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GETTING THE RELATIONSHIP RIGHT BETWEEN PHARMA AND PHYSICIANS

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Sales and marketing activities represent a regulatory risk

What does your company have in common with the pharmaceutical companies that have been investigated and prosecuted for sales and marketing compliance violations?

Chances are, like them, your company has a Code of Conduct and an operating compliance program.

Evidently, those simple levees aren't enough to hold back the flood of recent actions by the US Food and Drug Administration (FDA), the US Department of Justice (DOJ), and state attorneys general against the pharmaceutical industry. Estimates are that in the last two years alone, pharmaceutical manufacturers have paid \$1.6 billion in fines and penalties to resolve enforcement actions related to Medicare and Medicaid fraud. According to one group, more than 180 additional cases are under seal, representing the potential for billions more in recovery by the government.

Pharmaceutical companies need to recognize that their sales and marketing activities represent a growing vulnerability to compliance, reputation and revenue and take action to proactively manage those risks.

Here comes the flood

The nearly-unanimous forecast for pharmaceutical commercial operations in 2007 is that investigations, prosecutions, settlements, fines and penalties will continue to rise – in the US, and around the world.

The enforcers go beyond the usual cast of FDA regulators and the OIG (the Office of the Inspector General) of the Department of Health and Human Services. Prosecutors from the Department of Justice (DOJ) and even many states are also taking on the roles of investigator and enforcer. And what they're enforcing include the federal Anti-Kickback Statute, the federal False Claims Act, and a growing number of state False Claims Acts. Under the Anti-Kickback Statute, for example, it is a criminal offense to offer, pay, solicit or receive remuneration – in short, to give anything of value – to induce or reward referrals, purchases or recommendations for products or services that are reimbursable by a federal healthcare program. Both sides of a "kickback" are subject to penalties including imprisonment, fines and, often most significant for pharmaceutical manufacturers, exclusion from any federal healthcare program.

As bad as that sounds, these days the Anti-Kickback Statute may only be a launching pad. Prosecutors are increasingly taking the evidence gathered to show a kickback, and using it in subsequent False Claims Act prosecutions. The reason is a simple return on investment. According

to the non-profit group Taxpayers Against Fraud (TAF), for every dollar spent by the federal government to investigate and prosecute healthcare fraud in civil cases, the federal government receives \$15 back in recovered funds.

Several factors contribute to the anticipated escalation of Anti-kickback and False Claims Act violations, including the role of whistleblowers; glaringly flawed promotion; a growing focus on costs to Medicare and Medicaid; the increasing move by state governments to enact their own fraud laws; and the public perception toward pharmaceutical manufacturers, drug prices, and drug marketing.

The vast majority of cases are initiated by whistleblowers. TAF notes in a recent study that, of the six False Claims Act cases successfully settled in 2005-2006, all were launched by whistleblowers. The qui tam provisions of the federal False Claims Act give individuals the right to sue drug companies to recover funds on behalf of the government and to receive a percentage as high as 25% of all recovered funds. According to TAF, \$3.9 billion has been recovered in the past six years from pharmaceutical manufacturers due to the complaints by whistleblowers—both inside the pharmaceutical company itself and in affiliated organizations—who may have intimate knowledge about the company's marketing and sales policies and practices.

The doctor in the middle

All of this enforcement firepower has its sights on your sales effort. That's what makes the task of commercial compliance so daunting: all those efforts get tested hundreds or thousands of times every week, in every individual interaction between a company's sales and marketing staff and healthcare providers.

In all these interactions, two potential pitfalls stand out as getting the most attention from regulators: financial arrangements between your company and healthcare providers; and the off-label promotion of drugs.

Financial arrangements

In testimony on February 9, 2007 before the US House of Representatives Committee on Oversight and Government Regulation, Lewis Morris, chief counsel to the Inspector General, described several common twists on the financial relationship pitfall, citing two cases that involved several

kickback schemes. One involved sales representatives of the companies giving physicians free samples in return for ordering their products. Morris noted that, while it is lawful to give a physician drug samples for use by his or her patients, the physician may not sell the samples. In the example he cited, the sales representative knew and expected that the physicians would bill Medicare and other Federal healthcare programs for the samples and be reimbursed. Of equal concern to the OIG, patients were required to pay their physicians a 20% Medicare co-payment for samples they should have received at no cost from the physician.

In a second example, Morris noted that “. . . some drug companies, aided by aggressive sales forces intent on meeting their sales goals, can be very creative in finding ways to induce physicians to order their products.” He then cited a case in which a group of high-prescribing physicians and their guests were invited to an all-expense-paid trip to a conference in France. The trip was part of a concerted sales campaign to generate \$6 million in sales in six days to those same physicians.

A final example demonstrates an increasingly scrutinized activity: the consulting arrangement. In one case, OIG showed that physicians received substantial fees for attending conferences as “consultants.” Those same physicians participated in promotional events including events held at expensive resorts. The “tell” in these arrangements, according to the government, was that these physicians provided few or no significant consulting services. In short, it's a kickback, and not a real consulting arrangement, if the physician never has to complete the intended deliverable to get paid, or if his or her compensation at a level in excess of the market value.

Off-label promotion

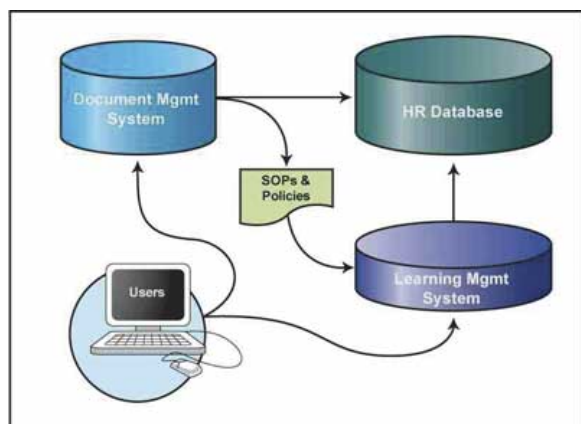
Off-label promotion is frequently the trigger of investigation and prosecution by the OIG. It is not illegal for a physician to prescribe a drug for an off-label use; it is illegal for manufacturers to promote uses other than those that are FDA approved.

A more sophisticated take on off-label promotion is that it can be a double whammy. As OIG's Morris noted in his testimony, “many of these off-label marketing schemes also involve illegal kickbacks to induce sales for non-FDA-approved uses.”

OIG has identified a number of activities that may fall into this category, including:

- **“medical science liaisons”** who represent themselves as medical authorities in a particular disease to speak on off-label uses;
- **“independent,” objective medical education events** that promote discussions of off-label uses, with manufacturers contributing advice or assistance about content, speakers and topics of the event;
- **articles written and paid for by manufacturers** advocating off-label uses, but listing the physician as the author.

Since companies can have many legitimate consulting agreements with physicians, keeping track of each agreement and receipt of its deliverables is not only difficult, but crucial to compliance.



PERFORMING TRAINING, DOCUMENTING ITS RESULTS AND STORING THE RELEVANT GUIDANCE PROTECT THE MANUFACTURER.
credit: Kaplan Eduneeing

Plugging the hole

So what's a compliance-minded pharmaceutical company to do? Virtually all industry players say they want to comply and mean it. The understanding of the costs of noncompliance in reputation, morale, stock value and revenue, is universal. The first step is to recognize that compliance responsibilities exist at each level of an organization, from corporate directors to subcontractors. A good compliance program must run from top to bottom in order to be effective and to be taken seriously by regulators and employees alike.

• **Corporate directors are expected to fulfill two primary “duty of care” responsibilities:**

reasonable inquiry and oversight. Although directors have the right to rely on company officers and employees for program management and compliance, they are required to make reasonable inquiries to ensure that the responsibilities of those individuals are being fulfilled. Directors, as well as senior executives, must also make good faith efforts to assure that the company has a compliance program capable of preventing, detecting and correcting violations. They must ensure that the company has an information and reporting system capable of providing relevant, compliance information to the Board's attention in a timely manner.

• **Compliance officers and program managers are charged with the day-to-day administration and management**

of the company's total compliance effort including training and testing for competence, documentation of all training activities, distribution and validation of critical information, identification and resolution of potentially non-compliance activities, whistleblower protections, and secure storage of related data. The compliance officers and program managers, in collaboration with marketing personnel, will often design and manage programs and procedures directly relating to the financial relationships with healthcare providers.

Sales and marketing personnel are of course the focal point for all these efforts. They must be trained, informed, and compliant. Indeed, the adequate training of sales personnel is often the centerpiece of a Corporate Integrity Agreement or Consent Decree marking a company's settlement of charges with the government.

Best practices

With all these different roles and responsibilities in mind, a company can next focus on four critical components of a compliance effort that meets best practices:

- adequate knowledge of responsible parties appropriate distribution and validation of accurate information
- regular monitoring of the compliance program, with specific attention to the competency of employees and subcontractors
- documentation of all records in audit-ready format.

Any of these components can fail at any level of the organization, leading to a domino effect that puts the entire organization and individual parties at risk.

Adequate knowledge. The issue of adequate knowledge among responsible parties centers in part on content and delivery. Certainly, this means all courses and training materials have to be kept up to date. But if one follows current best practices, it's not just about courses anymore. The content to be circulated in your compliance effort should also include standard operating procedures, corporate codes of conduct and policies, executive messages and more.

And to further check the content of your company's compliance program against "best demonstrated practices," see if you can answer "yes" to these questions:

- Is the content tailored specifically to your company and the situations your sales force encounters?
- Can your company validate that critical content was actually received?
- Even better, that the content was understood? (Many learning programs lack the crucial testing component that confirms comprehension of the material and the ability to apply it to the relevant job function.)

As noted above, each level of the organization, from sales employee through Director, has specific compliance functions to perform. That means they each have specific knowledge needs, and the superior compliance program should reflect that fact. Sales personnel are especially vulnerable to changing knowledge needs created by new products, new approved uses, and constantly changing regulatory requirements. Without identifying who knows what and where the gaps are, companies are unlikely to reduce the risk of noncompliance.

The instructional design of learning activities for directors is equally likely to be very different than those for sales personnel, who may be better served by techniques including simulations, advanced graphics and interactivity. The need to target the knowledge needs of individuals is gaining increasing urgency as more

experienced personnel approach retirement age, and companies experience an influx of new employees or outsourced salespeople—including workers who grew up with computer games.

Distribution and validation of information: The compliant distribution of information involves more than simply sending out relevant materials. Even though those materials may be varied and numerous, a company's compliance function and senior management need information control. So also ask yourself, "Does our compliance effort permit the easy, targeted distribution of materials to responsible parties? Are we routinely documenting our management of critical information?"

Monitoring, analysis and adjustment: For a compliance effort to truly affect the behavior of a team, you need visibility and flexibility. The ability to monitor, analyze and adjust programs can spell the difference between illegal and legal marketing and sales actions. The standard of compliance is the effectiveness of the program, not the design and implementation and authorities have made clear that the existence of a responsive compliance program will be considered in their enforcement actions. Technology can be the solution to tracking and monitoring compliance. For example, procedures on new and existing physician relationships covering remuneration, fair market value pricing for the engagement, tracking of deliverables, and time sheets or activity logs will safeguard against violations of the Anti-Kickback Statute.

Audit-ready documentation. The monitoring function dovetails with the documentation of all relevant compliance activities in an audit-ready format that is readily available to inspectors and investigators. Periodic, at least quarterly, reports regarding compliance should be shared with senior management and the Board. A parallel compliance responsibility dependent on effective documentation is adverse event reporting and follow-up, which has come under increased scrutiny by regulators and the public since the highly publicized Vioxx recall. And so it's prudent to ask: Is the distribution, receipt and acknowledgement of compliance training and information documented with unimpeachable records, such as with systems that are fully compliant with 21 CFR Part 11?

Culture of compliance excellence

Rising costs of medication, highly visible marketing activities, questions about drug efficacy, and the well-publicized recall of popular drugs have combined to create a tide of public distrust against the pharmaceutical industry. Regulatory authorities and government agencies are being pushed by Congress and the public to flex their muscles against what is often seen as a greedy, uncontrolled industry. Whistleblowers, often fueled by a sense of integrity and ethics, are focusing the spotlight on what they perceive as a lack of ethics and legality by pharmaceutical companies. Not surprisingly, the resolution and publicity surrounding recent fraud cases only supports the negative public perception about the industry.

Compliance is more than a detached business function required as a “cost of doing business.” It can, and should, serve as the driver of a corporate culture of excellence in which knowledge and behavior are interrelated, risk and performance are inseparable, and risk is continually managed at all levels. Most important, it effectively serves as the foundation for the company’s ability to achieve its most critical objective: to provide patients with medical treatments that improve health and well-being.

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