BY ELISABETH PENA VILLARROEL

Culture of Compliance

CUTTING THROUGH THE CONFUSION

A few years after the Pharmaceutical Research and Manufacturers of America (PhRMA) code and the Office of the Inspector General (OIG) guidance, and the more recent implications of the Accreditation Council for Continuing Medical Education (ACCME) standards and FDA draft guidances regarding communication with healthcare providers, there is the perception that pharmaceutical companies are still struggling with compliance. But the issue for industry experts at pharmaceutical companies and service suppliers is not about being compliant, but rather the implications and application of the many regulations and guidances that apply to the marketing of their products. To complicate matters, the industry is being pummeled by bad press and increased scrutiny, where critics highlight exceptions in marketing compliance as reasons why the industry is failing in this area.

EXPERTS SAY TO APPEASE CRITICS AND PREVENT FURTHER EMBARRASSMENTS, PHARMACEUTICAL COMPANIES NEED TO GO BEYOND SIMPLY FOLLOWING THE RULES AND CREATE A CULTURE OF COMPLIANCE WITHIN THEIR ORGANIZATIONS TO FOSTER AND PROMOTE AN ETHICAL ATMOSPHERE THAT WILL RESULT IN COMPLIANT BEHAVIOR.

THOUGHT LEADERS

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A COMPLIANT STATE?

The number of regulations and guidances that now impact pharmaceutical companies is daunting. Judging whether a company is behaving in a compliant manner depends on the regulations themselves and the people being asked.

CATHERINE SAZDANOFF. Abbott

It isn't enough for companies to take the PhRMA code, photocopy it, and hand it out to employees. **ETHICS AND COMPLIANCE NEED TO BE INTEGRATED WITHIN THE BUSINESS.**

SHERMAN. This industry is now hyper-regulated, and this has created a situation in which compliance becomes difficult. Even if a company thinks it is compliant with all of the guidelines set by the FDA, there is the PhRMA code to consider. And while the PhRMA code is voluntary, the OIG states that companies should really follow the PhRMA code, which raises the question: Is it really voluntary? There are a lot of different stakeholders telling people what they should do, so the pharmaceutical industry is now beholden to a lot of organizations and that makes compliance difficult.

SAZDANOFF. The healthcare industry is in the spotlight for a variety of reasons. Healthcare is very important to everyone, it involves a high proportion of government spending, and there are a lot of new legal developments. But the industry continues to challenge itself and be challenged by its stakeholders, as it should be, to raise the bar for good marketing practices. And there are a number of ways in which the industry promotes that with initiatives such as the PhRMA and AdvaMed codes.

FREEMAN. Some of the challenges the industry is facing are because of the continued evolution of, and uncertainty over, the standards for marketing compliance. While great strides were made with the adoption of the PhRMA code, requirements have not become fixed. Instead, individual states — California, Vermont, and other states — continue to impose new and changing requirements. That said, it seems negative attention on marketing practices is closely linked with the more general negative perceptions of the industry. We can try to rehabilitate the industry's reputation by establishing clear standards of behavior, such as the development of the PhRMA code, and by following those standards.

CORSON. The industry is accustomed to a high degree of regulation and has been very proactive in the promotion and understanding of the final OIG guidance. The bigger challenge comes from the state level, where individual state laws may conflict with other regulations or differ from state to state. This type of inconsistency can create significant resource

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SHERRY CORSON. Solvay Pharmaceuticals

The industry is accustomed to a high degree of regulation and has been very proactive in the promotion and understanding of the final OIG guidance. **THE BIGGER CHALLENGE COMES FROM THE STATE LEVEL, WHERE INDIVIDUAL STATE LAWS MAY CONFLICT WITH OTHER REGULATIONS OR DIFFER FROM STATE TO STATE.**

issues and compliance concerns, because the need to remain current and meet all requirements is imperative to conduct business. Ideally, consistency across states on matters such as drug sampling, midlevel practitioner prescribing rights, promotional gift limits, and general reporting requirements would be helpful.

NASH. The industry is working very hard to achieve compliance. But there are still a lot of gray areas with the rules. Companies are struggling with the PhRMA code, for example. It's a helpful guidance but doesn't go far enough in many situations. I also think companies need to do a better job of encouraging their employees to approach managers and compliance officers with questions. Some of the "urban legends" can get out of hand and create a culture of fear.

PITTS. Pharmaceutical companies always strive to be in total compliance. You'd be hard pressed to find a pharma company that does not view compliance as a top goal. Do they make mistakes? Of course, but that doesn't mean they are in any way trying to skirt the issue or push compliance to its limit; they are

JOHN KAMP. Coalition for Healthcare Communication

THERE IS UNCERTAINTY NOW BECAUSE INVESTIGATORS ARE USING NOVEL APPROACHES TO INTERPRETING THE LAWS TO CREATE WHAT I THINK ARE NEW WRONGS. So no one knows for sure exactly what the laws forbid. This creates a cold wind across the industry.

doing exactly what the laws say they need to do. The reason there has been so much recent attention from Washington is that politicians have found a sound-bite platform that resonates with the media. The pharma industry is not viewed positively, so anything that it does is painted with a broad, and extraordinarily negative, brush.

NOON. The pharmaceutical industry is struggling with how to make the regulations fit within day-to-day business. Companies would really like some black-and-white answers as to what is appropriate or inappropriate when marketing a product. Unfortunately, if the government steps in to issue a regulation around the marketing of any type of healthcare product, including pharmaceuticals, it appears that it would prefer that companies just not engage in marketing at all. Companies have to explore ways to go about getting the word out about their products. They need to ensure that healthcare professionals are aware of what those products can do without stepping over the line and engaging in practices that may appear to be trying to induce a sale.

ACOSTA. I don't believe the industry as a whole is struggling with compliance; these are sophisticated companies that routinely face regulation and scrutiny. The many lawsuits we are seeing apply today's current thinking to conduct of the past. This notwithstanding, the industry still has work to do to fully understand its own practices and put appropriate controls in place. This is still a major work in progress for many companies, even for large ones. The main task remains educating senior marketing and sales executives that many of the activities on which they have previously relied can no longer be pursued or may have to be relegated to other areas of the business.

TABUENA. The pharmaceutical and related life-sciences industries are struggling with marketing compliance. This shouldn't be wholly surprising as it parallels what we've seen in other areas of healthcare. That sales, marketing, and promotional activities of manufacturers can unduly influence physician prescribing practices has long been recognized. Underlying any "marketing activity" is the hope for future business — otherwise what is the point? How financial relationships intersect, conflicts of interest, the anti-kickback statute, and the False Claims Act and how these are viewed by the government is nothing new in healthcare. Knowing where to draw the line between promoting awareness and an unlawful inducement is the challenge. The best defense is a proactive compliance program. Having a compliance function with real clout in the organization that provides a balance between operational incentives has had some proven success, although the amended federal sentencing guidelines illustrate that a compliance program must meet several significant criteria to succeed. It's not easy; healthcare has been grappling with this for close to a decade, and compliance programs are only recently beginning to take hold.

KAMP. The issue for all of us is the uncertainty around accredited CME. Most of that uncertainty is being created by a series of investigations by people within the Department of Justice, who are acting under the auspices of the HHS Inspector General. Essentially, those investigators are looking for any

LAWRENCE SHERMAN. Jobson Education Group

A problem that is emerging is that companies are now putting guidelines in place that are more strict than the ones they are required to follow. **COMPANIES ARE NOT ONLY FOLLOWING ALL OF THE DIFFERENT GUIDELINES, BUT THEY ARE TAKING IT TO THE NEXT LEVEL TO MAKE SURE THEY ARE PROTECTED.**

JODY NOON. Deloitte & Touche

INTERPRETATION OF THE VARIOUS GUIDANCES IS AN ISSUE. A marketing practice, such as distributing mouse pads with a product logo, might be okay for one company but might not be okay for another company. The lack of clarity around acceptable business practices might prompt a whistleblower to take action, when there was no intent to break the law.

evidence of violations of the Food and Drug Act, the False Claims Act, and the Anti-Kickback Act. Many of these investigators are using novel approaches to interpreting these laws to create what I think are new wrongs. These creative investigations create uncertainty. No one knows for sure exactly what the laws forbid. Understandably, this is suppressing the inclination of the drug industry to support CME.

DOYLE. The entire industry is struggling. There is no consistency with compliance standards and policies. The OIG guidance is just that, a guidance subject to legal interpretation. The end results are different legal interpretations and different types of compliance policies. There is not a clear industry standard regarding promotion and CME. That said, I believe the industry is trying to comply to the best of its ability to avoid investigations and significant fines. But, because of the lack of consistency, the perception is that some companies are not as "OIG compliant" as others, and the playing field is "not fair." Moreover, smaller pharmaceutical manufacturers do not seem to be aware of the OIG compliance guidance, or they are not taking action because they do not have the resources to address the issues at hand. Finally, physicians do not understand the rationale for the actions being taken by the pharmaceutical manufacturers with regard to compliance. This is resulting in increased frustration that is negatively impacting pharmaceutical manufacturers with their respective customers.

LEVY. There is an implication that the outliers in our industry are the norm. The whistleblowing cases are being held up as "standard" practices instead of as exceptions that should be corrected. There has been a wake-up call for industry CEOs and senior leaders, who now recognize that they need to know what is going on in every facet of their organization or risk a huge liability. I believe that the industry is taking very responsible actions in ensuring ethical marketing practices, and I believe that the pharmaceutical companies' customers, the healthcare professionals, have long been a self-policing mechanism. Physicians have always relied on clinical data to support their prescribing decisions and have always questioned inadequate or misleading information.

PITTS. Part of the problem is that federal regulations in general, and FDA regulations in particular, can be ambiguous. The unfortunate result is that a company doesn't always know if it is, in fact, in compliance. Regulators love ambiguity. Ambiguity is power, and drawing bright lines as to what is in compliance, in many respects, takes power away from the agency and the regulators. Clearly the goal is for companies to do the right thing on their own. But to do that, they need to know what the right thing is. And unless people know for sure what is in compliance, they will take the route they are most certain is in compliance. In short, they will use their judgment. The troubling thing is that being in compliance and doing the best thing for public health are not always the same thing. DTC advertising is an excellent example of this. One could look at the brief summary and say it does nothing to advance public health, but that is exactly what pharma companies are told to do. If they do anything other than what they are supposed to do, they run the risk of receiving a warning letter.

NOON. There are a lot of investigations and a lot of clamor around illegal conduct, but for the most part from an organizational standpoint, the conduct in question was not something that was condoned or pushed by the company. It may be the case of zealous sales agents who decided they wanted to be more entrepreneurial, but on an organizational level, noncompliance is not condoned.

COMPLIANCE BEST PRACTICES

To keep on top of all the rules and regulations, companies need to implement effective compliance programs and training and then put in place a checks-and-balances system for self-monitoring.

FREEMAN. One initiative that we consider to be a best practice was a 2004 project to distribute copies of the PhRMA code to all of our

TRACY DOYLE. Phoenix Group Holdings

A guidance is just that — guidance. **THE ONLY DIFFERENCE IS THE OIG GUIDANCE IS AN ENFORCEABLE GRAY AREA WITH FINES ATTACHED.** One company can interpret the guidance one way, and another company can interpret it another way. And then smaller pharma's interpretation can be completely different. Companies don't perceive themselves as being on an even playing field.

physician customers. This project gave us the opportunity to publicly and unequivocally declare our commitment to compliance and to educate physicians about the rules under which we operate. We explained that the PhRMA code rules are consistent with the AMA guidelines that govern physician conduct. This initiative also told both physicians and our salesforce that we can expect physicians to hold us to our commitment. We received very positive feedback from our salesforce and from our physician customers.

SAUNDERS. We keep marketing compliance simple. We try to follow three golden rules that we teach to all of our sales and market professionals in the company: promotional messages are always within label, truthful, and fair balanced; we don't buy business; and we only obtain a customer's service for sound business reasons, and we always pay a fair market price. These rules are very easy to understand, and our people know what is expected of them. Essentially we teach our sales and marketing professionals that if they live by those rules, 99% of the time they are going to be in compliance.

CORSON. Our company focuses on therapeutic area alignment, not just in sales and marketing but in regulatory and clinical areas as well. We provide the opportunity to sharpen internal expertise and establish clear team direction. Having key corporate areas aligned by therapeutic discipline translates into consistency in product and process knowledge,

THE MANY MANDATES OF PHARMACEUTICAL MARKETING

A LIST OF THE GUIDANCES, GUIDELINES, LAWS, REGULATIONS, AND ACTS PHARMACEUTICAL COMPANIES NEED TO CONSIDER WHEN MARKETING THEIR PRODUCTS.

INDUSTRY-SPECIFIC GUIDANCES

MAY 2005

Accreditation Council for Continuing Medical Education (ACCME): Standards for Commercial Support

Adopted in September 2004, the standards were designed to ensure the independence of CME activities from commercial interest.

FEBRUARY 2004

The Food and Drug Administration: Draft Guidances — Brief Summary: Disclosing Risk Information in Consumer-Directed Print Advertisements; "Help-Seeking" and Other Disease Awareness Communications by or on behalf of Drug and Device Firms; and Consumer-Directed Broadcast Advertising of Restricted Devices

Designed to improve communications to consumers and healthcare practitioners about health conditions and medical products, these guidances provide new direction to sponsors on how to provide higher-quality health information to the public.

JANUARY 2004

Advanced Medical Technology Association (AdvaMed): The Code of Ethics for Interactions with Health Care Professionals

Voluntary code of ethics facilitates members' ethical interactions with individuals or entities that purchase, lease, recommend, use, arrange for the purchase or lease of, or prescribe members' medical technology products in the United States.

MAY 2003

Office of the Inspector General (OIG): Final Compliance Program Guidance for Pharmaceutical Manufacturers

Sets forth general views on the value and fundamental principles of compliance programs for pharmaceutical manufacturers and the specific elements that pharmaceutical manufacturers should consider when developing and implementing an effective compliance program.

JULY 2002

Pharmaceutical Research and Manufacturers of America (PhRMA): Code on Interactions with Healthcare Professionals

Marketing code governs the pharmaceutical industry's relationships with physicians and other healthcare professionals.

APRIL 1988

The Food and Drug Administration: The Prescription Drug Marketing Act

The Prescription Drug Marketing Act was enacted to address certain prescription drug marketing practices, including the distribution of free samples, the use of coupons redeemable for drugs at no cost or low cost, and the sale of deeply discounted drugs to hospitals and

Source: Ted Acosta, National Leader, Health Sciences, Investigative and Dispute Services, Ernst & Young. For more information, visit ey.com.

PETER PITTS. Manning Selvage & Lee

AN IMPORTANT QUESTION TO ASK THE PEOPLE WHO ARE SLAMMING THE INDUSTRY IS: ARE YOU UPSET THAT COMPANIES ARE NOT IN COMPLIANCE, OR ARE YOU UPSET BECAUSE OF WHAT COMPLIANCE ACTUALLY MEANS? The latter is the answer. Companies are in compliance, but people are not satisfied with what being in compliance means.

targeted training, streamlined cross-functional communications, and the opportunity for cohesive regulatory, legal, and compliance support. For compliance, consistency and communication are key.

FREEMAN. Serono has a number of different training programs in place for marketing compliance. Marketing compliance is a key element of our new hire orientation program and continues through quarterly online courses, periodic Webcasts, in-person training sessions, and written coursework. We use assessment tools to ensure that the messages are understood, and we make sure we provide ample opportunities for addressing questions.

SAZDANOFF. At Abbott, we have built our compliance program around the elements laid out in the U.S. Federal Sentencing Guidelines, which includes components such as an infrastructure of ethics and compliance support at the corporate level that has direct links to executive management and the Abbott board of directors; written standards, such as Abbott's code of business conduct, policies, and procedures on a variety of topics; and communications and training. Our ethics help line is available 24/7 and is a confidential means by which people can ask questions and raise concerns, anonymously if they wish. We have tried to make sure all the elements listed in the Federal Sentencing Guidelines are addressed in our compliance program.

SAUNDERS. We have two types of compliance training. We require that, annually, all employees, new or old, go through a series of

healthcare entities.

LEGAL STANDARDS AND OTHER SOURCES

California's Comprehensive Compliance Programs for Pharmaceutical and Medical Device Companies — July 2005

In September 2004, California passed a law requiring pharmaceutical companies to adopt Comprehensive Compliance Programs (CCPs) relating to their interactions with medical professionals. The law, effective July 5, 2005, applies to companies if they engage in pharmaceutical detailing, promotional activities, or other prescription drug marketing in the state. CCPs must be "in accordance with" guidance released by the PhRMA and recommendations of the OIG. These guidelines and recommendations encourage the establishment of CCPs to address concerns regarding the interaction between pharmaceutical companies and healthcare professionals and to address the public and private sectors' goals of reducing fraud and abuse, enhancing healthcare provider operation functions, improving the quality of healthcare services, and reducing the cost of healthcare.

Federal Sentencing Guidelines — 1984

Among other things, the Sentencing Reform Act of 1984 created the U.S. Sentencing Commission as an independent agency in the Judicial Branch and directed it to develop guidelines and policy statements for courts to use when sentencing offenders convicted of federal crimes.

A 2004 amendment to the act relates to the effort that a company should put into compliance. The guidelines offer incentives to organizations to reduce and ultimately eliminate criminal conduct by providing a structural foundation from which an organization may self-police its own conduct through an effective compliance and ethics program.

Federal Anti-Kick back Law — 1972

The Federal Anti-Kickback Law prohibits anyone from knowingly and willfully receiving or paying anything of value to influence the referral of federal healthcare program business.

False Claims Acts — 1863

The False Claims Act imposes civil liability on any person or entity who submits a false or fraudulent claim for payment to the U.S. government. The False Claims Act allows an individual who knows about a person or entity that is submitting "false claims" to bring a suit on behalf of the government and to share in the damages recovered as a result of the suit. The Act underwent significant changes in 1986. Pharma companies may be liable, generally, if their promotional practices or claims caused providers to submit reimbursement claims for off-label uses to Medicare and other federal health insurance programs.

INTERNATIONAL INDUSTRY CODES

European Federation of Pharmaceutical Industries Association's (EFPIA) Code of Practice on the Promotion of Medicines.

At the initiative of the European pharmaceutical industry, the EFPIA Code took effect Jan. 1, 1992. Amendments and revisions were enacted in 1993 and 2004.

Eucomed Guidelines on Interactions

TED ACOSTA. Ernst & Young

THE FEDERAL SENTENCING GUIDELINES ARE A VERY GOOD FOUNDATION if a company is trying to figure out what its compliance program should be and what elements should be present from the government's perspective.

Web-based modules that are interactive. We don't just throw the rules at people; we use hypothetical scenarios and case studies to explain how the regulations apply to real-life situations. We also teach compliance at the same time as sales training. We are of the belief that compliance is something that is embedded into the way we do business. We have built into the regular sales-training process how employees should do things from the get-go. Compliance training is embedded in all of our sales training and product training.

SHERMAN. We run voluntary workshops for the various commercial supporters of our CME activities. We provide guidance on all of the different rules and regulations and practical examples of how to work within them. That ensures everyone is protected, guidelines are followed, and everyone's needs are met. We also put together a book, CME Source Guide, which has all of the guidance documents, the FDA, OIG, PhRMA, and ACCME guidelines, and we give these out when we do workshops. It provides one easy reference point for all of the guidelines that impact the pharma industry for CME.

ROBERT FREEMAN. Serono

Our overall corporate incentive program for all employees is based on a balanced scorecard approach. Each year the scorecard includes a number of compliance measures. **ALL EMPLOYEES THEREFORE HAVE AN INCENTIVE TO SUPPORT OUR COMPLIANCE GOALS SO WE CAN ACHIEVE THE SCORECARD TARGETS.**

LEVY. First and foremost, it is crucial that anyone advising the industry understand how various regulations are shaping the future and then provide solutions that achieve client objectives in a responsible, compliant manner. The complete separation of educational initiatives from promotional initiatives has been the most visible action by our clients to enhance compliance. At Ferguson, we are responsible for staying current with the regulations from the FDA, OIG, and ACCME; educating our clients on an ongoing basis; and developing comprehensive marketing solutions, including educational components.

NOON. The key is taking what the regulations require, what the PhRMA code has in place, looking at all the guidances out there, and interpreting that information for the people who are in the field to provide them with good business guidance. Training and communication are key. A lot of companies have done very well with establishing policies and procedures and making sure that they have in place what people can and can't do, but it is key to take that next step and give people case scenarios and a place to call if they have questions; this is what we call "operationalizing" the rules. It is also important to help sales reps not only understand the rules, but understand why the rules are in place.

CORSON. We use several different methods to introduce, conduct, and reinforce various aspects of training. We have found that live presentations from internal experts on topics such as drug safety reporting, promotional regulations, drug sampling, OIG, PhRMA, and HIPAA provide the best opportunity for comprehension as well as clarification and dialogue. All levels of our sales training program include information on compliance with an opportunity for Q&A.

SAUNDERS. As another best practice, we look for ways to increase our internal control environment, while also making the business better or more efficient. For example, with respect to how we award grants, in the past sales reps could be involved in grants or CME, working with physicians, or facilitating physicians' applications for participation in these types of programs. Today, we have a centralized customer-service center with a toll-free number; we've taken the reps out of the equation. This has given the reps more time to focus on doing their business and talking about the benefits of our products to physicians rather than paperwork and managing applications. This also has allowed us to centralize and monitor where we are spending our money. So this was a win-win; we have more control over how we spend our money with customers and more rigor within that process, and the reps have more time to focus on what they need to do, which is get out and talk to physicians about our products and how they benefit patients.

FREEMAN. We monitor employee compliance with the policies we've established in a variety of ways. Certain compliance metrics

RICH LEVY. Ferguson

THERE IS A MISCONCEPTION THAT MARKETERS WANT TO "BEAT THE SYSTEM" OR "WORK AROUND REGULATIONS."
While the exceptions have made news, the best marketing has always involved putting pharmaceuticals into the appropriate clinical context and arming prescribers with concise, factual information about benefits as well as risks.

are included in monthly management reports and in quarterly reports to our compliance committee. We also use our internal audit function to complement the monitoring activities coordinated by the compliance department.

SAZDANOFF. We have different types of monitoring, depending on the activity we are evaluating. We have an up front review and approval process. For example, the Office of Ethics and Compliance would review and approve a proposed marketing program before it gets set up. There also is an in-process check. For example, when an employee puts in an expense report for reimbursement, we have a corporate program, separate from our group, that reviews the items for financial purposes as well as for ethics and compliance. At the back end, we conduct formal monitoring, such as pulling documentation around an activity that has already taken place, to evaluate whether it has been done in compliance with applicable procedures and controls.

CORSON. We monitor compliance in several ways, such as traditional audits and investigations as well as benchmarking against proven compliance initiatives at other companies within the industry. As our program continues to evolve, and as the legal and regulatory authorities continue to provide guidance, our corporate monitoring efforts will evolve as well. Employee surveys and feedback tools are the newest measures being discussed.

COMPLIANCE CHALLENGES

Regardless of whether individual companies are promoting and fostering compliant marketing and sales behaviors, all stakeholders in the industry's sales and marketing arena face similar challenges when it comes to interpreting and implementing the many guidelines.

DOYLE. Regarding promotion, it is now very difficult to accomplish anything. All ideas must be reviewed by legal and outside counsel. Because legal has no experience with marketing or marketing tactics, there is no sense of urgency to approve the concept. Additionally, legal and outside counsel tend to interpret things literally, and the spirit of marketing is lost. Moreover, all elements of an approved tactic must be reviewed. Consequently, there is a two-week lead time and a two-week review process for tactical materials; concepts are mired in a bureaucratic abyss. The end result is that program integrity is compromised; customer relationships are compromised, meaning advocates are lost because of frustration; and the bottom line is greatly affected because of a loss of business, namely decreased sales performance.

LEVY. Time, money, and resource prioritization coupled with multiple stakeholders who have different, and often conflicting, needs are the barriers the industry faces in terms of becoming more compliant. In a perfect world, we would have decades of experience with each new pharmaceutical product, unwavering clinical evidence, and a mechanism to miraculously empower healthcare professionals with all the information regarding risks and benefits accurately and instantaneously. Even if this perfect world existed, patients would still suffer from diseases and would have to wait for access to new therapies, and healthcare professionals would still weigh risks and benefits in recommending medication, resulting in overtreatment or undertreatment on an individual basis. The pharmaceutical industry remains the largest provider of information and education to healthcare professionals. The increasing regulatory requirements involve human resources and financial resources as well as time. As resources are finite; the money involved in building compliance measures comes from R&D and education budgets as much as it comes from marketing. There has to be a balance between allowing industry to do what it does best — treating and curing disease — and ensuring responsible practice in communicating the results.

SHERMAN. The industry has had to shift on the fly. All of a sudden, the people who had been in the background — regulatory, compliance, legal — are now in the forefront. These people were necessary cogs in the machine in the past, but now marketers have to work with them before anything gets done. New policies and procedures have been set as to how marketers and sales people interact with their customers, how they interact with their vendors and suppliers, and how they interact with their educational providers. The pharma industry has had to take a 180-degree change of position from where it used to be in regard to CME.

DOYLE. For CME, most pharmaceutical companies have developed an independent grant-review process. The grant-review department is grossly understaffed, review times can be as long as four to six months, but budgets are not released until late in the fiscal year or early in the following fiscal year. The end result is mid- to late-year CME initiative roll outs. Furthermore, in the spirit of compliance, many companies are removing sales representatives from the audience-generation process, which was a tried-and-true method of generating attendance. The question then arises, is CME worth it? The answer is of course it is

BRENT SAUNDERS. Schering-Plough

We are trying to get away from a very rules-driven approach to marketing compliance and focus more on a values-based or integrity-driven compliance program. **OUR MISSION IS TO EARN TRUST EVERY DAY, AND THAT IS NOT JUST FOR OUR CUSTOMERS AND PATIENTS, BUT IT ALSO APPLIES TO OUR EMPLOYEES INTERNALLY.**

because it educates the community on disease states, which is greatly needed. But, because of compliance barriers, many commercial supporters may limit support.

KAMP. There are some investigators who are taking the law into their own hands and maybe doing things that are entirely inconsistent with the public health. For example, people are being scared into believing commercial support for CME might be a bad thing. The commercial support for CME is very important. Doctors want most to learn about new drugs and new uses of existing drugs, and drug companies are the ones with the financial resources to support that knowledge. This supports good patient care. Even though the support comes from commercial providers, the FDA and the ACCME require that the providers of CME apply independent judgment to the content of the CME programs. The companies that I know best have always gone out of their way to follow the FDA guidance and the ACCME rules.

NOON. The whole notion of compliance and setting it up in an organization is challenging in today's environment. Previously, companies followed FDA guidances, and those were contained within the manufacturing and research part of the business. Now that is broadening beyond the scope of the FDA and moving into areas overseen by OIG. Companies also have to consider Sarbanes-Oxley, government price reporting, the Medicare prescription drug act, and so on. Companies are really grappling with how to set up an efficient structure that makes sense for all areas of the business. They have to look at where compliance resides within the organization and set up a structure that makes sense.

LEVY. The bar keeps getting higher in terms of the actions that define exemplary compliance. To reverse this trend, there must be a reasonable middle ground that healthcare professionals, industry, and regulatory bodies agree on regarding reasonable preventive measures to ensure compliance and remedies for ethical violations. OIG has been most successful at changing behavior through fines.

NASH. I don't think anybody would argue that the relationship between consumers and the industry is suffering. The safety issues with Cox-2s may have put it over the top. The amount of DTC advertising is so much more prevalent now than it was even a couple years ago, that when things go wrong, the scrutiny from the FDA and the general public multiplies exponentially.

KAMP. No industry is perfect, but I have no reason to believe that most companies have not been careful. At the same time, these HHS-OIG/DOJ investigations are creating new laws, new wrongs, then applying these to behavior long past. Thus, many actions that company lawyers thought were appropriate and legal at the time are now being found illegal. That's not fair. Meanwhile, patient care may well suffer because doctors will have less information readily available to them. That is a serious public-health problem.

COMPLIANCE SOLUTIONS

Regardless of who is at fault, industry experts agree efforts should be made to improve compliance to relieve some of the pressure being placed on the industry.

DOYLE. The members of PhRMA should get together with the respective attorneys and agree on reviewing the guidances. They should provide a clear, standardized front so everyone is on the same page with compliance to make sure the processes and bureaucracy are standardized. Right now, each company has its own standards. From a medical-education company perspective, I don't even know what I can sell anymore. If the members of PhRMA were to get together, they could issue a statement that all agencies and vendors could review and understand how to work within the current compliance confines.

SAZDANOFF. My counterparts and I, in peer companies on both sides of the industry, have formed compliance groups so we can get together and share best practices and continue to educate ourselves on compliance initiatives, whether they are legal developments or better modes of promoting ethics and compliance in our companies. On the pharma side this group is called the Pharmaceutical Compliance Forum; on the device side it is called the Device and Diagnostic Compliance Group, which is a group that Abbott helped to found last year. These groups are very active in terms of talking about best practices, as well as sponsoring or taking part in public forum discussions of best practices to try to make sure we get the message out as widely as we can that the industry is interested in promoting best practices in this area.

PITTS. The government needs to remove the FDA's shackles. Congress needs to change the law and allow for greater transparency for things such as clinical trials. The reason the FDA doesn't share information with the public is because it is not legally allowed to. This is conveniently left out of a lot of the articles in the general press. Information that is given to the FDA by law is considered commercially confidential. It is in Congress' power to change that. But, rather than actually being proactive and changing legislation, legislators point to the FDA and say the agency is not doing a good job. This is unfair and deleterious to the public health; it doesn't move the debate forward. The pharmaceutical industry, from a marketing standpoint, is in compliance. But companies need to engage, rather than lobby, with the government, the FDA, and the media and demand brighter lines for what being "in compliance" means and how this can change to better advance the public health; and that requires a legislative change.

PAUL NASH. HCPro

EDUCATING REPS ON THE DANGERS THEY ENCOUNTER IN THE FIELD AND GIVING THEM A BASELINE UNDERSTANDING OF THE LAW ALLOWS THEM TO MAKE APPROPRIATE DECISIONS. This kind of training provides a foundation for a culture of compliance.

JOSÉ TABUENA. KPMG

If the salesforce does not buy leadership's commitment to ethics and compliance it will not be motivated to act accordingly. **IT SHOULD BE NO SURPRISE THAT THE RECENT INSTANCES OF CORPORATE WRONGDOING INVOLVED LEADERSHIP AT THE HIGHEST LEVELS.**

LEVY. The most promising solution is a standardized "level of evidence" for communicating data and other information. While there are not yet universally accepted levels of evidence, there are thresholds being developed within specific academic settings and associations that help to create standards for evidence-based CME. The basic concept is to rate different sources of clinical evidence to prevent, for instance, an anecdotal experience of one physician being equated with a placebo-controlled trial. Since there are so many sources of information — expert opinion, published research, meta-analysis, association guidelines, and so on — it is important to agree on a standard for evaluating these sources. This will help healthcare professionals to evaluate information and apply their learning to clinical practice as well as resolve conflicts of interest. The overarching need is to eliminate bias in education and present fair and balanced evidence for recommendations. It is important to note that healthcare professionals still want and need specific recommendations based on the evidence, so this would also provide an incentive for companies to support the use of their products with the best evidence possible. I believe this would be universally embraced by industry, healthcare professionals, and regulatory agencies as it would reward more robust clinical evidence and alleviate the concerns associated with misrepresenting data.

NASH. Because of the safety issues brought to light over the past few months with certain high-profile drugs, consumers will pay more attention to risk and side-effect data. The better "information" that companies can provide, the more trust they will gain from better-educated consumers.

TABUENA. From my experience, there are five elements that are critical for an effective compliance program. The first is the tone from the top. This sounds trite, but without commitment from the board in providing oversight and discipline from leadership, a compliance program is bound to fail. A key is to have an independent function led by a chief compliance officer at a senior executive position with direct access to the board and audit committee. Education and awareness is the second critical element. The importance of an ethical culture and the expectations and standards of the sales and marketing staff need to be communicated. Monitoring and auditing also are critical; people comply with what they are measured on. Not only can issues be identified before they become significant problems, but effective monitoring can serve as a deterrent to noncompliance and misconduct. I believe the OIG and sentencing guidelines should note the importance of managing conflicts of interest, because the lack of independence in decision making is the root of most corporate misconduct. Organizations should take steps to monitor and audit for conflicts of interest, such as the data analysis techniques used in the area of contract and procurement fraud. Finally, being mindful of incentives is important to prevent fraud and misconduct; instances of noncompliance are often due to individuals gaming the system.

C-LEVEL COMPLIANCE

By creating a chief compliance officer position, or elevating this role to the executive level, companies can send a message to their employees that they are serious about compliance.

ACOSTA. The pharma industry is very sophisticated about compliance of its research and development processes, investigation of drugs and products, clinical trials, manufacturing, and other related functions. Interestingly it has taken a little longer for the industry to embrace these same compliance concepts in their sales and marketing operations. Even some of the large companies didn't have a compliance officer for sales and marketing until a few years ago. Compliance positions are now being created and elevated to a senior level in this area, and the trend now is to have that individual report directly to the president.

TABUENA. If sales reps don't buy leadership's commitment to ethics and compliance they will not be motivated to act accordingly. It

should be no surprise that the recent instances of corporate wrongdoing involve leadership at the highest levels. I've seen instances where the compliance officer, if one exists, has no real authority or resources to perform the role. Also, unless performance incentives are more balanced to reflect a commitment to ethical conduct, employees will tend to be disproportionately influenced to act in ways to meet financial goals and objectives.

FREEMAN. The compliance officer position at Serono initially was created in 2002. The prominence of the position was later increased by making the full-time compliance officer a member of the senior-management team.

SAUNDERS. Schering-Plough has had compliance officers for the last six to seven years. I joined the company 18 months ago, and my position is new in the sense that I am part of the executive management team, the first truly high-level compliance officer the company has had. I have a global compliance mandate, whereas before the company had more of a diversified approach to compliance, where each business unit had its own compliance officer.

SAZDANOFF. Historically, the general counsel position at Abbott included the compliance officer responsibility. A stand-alone position of chief ethics and compliance officer was created in 2000 as part of the legal division reporting to the general counsel. In 2003, this function was moved out of the legal division and made a separate corporate functional group that reports directly to the chairman and CEO.

CORSON. The compliance officer role in our company became a formalized position under QA in early 2004, but the the position existed informally within our QA department before that. Additional resources are to be added during 2005.

ACOSTA. There are both ideological and operational barriers. If senior management does not understand how compliance relates to good business, compliance efforts have a limited, if not harmful, effect. When compliance is not endorsed by senior management, the effort is underfunded, has no owner, and is delegated to non-key stakeholders. This relegates the effort to one of a corporate nuisance, and that can create a false sense of security, which bears no relationship to the business.

A COMPLIANCE OUTLOOK

As time passes, companies will get a better handle on the rules and regulations and will be able to focus more clearly on their primary objective — furthering public health.

PITTS. Companies right now work hard to be in compliance; that is their job, which is why they have compliance departments. The question is will what "in compliance" means change to better reflect what the public wants and in ways that will advance the public health? That is the key question, and that can't be answered by the pharmaceutical companies alone; it has to be answered by legislators and regulators as well. Legislators need to realize that they can't throw stones; they actually have to do some hard work and find ways to advance the public health. What they will find to a large degree is that the current laws do the job extraordinarily well. There's no need to throw the baby out with the bath water, but they should be making smart changes that move things forward.

NASH. The U.S. Attorney's office in Boston has made it no secret that more legal action is coming. We don't know all that is being investigated, but off-label promotion appears to still be a major concern. I would say as individuals are indicted — and the news hits the front pages of the morning papers — coupled with high-profile drug safety investigations, that the attention on pharmaceutical marketing practices has yet to peak.

LEVY. Marketing compliance has already gotten better and will continue to move in that direction. The question is at what cost? As our clients build independent education divisions and add resources to the compliance functions of their organizations, what are we losing in R&D, education, and information access? The notion that education personnel or compliance personnel working in the industry are any less motivated than sales personnel to ensure that new medications are accessible and used appropriately is an oversimplification of the problem. Industry has a specific financial stake in developing and delivering drugs. It is up to the consumers of that information and product — healthcare professionals and patients — to evaluate and use these medications appropriately. While there is a role for regulatory bodies to ensure fairness and prevent ethical violations, this should be focused on the outliers that are in violation as opposed to industrywide condemnation.

ACOSTA. I expect that compliance will move from reaction to government enforcement and basic assessment and gap analyses to having well-crafted rules and regular auditing. Compliance will then focus more on sophisticated investigations and "key-hole" assessments.

DOYLE. I expect the situation will get worse. State attorney-general offices are actively soliciting whistleblowers from industry; attorneys are looking for revenue, and they are reaching out through conferences to identify potential companies to investigate. This is generating fear, and I think perceived threats will lead to a more conservative position in the industry.

SHERMAN. Things will get better in the near-term. People are struggling to find the right answers, but I am noticing dialogues between different companies. Over the next six to 12 months, companies are going to become more compliant and understand things better because now they are really taking an active role in figuring out how best to be compliant.

TABUENA. I believe things will get worse before they get better. As compliance programs began to emerge in healthcare and met with resistance, we had a saying: it would take CIA action before management gets the message. Board members are feeling the heat. Still, as organizations take a closer look at their sales and marketing activities, they may uncover issues they were not aware of that need to be addressed.

PITTS. I have seen research that shows that doctors believe that in the past pharmaceutical reps brought physicians important medical information and now they bring them sales and marketing information. Maybe a change in direction is required, and pharmaceutical companies should talk to their sales representatives and tell them they need to act less like salesmen and more like healthcare professionals who are valuable allies to medical professionals. But that also would require a change in the way these representatives are compensated and a change in the business model. Clearly, doctors need to view sales reps as an important tool in their practice, rather than just sales people.✦

PharmaVOICE welcomes comments about this article. E-mail us at feedback@pharmavoice.com.