutical manufacturers that participate in a Massachusetts healthcare program, and employ a person to sell or market a drug or device in Massachusetts, says Langdon.

Under the proposed rules, manufacturers who violate the requirements may be fined up to \$5,000

by the Council for each transaction, occurrence, or event that violates the new requirements, he says. The Massachusetts statute further provides that the law may be enforced by the Massachusetts Attorney General or a district attorney with jurisdiction over the violation, he adds.

Implementation of the Marketing Code of Conduct and the first annual disclosure report are proposed to be due by July 1, 2009 and July 1, 2010, respectively.

Two public hearings will be held to discuss the proposed rules, one in Boston on January 9 and one in Worcester on January 12. ■

■ **Eileen Kahaner**, Sidley Austin, Washington, DC, ekahaner@sidley.com

■ **Mark Langdon**, Sidley Austin, Washington, DC, mlangdon@sidley.com

## CBO gives the Sunshine Act an ambiguous “thumbs up”

According to the Congressional Budget Office (CBO), the reporting system the Physician Payment Sunshine Act would create, and the data that would be collected as a result, could become a building block for further regulations that might reduce future costs below the level that they otherwise would attain.

CBO’s findings, however, were ambiguous, at best. The agency concluded earlier this month that it cannot estimate how disclosure of payments to physicians by manufacturers might affect spending for Medicare. Over time, however, it believes disclosure has the potential to reduce spending.

According to CBO, the arguments to support this option include the following:

- Medicare could use the information it would provide to better understand and evaluate relationships between physicians and device and drug manufacturers.
- The Centers for Medicare and Medicaid Services could use the information, in combination with data from claims, to improve its understanding of physicians’ practice patterns and trends in the utilization of drugs and devices.

# Senior Pfizer executive explains Pfizer's disclosure and transparency initiatives in the face of growing public scrutiny

*From clinical trials to post-market surveillance, the new watchword is transparency, says Cathryn Clary*

## **Medical schools, journals fight industry influence**

*"Just about every segment of the medical community is piling on the pharmaceutical industry these days, accusing drug makers of deceiving the public, manipulating doctors and putting profits before patients."*

September 11, 2008, Associated Press

## **Medical device payments to doctors draw scrutiny**

*"Patients may notice the notepads and pens bearing drug company logos in their doctor's office. They may have read accounts in recent years of drug companies paying doctors to try to influence what they prescribe. Few are aware of the deeper financial relationship their doctor may have with medical device companies and how that may influence their care."*

September 8, 2008, *Star Tribune*

**I**t is against this backdrop that **Cathryn Clary**, vice president of external medical affairs at Pfizer, recently outlined Pfizer's response to the wave of public criticism related to alleged conflicts of interest throughout the pharmaceutical industry.

Pfizer, the world's largest drug company, has often been in the forefront of efforts to improve transparency and restore public confidence in the face of these mounting criticisms. However, Clary warns that even perceived conflicts of interest can become reality in the eyes of legislatures, regulators and the public, regardless of their basis.

"It seems almost daily we read about the next scandal of conflict of interest," says Clary, who manages Pfizer's strategic partnerships with external medical customers such as academic medical centers, medical associations, and public health organizations.

According to Clary, several trends have become abundantly clear. First, she says, concern about conflicts of interest between the commercial aims of

the pharmaceutical industry and providers of clinical care are more in the public eye than ever before. A simple search reveals "an astronomic increase" in articles about conflict of interest, she points out.

Second, says Clary, the industry is meeting these concerns head-on. "The industry is undergoing massive transformation," she says. At Pfizer, these disclosure initiatives range from the clinical trial stage through post-marketing commitments.

Notably, however, the industry's efforts have failed to dissuade its critics and the public at large, says Clary. To the contrary, legislators, the media, and the public remain deeply distrustful about the industry's motives and its integrity. "The trust level in our industry is at an all time low," she says.

## **A shifting landscape**

Clary, who joined Pfizer in 1996 to work on the SSRI anti-depressant, Zoloft, recalls the accolades the industry used to receive from the mainstream media. For example, she cites the positive response of the *New York Times*, *The Washington Post*, and other major media outlets regarding a trial she managed, which led to a new indication for the treatment of social phobia, social anxiety disorder, and anxiety disorder. "They asked no hardball questions about the data we discussed," she says, "and the articles they ran were fantastic."

That changed in 2003, she says, when concerns were raised about adolescent suicide potentially associated with SSRIs. The allegations were that

---

**Pfizer's Cathryn Clary warns that even perceived conflicts of interest can become reality in the eyes of legislatures, regulators and the public, regardless of their basis in fact.**

---

some companies had not reported data in a timely fashion to regulatory authorities and had failed to publish certain data in medical journals.

At that point, says Clary, the relationship with the press shifted dramatically. In fact, the same reporters who had been “almost fawningly positive” about the company’s information were suddenly “outright suspicious,” she says. “They looked for the negative.”

According to Clary, the shift in attitude among reporters was so marked that both positions may have demonstrated some bias. But the fundamental point to understand, she says, is that pharma is still living in the “very negative climate” that ensued.

### **Potential conflicts of interest are ubiquitous**

Conflicts of interest are ubiquitous in clinical care, says Clary. For example, when a surgeon diagnoses a patient with appendicitis and stands to make a fee for performing that operation, a conflict of interest is present. “In a market-driven healthcare system, we have all learned to accept and live with these conflicts because the physician’s fiduciary duty to the patient is assumed to be paramount,” she says.

The question facing the industry, she says, is whether there is an irreconcilable conflict between a drug company’s desire to maximize the sale of its product weighed and a physician’s duty to make the best decisions for their patients.

In short, the question is whether gifts, funding, or other types of interactions with the industry cause physicians to violate their primary fiduciary responsibility. “Physicians don’t believe it,” says Clary. In fact, she says, the data that show that few physicians believe they are making decisions based on these factors even though some believe their peers may be doing so.

### **A proactive response**

According to Clary, some of the disclosure initiatives on the part of the industry have been in response to events. But many of the more recent changes have been “very proactive,” she maintains.

For example, while the concerns surrounding SSRIs triggered Congressional hearings and litigation, they also led to voluntary disclosure of clinical trial results on the Internet, which has now been codified in FDA Amendments Act (FDAAA).

To illustrate how fundamentally things have changed in five years, Clary points out that in 2003 the expectation of the medical community was that negative trial results would not be published. In fact,

journal editors would not accept them because they were not interesting, she says. Today, however, there are journals that specialize in negative trial results.

Meanwhile, companies have altered their publication policies dramatically, says Clary. For example, Pfizer began by requiring the registration of all ongoing clinical trials on the government web site, clinicaltrials.gov. However, Pfizer went beyond the statutory requirement to register trials for serious or life-threatening diseases to include the results—positive or negative—of all trials for its marketed products, she reports.

A more recent step taken by Pfizer, says Clary, is the disclosure of study results for investigational medicines where the investigation has been discontinued and the drug is not going to make it to market. She says Pfizer took this step because investigators indicated it would be helpful to examine trial results for these medicines.

### **No measurable impact in restored public confidence**

Unfortunately, says Clary, “the trust level in our industry really has not improved all that significantly in the last five years.” Rather, she says, since the events of 2003, public concerns about conflicts of interest and their potentially adverse effects on healthcare decision making have continued to dominate the media. They have also led to multiple Congressional investigations, document searches, litigation, and personal embarrassment for some individuals, she adds.

---

*The industry’s efforts have failed to dissuade its critics and the public at large, says Clary. “The trust level in our industry is at an all time low,” she says.*

---

This has affected not only the industry, Clary points out, but the National Institutes of Health and the FDA, as well as academic centers, academic faculty and recipients of NIH grants and pharmaceutical funding. Most recently, she says, it has reached medical and professional associations and patient advocacy groups.

In fact, she says, concerns are now being expressed about the pernicious effects of industry

funding not only on physician prescribing, but formulary decision making, clinical guideline development, research design, publication of data (including ghost writing), the education of physicians (including CME), and many other areas.

Notably, says Clary, many of these concerns are based on industry practices from many years ago. Moreover, in most cases, there is little more than anecdotal data about the alleged wrongdoing to support some of the proposed remedies. Nevertheless, that is the landscape the industry continues to confront, she says.

### **AAMC enters the fray**

According to Clary, industry's evolving relations with academic medical centers illustrate this problem. In 2006, the president of the American Association of Medical Colleges (AAMC) and a number of his colleagues published an article in the *Journal of the American Medical Association* (JAMA) calling for new guidelines for interactions between industry and academic center physicians related to education and promotion. The authors advocated many specific actions they believed would mitigate what they considered excessive influence by industry over clinical decision making, says Clary, despite a lack of specific evidence that such negative influences present.

The authors examined gifts to physicians, provision of meals, consultancies, centralizing continuing medical education (CME) funds, and ghost writing. While the article initially led to some indignation on the part of the industry, Clary recalls, that was followed by "considerable soul searching" and a mixed reaction from the faculty of academic centers, which stood to be most directly affected by the changes.

In early 2007, the AAMC convened a task force that included a variety of individuals, including four pharma CEOs, several deans of academic medical centers, and other representatives of the academic world. At the initial task force meeting, Clary presented a primer regarding industry practices related to sales, promotion, medical education, medical science liaisons, and the like. She says it was striking then—and continues to be striking today—how poorly many stakeholders understood the difference between promotion (legal activity regulated by the FDA) and education (a professional activity regulated by professional bodies such as ACCME). "There was just a lot of basic explaining that we had to do," she reports.

It is important to remember that in the conflicts of interest world, "perceptions can become reality whether or not it's true," says Clary. The perception held by this group was that commercial practices in academic centers needed some change, she says.

The process that followed, says Clary, led to an increased mutual understanding and a set of recommendations approved by the AAMC in June. Those recommendations call on individual academic health centers to create policies that place restrictions on where and how sales reps can call on faculty. They also call for the elimination of any meals or gifts from industry to physicians, the central distribution of samples (which are viewed as gifts by the AAMC), and, where possible, for CME funding to be given to a central body in the academic center.

The AAMC also approved a prohibition against ghost writing, notes Clary, which was defined as non-disclosed editorial help. Technical writers who are utilized by the industry in non-pharmaceutical industry trials were deemed to be appropriate as long as they were on the disclosure statements of the journals, she adds.

Perhaps the most contentious recommendation in the report, says Clary, was a statement that strongly discouraged academic faculty from participating on promotional speakers' bureaus. While the goal of their report was to achieve a

consensus approval among all participants, she says the CEOs of both Pfizer and Eli Lilly refused to sign on to the above recommendation because both companies believe there is value in having academic faculty deliver talks about drug products on-label (and regulated by FDA) to help educate community physicians.

---

**Clary says it is often striking how poorly many stakeholders understand the difference between legal activity regulated by the FDA) and professional activity regulated by professional bodies such as ACCME.**

---

## Radical AMA policies rejected

Concurrent with the AAMC task force, many other entities, including the pharmaceutical industry itself, were examining their own policies and beginning to revise them in order to meet the needs of stakeholders, who were clearly calling for a lot more transparency, says Clary.

This includes professional associations, which have begun to more closely examine the nature of their interactions with industry, says Clary. For example, she says, the American Psychiatric Association (APA) recently responded to Senator Charles Grassley's (R-IA) request for information about all funding from the pharmaceutical industry over the last five years.

Meanwhile, industry funding of physician education, in the form of CME, has also come under intense scrutiny, she points out.

The conflict of interest debate reached "a fairly intense peak" earlier this year, says Clary, when the Council on Ethical and Judicial Affairs for the American Medical Association (AMA) issued a report to the House of Delegates' meeting in June. The report not only called for an end to industry funding of CME, but also of fellowships, scholarships, meetings, and many other items supported by industry.

Fortunately, the report was rejected and referred back to the committee, says Clary. Notably, she says, the debate included a number of passionate speeches by medical society leaders who opposed the proposal. "But we really have not seen the end of this debate," she cautions.

## Pfizer addresses CME

Clary points out that Pfizer has made significant changes in how it thinks about and supports independent CME. Prior to the OIG guidance, decision-making about CME grants was "brand-centric" and typically included by companies in the marketing budget. Subsequently, like most other pharma companies, Pfizer created a CME department under the aegis of medical affairs. Marketing and sales personnel are no longer allowed to participate in the decision making, she says.

Grants are reviewed and approved based not only on whether they are not only consistent with the therapeutic areas in which Pfizer has a business interest, says Clary, but whether the ACCME guidelines—including clear guidelines on resolution of conflicts of interest of the speakers—are followed.

"That is pretty basic compliance."

Since that time, Pfizer has focused on recruiting a staff that is expert in educational methodology. The company's aim, she says, is to go beyond compliant grant making and establish a preference for grants that reflect the best educational methodologies to drive physician performance improvement and patient outcome.

Pfizer has also begun to steer away from the large national symposia, which are very expensive (approximately \$900 to \$1,000 per learner), says Clary. Instead, the company is now focusing on interactive Internet learning methodologies. She says evidence shows this is far more effective in terms of driving quality of care and far less expensive (roughly \$90 to \$150 per learner). "We have been able to decrease our spending on CME at the same time that we are supporting an increase in quality," she says.

In addition, Pfizer concluded that Eli Lilly had done the right thing by beginning to publicly disclose its educational grant funding and charitable contributions to patient and medical groups. Pfizer took the same step in May of this year.

What amounts to Pfizer's most controversial decision, however, came in July of this year when the company announced it would no longer directly fund grant requests from entities—primarily medical education and communication companies—that are not providers of care. Clary says Pfizer thought "long and hard" about this decision but concluded that the education of physicians should be guided and controlled by physicians and the institutions that are accountable for them, such as professional associations, academic health centers and hospitals.

According to Clary, these groups are the most likely to understand the clinical and educational

---

***Concerns are now being expressed about the pernicious effects of industry funding on formulary decision making, clinical guideline development, research design, publication of data and CME, among other areas.***

---

needs of physicians and to direct others to carry out that mission. “We do continue to support medical education companies indirectly if they are working with the physician associations or the academic medical centers,” she adds.

Pfizer has received accolades for this decision from virtually every corner of academia and the medical profession, says Clary. “But there is still an ongoing debate about whether this was the right thing to do,” she adds, including whether it will decrease conflicts of interest. “We are continuing to evaluate the decision,” she says. “The jury is still out on that.”

Notably, Clary points out that an independent literature review of the evidence for bias in commercially-supported CME shows no such evidence. “This is an area that needs more study,” she says.

However, Clary maintains that an absence of evidence does not mean evidence of absence. In other words, simply because there is no evidence of bias does not mean that bias does not exist. “That really holds true in this case,” she maintains. That said, it would be optimal to inform the debate with real data before major decisions are made, she says.

### Drug promotion under fire

Needless to say, promotion is another area where conflict of interest concerns have been raised, says Clary. The argument made by critics is that gifts to physicians may lead to an unconscious wish to reciprocate helped prompt additional voluntary changes in the PhRMA code, she says.

Even the industry’s critics agree that the gifts in question are largely symbolic, says Clary. But the hope, she says, is that changes in the PhRMA code and the even more significant changes the industry is undertaking will convince the industry’s critics that it is serious about providing information that physicians need to prescribe drugs appropriately.

Oddly enough, says Clary, the major detractors of the PhRMA Code have been practicing physicians. The reason is not because they are losing gifts and meals, she explains, but rather because of the message it appears to send, namely that they can be bought.

### Examining new promotional models

One question facing the industry, says Clary, is whether the traditional “sales rep model” as it currently exists will continue *ad infinitum*. “Maybe.

Maybe not,” she says. “But it is probably worth continuing to think about what’s next in this Web 2.0 era.”

Encouraged by Pfizer CEO Jeff Kindler’s “push for innovation,” Clary reports that Pfizer has started to pilot different approaches. For example, Pfizer was the first pharma company to develop a partnership with Sermo, an on-line social networking site for physicians. “We are learning a great deal about how to have conversations on-line,” she says. “It has been interesting to interact with a community of physicians, all of whom are anonymous.”

However, trying to figure out how to accomplish this has been very challenging, says Clary. Moreover, it is unclear how FDA plans to establish regulatory requirements in areas such as safety reporting and on-label discussions, she adds.

Clary says it is essential that the industry maintains a voice on its products, about which it is expert. “We need to be able to bring that information to the marketplace,” she says. “But we do need to find new ways of doing so to complement the traditional model.”

According to Clary, the anonymity of the Sermo physicians has enabled some tough conversations. “We have heard some pretty raw criticism,” she reports. “But in the end, I think it’s going to better help us to serve our customers and the patients they serve.”

### Patient safety

Clary says any discussion of conflicts of interest would be incomplete without some discussion of patient safety. The mistrust on the part of the public that started with SSRI adolescent safety issues in 2003 was significantly exacerbated by the controversy surrounding Vioxx and other COX-II inhibitors. “This mistrust really hasn’t changed significantly,” she says.

Against this backdrop, industry and regulators have been working diligently to improve the already

---

***Pfizer’s most controversial decision in the area of CME came in July of this year when the company announced it would no longer directly fund grant requests from MECCs.***

---

active pharmacovigilance system, says Clary. She points out that Pfizer was the first company to proactively and publicly disclose on its web site the status of all its post-marketing commitments to enable the public and interested parties to monitor the progress of new studies.

“Compared to just a few years ago, there are significant changes in the transparency of clinical trial and safety information,” says Clary. “We continue to examine what other types of information that the public may call for or what other policy changes might be needed.”

### Looking ahead

According to Clary, the industry must now take a long-term view and understand its long-term interests. It is important to remember that pharmaceutical companies have been doing business for generations, in the case of Pfizer, almost 160 years, she says.

“It’s not that growth and producing and maximizing shareholder value are not paramount, but growth has to be sustainable,” says Clary. “Our business of developing and selling new medicines just isn’t sustainable in the long run without the trust of our customers.”

**“There is increased transparency that we couldn’t even have imagined six years ago,” says Clary.**

While sustainable growth depends on cutting edge of drug discovery, she says, it also depends on designing high quality studies that are conducted ethically and reported quickly,

accurately, and responsibly. “We gain nothing by misleading our customers,” she says. “What results from that can only be a breach of trust that takes years to repair.”

In this light, the interests of regulators, academic researchers, and physicians are far more aligned than is often assumed, argues Clary.

“There is increased transparency that we couldn’t even have imagined six years ago,” says Clary. “Sometimes, one or the other of us may stray a bit over the line, but we have the systems in place to pull ourselves back.”

“Inevitably, we are going to continue to evolve,” she concludes. “Let’s hope that the public’s trust will follow.” ■

## Leading state and federal policymakers and prosecutors to address drug and device disclosure

*Below is a list of leading state and federal prosecutors who will address the First Annual Summit on Disclosure and Transparency March 5–6, 2009, in Washington, D.C.*

*See next page for the full agenda...*

### STATE AND FEDERAL POLICYMAKERS

**Christopher J. Armstrong**, Esq., Investigative Counsel, Committee on Finance, The Honorable Chuck Grassley, Ranking Member, United States Senate, Washington, DC

**David A. Catania**, Esq., Member and Chair, Committee on Health, City Council, Washington, DC

**Senator Charles Grassley** (R-IA), Ranking Member, Senate Finance Committee, United States Senate, Washington, DC

**Mark C. Montigny**, Massachusetts State Senate, New Bedford, MA

**Sharon Anglin Treat**, Esq., Maine State Representative, Chair, NLARx, Augusta, ME

### STATE AND FEDERAL PROSECUTORS

**Julie Brill**, Esq., Assistant Attorney General, State of Vermont, Montpelier, VT

**Michele Brown**, Esq., Counsel to the United States Attorney, US Attorney for the District of New Jersey, Newark, NJ

**Christopher J. Christie**, Esq., Former United States Attorney for the District of New Jersey, Newark, NJ

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

**Daniel R. Miller**, Esq., Deputy Attorney General, Director, Medicaid Fraud Control Unit, Delaware Department of Justice, President, NAMFCU, Wilmington, DE

**Mary E. Riordan**, Esq. (Invited), Senior Counsel, Office of Counsel to the Inspector General, Office of Inspector General, US Department of Health and Human Services, Washington, DC

## ***Early-Bird Discount expires December 31***

### **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: Special Election Update**

- 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 important event.**

***Only one month away!***

## **CBI's 6th Annual Pharmaceutical Compliance Congress**

**January 26-27, 2009 • Washington, DC**

Below is a rundown of the innovative first day of CBI's upcoming compliance conference.

To view the entire program, visit: [www.cbinet.com](http://www.cbinet.com)

### **Special Luncheon hosted by Deloitte**

**L. Stephan "Steve" Vincze**, National Managing Director, Life Sciences/Forensic & Dispute Services, Deloitte Financial Advisory Services, LLP

**Janet L. "Lucy" Rose**, National Managing Director, Life Sciences Regulatory & Capital Markets Consulting, Deloitte & Touche LLP

### **President/CEO Address: Critical Issues Facing the Pharmaceutical Industry for 2009**

**Ludwig Hantson**, Head Pharma, North America and CEO, Novartis Pharmaceuticals Corporation

### **Keynote Panel Discussion: Recent Healthcare Fraud Investigations: A Closer Look at Integrity Obligations**

**Lynn Shapiro Snyder**, Senior Member, Epstein Becker & Green (moderator)

**Kathy DiGiorno**, Vice President and Chief Ethics and Compliance Officer, Medtronic, Inc.

**Thomas Forrester**, Vice President, U.S. Corporate Compliance Officer, sanofi-aventis

### **Government Enforcement Panel: Government Perspective on Scientific Exchange and Drug Promotion**

**Kathleen Meriwether**, Principal, Ernst & Young (moderator)

**Demetrious Kozoukas**, Associate Deputy Secretary, Health and Human Services

**Gerald F. Masoudi**, General Counsel, U.S. FDA

**Michael Loucks**, First Assistant U.S. Attorney, U.S. Attorney's Office for the District of Massachusetts

**Daniel R. Miller**, Deputy Attorney General Director, Delaware Department of Justice, Medicaid Fraud Control Unit

**Christopher J. Armstrong**, Esq., Investigative Counsel, Committee on Finance, The Honorable Chuck Grassley, Ranking Member, United States Senate



**Matthew Hay**, Editor & Publisher

**Jonathan Wilkenfeld**, Senior Writer

1602 Belle View Blvd., No. 840

Alexandria, VA 22307

Phone: 703/501-2019

[RxCompliance@aol.com](mailto: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.**