Drug safety emerges as primary risk area

Earlier this month, an Assistant U.S. Attorney with the Eastern District of Pennsylvania cited drug safety as the primary risk area now facing pharma companies. Far from being a theoretical fraud theory, the government already has several ongoing investigations in this area. Several experienced defense counsel believe investigations of this variety will span the next decade. Similar investigations are underway overseas, they report.

Meanwhile, investigations of pharma sales and marketing overseas continue to proliferate. Former OIG Senior Counsel Ted Acosta, now director of pharma compliance with Ernst & Young, reports activity in literally dozens of countries. See p. 11 of this issue for a primer on international investigations by Hogan & Hartson attorneys Linda Horton and Stephen Immelt and more in upcoming issues of Rx Compliance Report.
Caremark and GlaxoSmithKline settlements mark tip of the iceberg, say *qui tam* attorneys

*Cont. from page 1*

Notably, these two cases mark virtually the only settlements in FY 2005, despite a caseload of over 150 False Claims Act cases. *Qui tam* attorneys say that several major cases are, for all practical purposes, completed. However, the states and the federal government are squabbling over their respective share of the settlement.

**Caremark faces further litigation**

According to Burns, Caremark’s problems are far from over. “Caremark is facing a lot of litigation,” says Burns, who maintains that Caremark was likely willing to settle the case against AdvancePCS because it acquired that company and its concomitant legal problems. He says that fact likely offered the company some “emotional cover.”

According to Burns, Caremark faces several more False Claims Act suits including suits in California and Florida, and another in Texas, which was joined by Tennessee and Arkansas.

“It’s a bad day when the government joins the case,” says Burns, who points out that state governments and the federal government intervene in only a limited number of cases. “They just don’t join that many lawsuits, either the states or the Feds,” he says.

To illustrate his point, Burns notes that the federal government spends several trillion dollars a year buying goods and services. However, it processes only about 100 False Claims Act cases annually. “States do even less than that,” he adds. “No state that I know of does five False Claims Act cases a year.”

**Medco case hard-fought**

The Caremark settlement is likely just a precursor to final resolution of the ongoing investigation of Medco by the Eastern District of Pennsylvania. That case, which involves 25 separate fraud counts, has the potential to be much larger.

The presiding judge in that case died several weeks ago, and it was assigned to Judge Norma Shapiro, who has a reputation for settling difficult cases.

Medco can be accused of a lot of things, but rolling over for the government is not one of them. Both the whistleblowers and the lead prosecutor have been the focus of a major defense effort employed by Medco. Informed opinion is that the case will go to trial early next year.

**Serono settlement nears**

One of the largest pharma fraud cases under the False Claims Act is very near settlement, according to TAF. Details of the settlement are not public, notes TAF, but Serono previously announced that it had set aside $725 million in expectation of a settlement which is expected to encompass federal false claims charges as well as state claims and a criminal plea. Serono was charged with illegally marketing Serostim, an anti-wasting growth hormone sold to AIDS patients but also used illegally by body builders.

Serono is an interesting case, says Burns, in part because the drug in question is a very expensive drug used to prevent wasting in advanced stage AIDS patients. “It is fabulously expensive,” says Burns. “It costs a little over $7,000 per month.” Yet, some doctors were writing prescriptions for as long as a year.

According to Burns, Serono approached doctors to write prescriptions for Serostim in return for a trip to France. “There were a series of lies,” Burns maintains, “but the core lie was the kickbacks in the form of free travel to Paris to attend a conference.”

According to the suit, doctors wrote prescriptions that were not medically necessary. Millions of dollars worth of Serostim was allegedly sold by patients to middlemen, who then sold it to bodybuilders and athletes.

*See the next issue of Rx Compliance Report for “Ten Cases to Watch.”*

Patrick Burns, Taxpayers Against Fraud, Washington, DC, PBurns@taf.org
Drug Pricing

GlaxoSmithKline pays $150 million to settle drug pricing fraud case

The Department of Justice announced September 20, that GlaxoSmithKline has paid over $150 million to resolve allegations that the company violated the False Claims Act through fraudulent drug pricing and marketing of two anti-emetic drugs, Zofran and Kytril, used primarily in conjunction with oncology and radiation treatment.

The government alleged that GSK engaged in a scheme to set and maintain fraudulently inflated prices for Zofran and Kytril knowing that federal healthcare programs established reimbursement rates based on those prices. “The difference between the reimbursement rate of the federal health care programs and the actual price paid by healthcare providers for a drug is commonly known as the spread,” stated DOJ. “The larger the spread on a drug, the larger the profit or return on investment for the provider.”

The government contended that because reimbursement from federal programs was based on the fraudulently inflated prices, GSK caused false and fraudulent claims to be submitted to federal healthcare programs.

The government also alleged that, with respect to Kytril, the company engaged in a “double dipping” billing scheme by encouraging customers to pool leftover vials of Kytril to create an extra dose, which then would be administered to a patient and re-billed to Medicare and other federal healthcare programs.

The long arm of Ven-A-Care

The investigation commenced after the filing of a civil False Claims Act suit by Ven-A-Care of the Florida Keys, Inc., and its principals. As part of this settlement, the Ven-A-Care whistleblowers will receive a share of approximately $26 million. Ven-A-Care is responsible for an enormous number of similar cases. “Ven-A-Care is at the tip of the spear,” says one knowledgeable source. According to one attorney active in this area, Ven-A-Care recognized the exposure of drug companies in this area very early in the game—in the late 1990s—and pursued it aggressively.

As part of the settlement, GSK agreed to enter into an addendum to its existing corporate integrity agreement with the HHS OIG that, among other things, will require the company to report “accurate average sales prices” and average manufacturer’s prices for its drugs covered by Medicare and other federal healthcare programs.

Of the $150 million settlement, the federal recovery is approximately $140 million and the states’ recovery for their share of Medicaid is $10 million. The investigation was conducted by the Civil Division of the Department of Justice, the United States Attorneys’ Offices for the Districts of Massachusetts and the Southern District of Florida, the Office of Inspector General for the Department of Health and Human Services, the Office of Program Integrity of TRICARE Management Activity, and the National Association of Medicaid Fraud Control Units.

PBM investigations

AdvancePCS settlement imposes sweeping obligations on future PBM business practices

Defense counsel cites numerous questions raised by the settlement

Earlier this month, AdvancePCS, a pharmacy benefits manager (PBM) acquired by Caremark last year, agreed to a $137.5 million fine and a five-year injunction and settlement agreement with the U. S. Department of Justice and the U. S. Attorney’s Office for the Eastern District of Pennsylvania. The settlement resolved an extensive investigation into allegations associated with the PBM’s operational practices. The whistleblower suit was initiated by two former AdvancePCS executives. AdvancePCS admitted no wrongdoing.
The conduct in question occurred between 1996 and early 2004. The government alleged that AdvancePCS received kickbacks from drug companies in exchange for favorable treatment of their products under contracts with government programs, that AdvancePCS paid kickbacks as an inducement to signing contracts, and that excess fees paid to AdvancePCS in connection with fee-for-service arrangements resulted in the submission of false claims.

The settlement agreement and injunction impose sweeping prospective obligations on AdvancePCS, which will affect pharmaceutical manufacturers, client plans, and plan participants, says Greer Olsen Lautrap of Sidley Austin Brown & Wood in Washington, DC. Key provisions include disclosures designed to promote transparency and restrictions on drug interchange programs.

**Drug Interchanges**

The settlement also addresses drug interchanges, which are defined as any change from one prescription drug to another requested by or on behalf of AdvancePCS, says Lautrap. Excluded are interchanges initiated pursuant to a drug utilization review, for safety reasons, due to unavailability of the original drug, from a brand drug to its generic equivalent, or where the original drug is not covered by the client plan, she notes.

When a prescriber approves a drug interchange, AdvancePCS must provide plan participants with written and electronic disclosures that are easily readable and understandable.

The disclosures must:

- Explain that a drug interchange has been requested by AdvancePCS;
- Note that the plan participant’s prescriber approved the interchange;
- Describe the circumstances under which the originally prescribed drug will continue to be covered by the client/payer;
- Identify the drug shipped and the originally prescribed drug;
- Provide clear instructions on how to use the Advance PCS toll-free telephone number to call a pharmacist with questions about the interchange;
- Explain the switchback process; and
- State that the plan participant may decline the drug interchange and receive the original drug.

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**Kickback vs. transparency**

One of the interesting aspects of the recent PBM enforcement/settlement efforts is in the interplay between the legal theories articulated and the relief obtained, says Bill Sarraille, a partner with Sidley Austin Brown & Wood in Washington, DC. The settlement is predicated principally on the legal theories underlying the federal anti-kickback statute, he says. However, it does not prohibit PBMs from maintaining any of the financial relationships with pharmaceutical companies that have been challenged. Rather, it only imposes a requirement of disclosure and transparency on the PBM, he says.

Sarraille says that suggests the rhetorical question: “When is a kickback not a kickback?” On the basis of the structure of the settlement agreement, he says, the answer appears to be “When it is transparent.”

According to Sarraille, that raises some interesting follow up questions: “Will transparency provide a defense to a pharmaceutical company that enters into any financial relationship with a PBM? Should a pharmaceutical company mandate transparency in all arrangements with PBMs that have not yet entered into a settlement with the government? Is the difference between a financial arrangement that is subject to challenge and one that is acceptable merely transparency?”

“These and other questions are not answered by the AdvancePCS and Medco settlements,” says Sarraille.

For more on the settlement, see the next issue of Drug Pricing Report & Part D Compliance.

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Compliance program development

OIG outlines ten key “lessons learned” from existing corporate integrity agreements

Monitoring and auditing and co-promotion agreements cited among primary compliance concerns

An increasing number of pharma companies will undoubtedly fall under corporate integrity agreements (CIA) over the next few years. Some of those CIAs are likely to be amended as part of subsequent settlements. In many respects, these agreements reflect the OIG’s latest priorities in the area of sales and marketing compliance for the pharmaceutical industry, says Mary Riordan, senior counsel at the HHS OIG. According to Riordan, the questions and issues that arise in the development of CIAs are similar to many of the issues pharma companies face in trying to establish an effective compliance program. As a result, she says, drug companies not yet under a CIA should use these benchmarks as they develop and refine their compliance programs.

“To the extent that pharmaceutical manufacturers historically were not particularly focused on the fraud and abuse laws, my experience in dealing with a number of large manufacturers in the settlement process is that people are now focusing on these kinds of questions,” Riordan told attendees at Food & Drug Law Institute’s drug advertising and promotion conference September 19. “I would urge everybody to do that whether you are under a corporate integrity agreement with us or not,” she added. “It is just good business practice.”

Here are six key principles Riordan highlighted as current OIG priorities:

I. Know the people in your organization and those representing it

The first lesson, says Riordan, is to know the people in your organization and those representing your organization and their functions. As the OIG negotiates CIAs, a key part of the initial discussion is who will be covered by the CIA, says Riordan. That often requires a detailed discussion of the components and the divisions within the organization that may be involved in conduct that touches federal health care programs. For example, the OIG will certainly want to include the field sales force in the CIA.

However, in drug pricing cases, those functions that these people are playing and not be so wedded to just the names on the organizational chart,” says Riordan. “In designing a CIA, and I would urge in designing a compliance program, you want to make sure that you are looking at the functions that people are playing and that you are appropriately developing compliance measures that address those functions and that are relevant for those functions.”

II. Develop relevant training programs and policies

Riordan says the next step is to develop training programs and policies and procedures that are going to be relevant for people playing those functions. “You are not going to have to train your sales force the same way you are going to train your pricing people,” she says. Rather, she explains, the OIG tries to establish criteria or lessons to be provided in the training for specific persons in certain function areas. As manufacturers are implementing their own compliance programs, they must be cognizant of what function contractors are playing within the organization, says Riordan.

“Do you employ a contract sales force, for instance?” she asks. “If you do, are they trained about the requirements of the federal healthcare programs?...
Do they know about the federal anti-kickback statute? And do you have a good sense of how it is that they are behaving when they are acting out in the field on your behalf?”

III. Scrutinize co-promotion agreements and alliances
Another issue that has come up in the negotiation of CIAs, says Riordan, are co-promotion or other alliance-type relationships that companies may have with the sales force of another manufacturer. “Again, what assurances do you have that those employees of another organization have been trained on the fraud and abuse laws and are not, on your behalf, out there violating those laws?” she asks.

IV. Adequately assess promotional tools
Another important consideration, says Riordan, is for manufacturers to assess the promotional tools available to its sales force. “We in the OIG try to tailor our CIAs to look at this,” she reports. “You need to know, and we need to know, what it is that your sales folks have at their disposal when they are out there calling on healthcare practitioners,” says Riordan, including speaker programs, a variety of consultant arrangements, grants, gifts, and samples.

“We want to know what kind of training is provided in connection with these activities,” she adds, “and our corporate integrity agreements are very much focused on systems and processes that are in place.”

The OIG poses a number of questions in this area, she says. “For instance, if you are talking about consultants that you are hiring, how do you decide whether, how many, and under what circumstances you are going to enter those kinds of contracts?” she says. “What are the processes and criteria that are used to identify and select those healthcare practitioners whom you may retain as consultants for you?

V. Determine how information from contractors is used
Riordan says the OIG also wants to know what companies do with the information they receive from those contractors. “Is there any kind of tracking or monitoring of the prescribing habits of those individuals who are serving as consultants for you?” she asks. “Is this a legitimate consulting service for services that you really need or is it really just a way to funnel money to that healthcare practitioner?”

What is your process for establishing how much you are paying to these people? Are you setting the rates at fair market value?”

VI. Develop tools to measure aggregate payments
Another question that comes up increasingly as part of the OIG’s discussions with manufacturers in the settlement process, says Riordan, is the aggregate amount of money the respective sales force is providing to any individual practitioner. “If you are just looking at one individual grant, that by itself might not be a problem,” she says. “But if this single doctor has gotten five grants from you during the year and he is also a consultant for you and a whole variety of other funding mechanisms have been used to put money in the pockets of that doctor, that is the kind of thing that I want to hear about.

“I would just urge companies to develop a good way to track that so that you can look at the aggregate,” says Riordan, adding that some manufacturers are now developing those tools.

The first lesson, says the OIG’s Mary Riordan, is to know the people in your organization and those representing your organization.

VII. Establish effective internal monitoring
According to Riordan, the OIG also wants to know what kind of mechanisms are in place to internally monitor the sales force. For instance, she says, some companies report they do “ride-alongs” with their sales representatives to find out what is going on in the field. “Are you hearing reports from compliance officers of other organizations about your own sales representatives or the sales representatives of other manufacturing firms?” she asks. “Those may be good ways of finding out what is really going on in the field.”

In addition, says Riordan, there needs to be some type of a paper trail or an electronic trail and some type of auditing function. “We certainly include these audits as one of the main requirements in our corporate integrity agreements,” she says. While they have become very detailed in terms of what the
audits ought to look like, she says, the focus of the audits is mainly to try to understand whether the policies and procedures the company has set into place are being followed and whether there are accountability and control systems in place for the promotional tools being used.

For example, says Riordan, virtually all pharma CIAs to date require the selection of samples of “control documents” to determine whether the field sales force is properly documenting expenses, whether the salespersons are following the right processes to get grants approved, and whether those approvals, once obtained, have been filed.

“Those are important questions for you, as manufacturers, as well as for us,” she says, “because when we on the law enforcement side come and we hear that you have a great auditing program in place, but there is no paper trail, we really begin to question how effective that audit actually is.”

VIII. What is the message?
Finally, says Riordan, companies must know what messages about their products are being delivered by their sales representatives and their medical information departments. “What is the company’s policy about how the sales representatives are supposed to handle questions about off-label uses and what does your medical information department do with requests that may be channeled to it?” she asks. “What information does the medical information department give out and has that information been reviewed by counsel?”

All of those are important questions during settlement talks, says Riordan. “We want to understand what the policy is, how clearly has it been conveyed to the sales force, and whether there is a clear delineation between what the field sales force is saying and what the medical information department is saying.”

IX. Scrutinize call lists
Another area increasingly discussed, says Riordan, is oversight of the call lists of sales representatives. “There are some uses for products that are very clearly off-label and if you are calling on certain types of healthcare practitioners, they can be using a product off-label only” says Riordan. “For us sitting on law enforcement side, that is a great piece of evidence.

OIG puts spotlight on exclusion authorities
According to the OIG’s Mary Riordan, there is a good deal of coordination that goes on behind the scenes at the HHS OIG as it evaluates off-label and other promotion cases. In many instances, the government decides not to intervene. Nevertheless, these cases must be scrutinized, she says, “especially with the Medicare Part D program looming on the horizon in January,” says Riordan. “Of all times for HHS and the DOJ to be vigilant about what is going on in the pharmaceutical area, this is the time.”

“I fully expect that we will continue to be very actively involved in reviewing these cases and prosecuting these cases under the right circumstances,” says Riordan, who put the spotlight squarely on the OIG’s exclusion authorities. “Congress decided quite a long time ago that the OIG has the authority, and must, in certain instances, exclude providers, if they are convicted of certain crimes,” she explains. “Congress also gave us a permissive authority, which is applicable in situations where we do not have criminal convictions.”

Mandatory exclusion
There are two primary mandatory exclusion provisions that apply in pharmaceutical cases, notes Riordan. The first applies to the conviction of program-related crimes. If a pharmaceutical manufacturer is convicted of kickbacks, that is the basis for mandatory exclusion and that provider would be subject to exclusion from all federal health care programs, she warns.

The other increasingly important provision provides for a mandatory exclusion if there has been a felony conviction related to health care fraud, says Riordan. “This is becoming increasingly important,” she explains, “because the language that Congress wrote in that statute talks about fraud in connection with the delivery of a health care item or service.” Traditionally, she adds, the OIG has read that provision “broadly” and it believes applies to situations where a manufacturer may be convicted of off-label promotion or violating the Prescription Drug Marketing Act. “The language that Congress gave us is pretty broad there and we have interpreted it equally broadly,” she says. (cont. next page)
“I would urge manufacturers to look at the sales forces, what types of physicians the sales force is calling on, and [whether] that is an easy way to try and rein in any potential off-label marketing,” she cautions.

**X. Establish remedial action steps**

According to Riordan, a final question to pose is what steps the company takes in instances of non-compliance. “What is the scope of internal reviews?” she asks. “To whom is this information reported and what disciplinary steps are taken if there are violations? Is the board of directors notified of the problem? Is any kind of self-disclosure made to the appropriate government agencies?”

All of those are key questions to be asked in the context of corporate integrity agreements, concludes Riordan. “But again, we would urge there to be measures in place within voluntary compliance programs to address all instances of non-compliance.”

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**Leading federal prosecutor says “unprecedented” number of government interests scrutinizing pharma**

**Virginia Gibson,** Assistant United States Attorney in the Eastern District of Pennsylvania and Chief of the Civil Division, says the number of government agencies scrutinizing pharma is unprecedented. “There are many, many layers of government interests now involved in the pharmaceutical enforcement arena,” Gibson told attendees at the Food & Drug Law Institute’s drug advertising conference earlier this month. “It is really unprecedented,” she added. “I have been in an Assistant United States Attorney for nineteen years and I have not seen an area of prosecution that we have been involved in with the number of layers of government interests as there are in the pharmaceutical area.”

According to Gibson, there are four main reasons for this. The first is that prosecutors are dealing with the health and safety of the public in a broad perspective. “We are not talking about one physician practice, one hospital, one nursing home, or a chain of nursing homes,” she says. “Rather, we are talking about pharmaceutical products that reach huge numbers of people.”

The second factor is the amount of money involved. “We are talking about billions of dollars,” she says, “and in more recent years, it is government dollars.” When the government is the payer, that inevitably leads to more oversight, she says.

In addition, Gibson says the pharmaceutical industry had not focused on the fact that government reimbursement was becoming a higher percentage of its sales. “Instead, it focused on all of the government regulations [required] to get the product to market,” she says, “and not on what happens when the government becomes more involved in reimbursement.”

The fourth factor, says Gibson, is “the whistleblower wild card,” which continues to have a “very powerful influence” on the government’s agenda.

*See the next issue of Rx Compliance Report for a report on the government’s enforcement agenda featuring recent statements by several prosecutors.*
Compliance program development

In-house pharma counsel cites four key challenges to successful compliance program development

BMS attorney says coordination across various functions is critical ingredient

Federal and state scrutiny of pharma marketing practices has risen to unprecedented levels in the past several years. That scrutiny has been accompanied by guidance from the HHS OIG, voluntary guidelines from PhRMA, and corporate guidelines issued independently. In-house counsel Paul Savidge of Bristol Myers-Squibb, says the industry has learned important lessons about developing processes to build and maintain compliance.

Pharma companies face four primary challenges in this area, Savidge told the Food and Drug Law Institute’s advertising and promotion conference earlier this month.

I. Don’t make assumptions about the existing knowledge level

The first big challenge, says Savidge, is that you assume something about the knowledge level of the business. “When I say the business,” he explains, “I am talking about the whole gamut of the business, from marketing and sales organizations to medical organizations, and even the regulatory and legal organizations.”

“These groups are much more comfortable with their [own] understanding of the regulation of direct advertising promotions,” he warns. One mistake that some companies have made in developing compliance programs is that they have overestimated the amount of knowledge there is at all levels of the company about the ramifications of speakers’ bureaus, advisory committees, doctors as spokespeople, and CME events.

“The first [step] is to educate people, because the best way to build compliance in an organization is to have a common understanding of what the ramifications are for our activities as a highly regulated industry,” says Savidge.

“Don’t focus all of our education just on sales or marketing but also include the medical organizations,” he adds, “and make sure that your colleagues in legal and regulatory are also up to speed on these issues.”

II. Don’t make the compliance process too complex

The second biggest challenge facing pharma companies, says Savidge, are people who are not familiar with the process and do not know how to navigate through the compliance process. “It is very important that when we design the compliance program that we include in it a strategic plan for communicating the process and letting people understand how they are to avail themselves of the process,” he says. Likewise, he says, it is important to keep the process transparent and as simple as possible, especially as it pertains to the review process. “If you have a process that is difficult to fathom,” he warns, “it will not be used and it will lead to compliance issues.”

III. Establish effective coordination among various functions

The third big challenge facing drug companies, says Savidge, is that there are a number of regulatory organizations, including marketing, sales, and legal.

“It is very important from a compliance standpoint to have effective coordination among the various organizations that represent a function within a company,” he says.

“This is something that we have learned hard lessons about,” says Savidge, stressing the importance of making sure that there is a common understanding about whose jurisdiction a certain issue will fall within, such as legal, regulatory, or compliance. With the development of sophisticated compliance organizations within companies, he says, it is very important that the legal department and the compliance organization understand the points of accountability and responsibility. “It is important that these organizations present a united front on compliance issues to the sales and marketing organizations,” he adds.

IV. Discipline!

“The fourth biggest challenge that we have had is both discipline and discipline,” says Savidge. “There are two kinds of discipline,” he explains. “One is the
kind of discipline that is a reflection of the consistency we have for our compliance programs, ensuring that we are not operating in a no-harm, no-foul environment.” It is not an excuse, he adds, that there was no regulatory or legal issues raised about it. “The fact that there is a process means that everyone has to be disciplined to use the process,” he says.

The other kind of discipline is that part of the compliance process that reflects an agreement about the process for swift action by the company when transgressions are discovered. “It is about consistency and it is also about taking action and having strategic action plans in the face of wrongdoing,” he says.

— Paul Savidge, Bristol Myers Squibb, paul.savidge@bms.com

The Second National Medicare Prescription Drug Congress
The Leading Forum on the New Medicare Prescription Drug Coverage Legislation and Its Implications for Pharmaceutical Manufacturers, PBMs, Health Plans and Providers

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Hyatt Regency on Capitol Hill, Washington, DC
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The conference will focus on:
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- Marketplace response to new payment streams
- The effect of the MMA on access to medications for beneficiaries in the long-term care setting
- The MMA provisions related to the government role in adoption of health information technology
- The potential impact of centralized data on prescription drug use patterns
- The impact of the competitive acquisition program on beneficiaries and physicians.

KEYNOTE SPEAKERS:

David Brailer, MD, Ph.D.
National Health Information Technology Coordinator, Department of Health and Human Services, Washington, DC

Carolyn Clancy, MD
Director, Agency for Healthcare Research and Quality, Rockville, MD

Mac Crawford (Invited)
Chairman, President and Chief Executive Officer, Caremark, Nashville, TN

Julie Gerberding, MD, MPH
Director, Centers for Disease Control and Prevention, Atlanta, GA

Senator Chuck Grassley (R/IA)
Chairman, Committee on Finance, United States Senate, Washington, DC

Karen Ignagni
Chief Executive Officer and President, American Association of Health Plans, Washington, DC

Mark B. McClellan, MD, Ph.D.
Administrator, Centers for Medicare and Medicaid Services, Washington, DC

Marion McCourt
Vice President, Government Affairs, Policy and Managed Markets, AstraZeneca, Wilmington, DE

Congressman Pete Stark (D-CA)
Ranking Democrat, Health Subcommittee, Ways and Means Committee, United States House of Representatives, Washington, DC

Dale Wolf
Chief Executive Officer, Coventry Health Care Inc., Bethesda, MD

For more information, call 800/684-4549 or visit www.medicarecongress.com
Guest commentary

Marketing Pharmaceuticals and Medical Devices in Today's Difficult Enforcement Environment

By Stephen J. Immelt and Linda R. Horton, Hogan & Hartson, LLP

Today, companies do much more than publish print advertisements in medical journals and send sales representatives to visit doctors, armed with large satchels full of product literature, samples, and medically oriented gifts, often with the company logo or the product name.

These traditional activities continue as core features of companies’ advertising and marketing programs, complemented in the United States and New Zealand by direct-to-consumer advertising for certain types of products.

While print ads and detailing still are key tools for acquainting health professionals with drugs and devices, today it is also common for a manufacturer to be involved in a wide range of marketing activities, as well as scientific and educational relationships, with health care professionals.

Around the world, the pharmaceutical and medical device industries are subject to stringent laws affecting advertising and marketing of their products. What is allowed varies from one country to another, but many companies have engaged in such activities as company-sponsored marketing or educational events, educational programs for medical students or fellows, continuing medical education, sponsorship of doctors’ attendance at medical congresses (still common outside the United States), sponsorship of booths or other elements of medical congresses, satellite symposia, consultancies and expert boards, speaking engagements and speaker training, research grants, clinical trials, non-interventional studies, writing of journal articles, market research, provision of educational books, anatomical models, and other educational materials, donations of equipment, and charitable contributions.

Problem areas: off-label use, payments, and hospitality

Sponsorship of events can raise numerous legal issues. What if there are discussions of unauthorized products or unauthorized uses of approved products? Laws vary, but whether off-label discussions are permitted often depends on whether an event is viewed as a promotional activity or as a scientific or educational program.

For what purposes may a drug or medical device company give money or other pecuniary benefits to a doctor? While it is understood that payments for prescribing are strictly forbidden in many parts of the world, under what circumstances may doctors be hired as speakers, investigators, or consultants without such arrangements being viewed as improper inducement?

What kinds of hospitality may be funded by companies in connection with promotional events or with scientific or educational programs? It is in this area where change has been particularly rapid, at least in North America and Europe, yet is one in which companies are still getting into trouble with authorities and code bodies.

Increasingly, regulations or industry codes forbid certain forms of entertainment altogether, such as tickets to sports events, or seek to ensure that medical content predominates over hospitality.

It appears that those company relationships with healthcare professionals that involve off-label use, payments to doctors, or subsidy of travel and entertainment are the ones most likely to attract attention from regulators, prosecutors, and code officials. Officials are looking for evidence of illegal inducements to prescribe or use products—forbidden under many countries’ drug or medical device regulatory laws—or violations of various criminal code provisions.

In several countries, “dawn raids” have sent shockwaves through global and local companies doing business there. Among the laws recently cited in such investigations, and involving pharmaceutical or medical device companies’ relations with healthcare professionals, are ones that forbid bribery, kickbacks, waste of public healthcare funds, or even tax evasion. Criminal or civil remedies might be invoked, particularly where there is concern that company payments influenced the choice of products funded by a public healthcare system. Where such factors are present, the doctors as well as the drug or medical device company may get into trouble.
What laws are being enforced
In many cases, the laws in question are ones that have been on the books for some time but, without question, are being enforced more now than in the past. Take, for example, the situation in European Union member states. The basic EU-level legislative framework governing pharmaceutical marketing practices and manufacturers’ relationships with physicians and other healthcare professionals has changed little since 1992. The rules were recodified in the 2001 European Community code on medicinal products for human use. They were tightened, but only slightly, in the 2004 pharmaceutical review legislation. Overall, however, the legislative framework has been relatively stable and there is virtually no activity on this issue in the European Commission or European Medicines Agency.

What is different is increased enforcement in all parts of Europe, from Sweden and the UK in the North to Italy in the South, from Spain and France in the West to Poland and Turkey in the East. (See www.hhlaw.com/site/news.aspx?ShowArticle=2010 for examples of the kinds of activities that have been targeted by government bodies in Europe.)

Role of industry codes
Also important in this field are industry codes and, here too, there is a trend toward more enforcement as well as a great deal of redrafting. Codes in France, Italy, Spain, and the UK have been stringent for some time, reflecting the restrictive regulatory laws in those countries. Stricter codes have been put in place for Europe as a whole as well as in Denmark, Hungary, Italy, Norway, Sweden, Switzerland, and the United States.

A revision of the European Federation of Pharmaceutical Industry Associations code will become effective January 1, 2006, and this revision will result in further changes in national-level codes by the relevant industry organizations.

Hospitality in connection with marketing events will be severely limited, the rules against subsidizing attendance at events by spouses at congresses are reiterated, and the continued applicability of country requirements and codes when doctors attend events outside their home countries is clarified. The EFPIA code has little coverage of scientific and educational activities, but many European country codes do regulate this topic to some degree. For example, association rules in both Sweden and Switzerland are requiring doctors to pay part of their expenses to medical conferences.

In Italy, the trade association Farmindustria responded to a particularly challenging enforcement environment by adding a requirement that each member company employ a third party body to assess compliance with the association’s code.

Crackdowns in the UK and the US
In the United Kingdom a critical report by the House of Commons health committee, concerning the Influence of the Drug Industry, appears likely to generate an uptick in enforcement by the Medicines and Health product Regulatory Agency on advertising and marketing compliance, among other areas. At the same time, the Association of British Pharmaceutical Industry (ABPI) intends to maintain the high profile of its code enforcement body and is revamping and tightening its code of practice.

In the United States, the Neurontin settlement with Warner Lambert (Pfizer) is simply the most publicized example of the rising tide of U.S. enforcement actions. No discussion of corporate compliance plans would be complete without mention of this case, as the conditions of its settlement have been replicated in other companies’ compliance programs.

Pharmaceutical and medical device companies cannot do business in the United States without being aware of the panoply of requirements, industry codes, and “guidance” governing their advertising, marketing, and relationships with health professionals emanating not just from FDA and trade associations like PhRMA and AdvaMed, but also from the Office of the Inspector General, various U.S. Attorneys offices, and now the State of California. This regulatory Tower of Babel has led PhRMA to request that FDA be allowed to reassert its principal regulatory role in this arena.
Special Issues for U.S. companies
U.S. compliance and enforcement activities involving marketing practices have had a spillover effect on many companies’ international operations. Also, for many years, U.S. companies doing business abroad need to obey the Foreign Corrupt Practices Act in their employees’ dealings with health care professionals who are public employees. Some practices that have been common industry practices may be construed as bribes by U.S. or foreign enforcement authorities.

Still to be determined is whether Sarbanes-Oxley, and similar corporate integrity laws in other countries, will have an impact on medical product marketing. For example, lax controls on drug sales representative’s travel and expenses might be viewed as a Sarbanes-Oxley issue. Additionally, the Securities and Exchange Commission takes the position that companies must disclose material information about certain enforcement actions by foreign governments.

Diversity of enforcement bodies
Concerning pharmaceutical advertising and marketing practices, what distinguishes this area of regulatory vulnerability from others is the marked uncertainty about the direction from which governmental “strikes” will occur. In many countries it is not simply, or even principally, traditional drug regulatory agency officials that are coming after companies due to alleged marketing violations. Rather, a wide range of prosecutors with whom companies may have no established relationships are seizing documents and making public accusations.

How long will this go on?
We see no end in sight to the wave of enforcement. In fact, the negative publicity connected with the recent drug safety debate has focused upon widespread industry practices involving both promotional efforts and various relations with health professionals. Regulators have gotten the message from politicians and the public that they are supposed to “get tough” on the drug industry. Governments are trying to manage spending on social security programs, including outlays for medicines, which means that companies’ marketing practices are a prime target for actions under criminal codes and anticorruption, regulatory, or competition laws.

These recent trends, coupled with the fact that public money is spent on pharmaceuticals and medical devices, mean that enforcement bodies will continue to crack down on company practices believed to increase inappropriate product use.

Where both the source of a possible attack and its timing are unclear, a company’s best offense is a good defense: it needs to establish a compliance culture and “build a shield.”

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