BY ELISABETH PENA VILLARROEL

SALES & MARKETING Compliance

Keeping up with Global and Local Challenges

As pharmaceutical manufacturers continue to refine and adjust their compliance policies to meet a slew of regulations enacted over the past five years, they also are looking ahead and preparing for regulatory changes that could create many challenges. Six states have legislation that require pharmaceutical companies to report what they spend on physician sales, but the obligations differ in each state. The expectation is that many more states will follow. Additionally, New Hampshire has a prescription data restriction program. These initiatives have companies revisiting their compliance and marketing strategies to prepare for more changes. Compliance executives are looking to create flexible systems to keep up with the ever-changing environment.

Think Globally, Act Locally

As companies consider their global compliance plans, the prevailing philosophy is to look at the big picture but focus on the local details.

KANOVSKY. SANOFI-AVENTIS. Many of the specific compliance activities at Sanofi-Aventis are directed and coordinated at a local level, but they are consistent with our company's global philosophy. We think globally, but act locally. For example, we have a U.S.-compliance program that is consistent with both U.S. regulations and the Sanofi-Aventis corporate structure and philosophy.

BERTRAND. MEDIMMUNE. Our culture stressed compliance even before the company had a formal compliance program; ethical conduct and appropriate behavior have always been important. We formalized a compliance program about four or five years ago. It is a global program in the sense that we reach out to our sites in the United Kingdom and the Netherlands. But because most of the company's revenue and sales are in the United States, the program focuses most heavily on activities in the United States.

WALLACH. HEALTH MARKET SCIENCE. In Europe, prescription-level data for script volumes at the physician level are not available. As a result, sales and marketing efforts in Europe are geared toward aggregate physician data. One initial reaction to the blackout of script data in New Hampshire is that U.S. companies are looking at

Disclosure of Advertising and Marketing Spending

The following states have legislation that require pharma companies to disclose what they spend on advertising and marketing activities. These laws have not been challenged in the courts, and the West Virginia Attorney General has issued a legal opinion that the state has broad powers in the area of disclosure of marketing activities. In 2006, 11 other states proposed legislation that failed to pass.

STATE	PASSED	FAILED
California	X	
District of Columbia	X	
Maine	X	
Minnesota	X	
West Virginia	X	
Vermont	X	
Alaska		X
Colorado		X
Hawaii		X
Illinois		X
Massachusetts		X
New Hampshire		X
New York		X
Ohio		X
Pennsylvania		X
Rhode Island		X
Washington		X

Source: Sharon Anglin Treat, Executive Director, National Legislative Association on Prescription Drug Prices, Hallowell, Maine. For more information, visit nlarx.org.

ROBERT FREEMAN

Serono

Developing flexible systems and approaches is important. As each new guideline comes into place, we can prepare the necessary reports and meet the compliance requirements.

how their European counterparts are operating. From a global compliance perspective, the different levels of regulations that exist within the United States versus the European divisions of a company are starting to look more alike.

SAUNDERS. SCHERING-PLOUGH. We essentially follow three golden rules for our global marketing: we don't buy business, which goes to the notion of not paying kickbacks or inducements for prescriptions; our promotional messages are always within label, truthful, and fair balanced; and we only obtain a customer's services for sound business reasons and we always pay a fair market price. If a company follows these three rules, 98% to 99% of the compliance issues go away. There should be more focused rules with regard to different geographies or business practices. We also deploy a number of compliance strategies globally. For example, we have outlined leader behaviors that we expect all colleagues around the world to exhibit.

SRIVATSAN. COGNIZANT. Strategies to address global compliance issues should be focused on compliance dimensions drawn from business processes and data availability. Before establishing any enterprise standard, companies must clearly identify and understand the business processes and the associated data that are collected. Some key best practices include: accurately capturing data requirements needed for state/country reporting and disclosure; integrating data from many areas within sales and marketing to enable a single view of each healthcare professional; integrating travel and expense management for the field within salesforce automation tools; and focusing on automating workflow processes that involve compliance and proactively prevent noncompliant transactions. Some organizations have even created a centralized compliance office for standardized interpretation of laws around complex dimensions, such as key opinion leader management and grants.

Thought Leaders

WILLIAM C. BERTRAND JR. Senior VP, General Counsel, Corporate Compliance, MedImmune Inc., Gaithersburg, Md.; MedImmune is dedicated to advancing science and medicine to help people live better lives and is focused on the areas of infectious diseases, cancer, and inflammatory diseases. For more information, visit medimmune.com.

ROBERT FREEMAN. U.S. Compliance Officer and Compliance Counsel, Serono Inc., Rockland, Mass.; Serono, with global headquarters in Geneva, is a biotechnology leader focused on reproductive health, neurology, metabolism, growth, and psoriasis. For more information, visit seronousa.com.

STEVE KANOVSKY. U.S. Corporate Compliance Officer, Sanofi-Aventis, Bridgewater, N.J.; Sanofi-Aventis is developing leading positions in seven major therapeutic areas: cardiovascular, thrombosis, oncology, metabolic diseases, central nervous system, internal medicine, and vaccines. For more information, visit sanofi-aventis.us.

BRENT SAUNDERS. Senior VP, Global Compliance and Business Practices, Schering-Plough Corp., Kenilworth, N.J.; Schering-Plough is a global science-based healthcare company with leading prescription, consumer, and animal health products. For more information, visit schering-plough.com.

ERIC SIEGEL. VP, Deputy General Counsel, and Chief Compliance Officer, Cephalon Inc., Frazer, Pa.; Cephalon is a biopharmaceutical company that specializes in drugs to treat and manage neurological diseases, sleep disorders, cancer, and pain. For more information, visit cephalon.com.

NAGARAJA SRIVATSAN. Head of Life Sciences, North America, Cognizant Technology Solutions, Teaneck, N.J.; Cognizant is a provider of information-technology services. For more information, visit cognizant.com.

MATT WALLACH. Chief Marketing Officer, Health Market Science Inc., King of Prussia, Pa.; Health Market Science is a supplier of healthcare provider data in the United States. For more information, visit healthmarketscience.com.

JIM ZUFFOLETTI. President and Cofounder, openQ Inc., Charlottesville, Va.; openQ develops and delivers solutions for the strategic management of key relationships across the life-sciences industry as well as other industries. For more information, visit openq.com.

A Patchwork of State Regulations

With six states currently having widely varying regulations on sales and marketing practices, compliance executives are hard at work to keep up to date and to prepare for the next wave of regulations.

SAUNDERS. SCHERING-PLOUGH. State-level activities are difficult for global companies because individual pieces of legislation add to the complexity of compliance. It would be helpful if the states would adopt the PhRMA guidelines, the OIG guidance, or if there was some harmonization. As each state moves toward passing its own rules and regulations, we continue to develop systems, people, and training for each of the state requirements.

SIEGEL. CEPHALON. There are currently six states that have laws that impact pharmaceutical promotional practices. Each state has different requirements that impact us in different ways, and there are many more proposed state regulations in the works. It is very difficult to keep up with them. In order to do so, we participate in regular calls with one of our outside law firms to make sure that we have the most

Pharma's Response to Increased Regulatory Pressures

JIM ZUFFOLETTI
openQ

The challenge isn't being in compliance with one particular regulation or another; the challenge is putting in a process to accommodate changing requirements over time. It's not just about technology; this is a business challenge.

The pharmaceutical industry has witnessed a major shift in both federal and industry-related marketing regulations recently, forcing companies to practice business in a more regulated environment than ever before. Additionally, companies must also consider state-specific marketing regulations, which vary greatly depending upon the state. As a result, companies have been working diligently to determine and implement alternative marketing programs that are compliant while providing the strongest return on investment for the enterprise.

Emergence of KOL Programs as a Marketing Tool

Because companies can no longer rely solely on direct-to-consumer (DTC) advertising and salesforce efforts to increase drug and therapeutic revenue, peer-to-peer programs have emerged as one of pharma's most strategic means of reaching physicians and consumers in an educated and thoughtful way. Peer-to-peer programs play a major role in narrowing the knowledge gap between current product data and physician awareness. Influential physicians, or key opinion leaders (KOLs), are heavily relied upon by their peers to provide a realistic assessment of a drug's effectiveness. As a result, scientific discussions initiated by KOLs stand out.

A 2004 report by Cutting Edge Information highlighted KOL development as the second most important product-launch expenditure. Determining the best KOLs to collaborate with is especially important to the success of a particular drug or therapy. It is important for companies to understand the individual development objectives and capabilities of each KOL and to create a culture of transparent engagement and collaboration.

Maximizing KOL Relationships in a Highly Regulated Environment

Companies have begun searching for efficient and effective ways to manage those critical KOL relationships. Because the relationships are highly regulated on both a federal and state level, it was only a matter of time before KOL relationship management emerged as a business discipline in its own right. In an effort to maintain compliance, pharma companies are striving to accurately manage the KOL relationships while simultaneously integrating them across functional groups, from medical to marketing, and through the life cycle of a drug. Cross-functional KOL management helps to ensure appropriate use of these collaborative relationships across the organization.

Nevertheless, adhering to federal and individual state marketing compliance codes across the enterprise can still be a challenge for many companies. Since Vermont legislation differs from that of California, Louisiana, and West Virginia, companies must be well-informed about the continually changing state-specific pharma guidelines, as well as current federal and PhRMA guidelines. To best manage the fluidity of marketing regulations, pharma companies have begun adopting comprehensive and flexible technology solutions that help to achieve regulatory compliance. These strategic KOL management solutions enable companies to provide disclosure, to manage spending caps, and to enforce process roles and responsibilities. But meeting current regulations is only a starting point. With more than 20 states and countries considering legislation, a company's processes and its technology must be flexible and configurable to accommodate the ever-changing landscape.

As the pharma industry moves toward greater transparency, KOL management promotes peer-to-peer collaboration among physicians and, as a result, helps to create a strong dialogue between patients and their physicians on the best drugs and therapeutics for specific conditions. Companies that can create and successfully maintain meaningful and complex relationships with influential KOLs on a mass scale, while achieving regulatory compliance, will ultimately experience and attain increased market share and revenue.

Source: openQ Inc., Charlottesville, Va. For more information, visit openq.com.

In this day and age, everyone's requiring consistency.

Compensating thought leaders: does your company comply?

Today's life science research, development, and commercialization issues are becoming more and more complex. The appropriate payment of key opinion leaders requires increasing amounts of transparency in healthcare business practices. No standards or benchmarks as to "fair market value" for key opinion leaders have been established.

The upcoming *Benchmarks in Thought Leader Management* survey conducted by the BioPharma Advisors Network will shed light on thought leader remuneration throughout the industry. In this fully blinded third-party study that complies with OIG guidelines, top manufacturers, vendors, and thought leaders will be surveyed to determine current industry practices and reach a standard of thought leader pricing.

Taking part in this unique and timely research project will benchmark industry practices for key opinion leader payment and will benefit your company in the following ways:

- **Mitigating legal risks associated with the recruitment and payment of key thought leaders**
- **Obtaining exclusive, credible information about industry payment standards and practices**
- **Assessing fair market value for opinion leader services in various fields of medicine**
- **Avoiding the costs of conducting the research yourself and of paying too much for opinion leader services in the future**
- **Saving money by taking advantage of the low-cost, flexible study pricing**

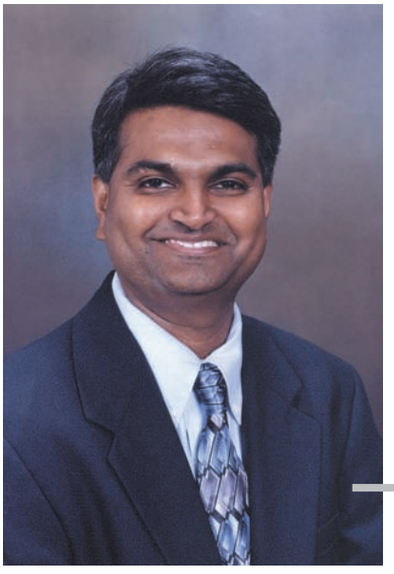
As an added incentive, your company will have the opportunity to ask additional questions specific to your business needs.

BioPharma Advisors Network
www.biopharmaadvisors.net

To learn more about the terms and conditions of the study, as well as how to get involved with this exciting research opportunity, contact Robert Nauman at BioPharma Advisors Network at **919.372.1658** or rnauman@mybpa.net.

WILLIAM BERTRAND
MedImmune

We continuously evaluate how we review our promotional materials and have refined our system to improve the pieces that we send out with our reps. This allows them to be responsible entrepreneurs with fully compliant pieces.



NAGARAJA SRIVATSAN
Cognizant Technology Solutions

The primary challenge facing the industry is to establish clear data ownership, stewardship, and governance for each of the key business processes. Any compliance effort is only as good as the data collected and owned by the organization.

MATT WALLACH
Health Market Science

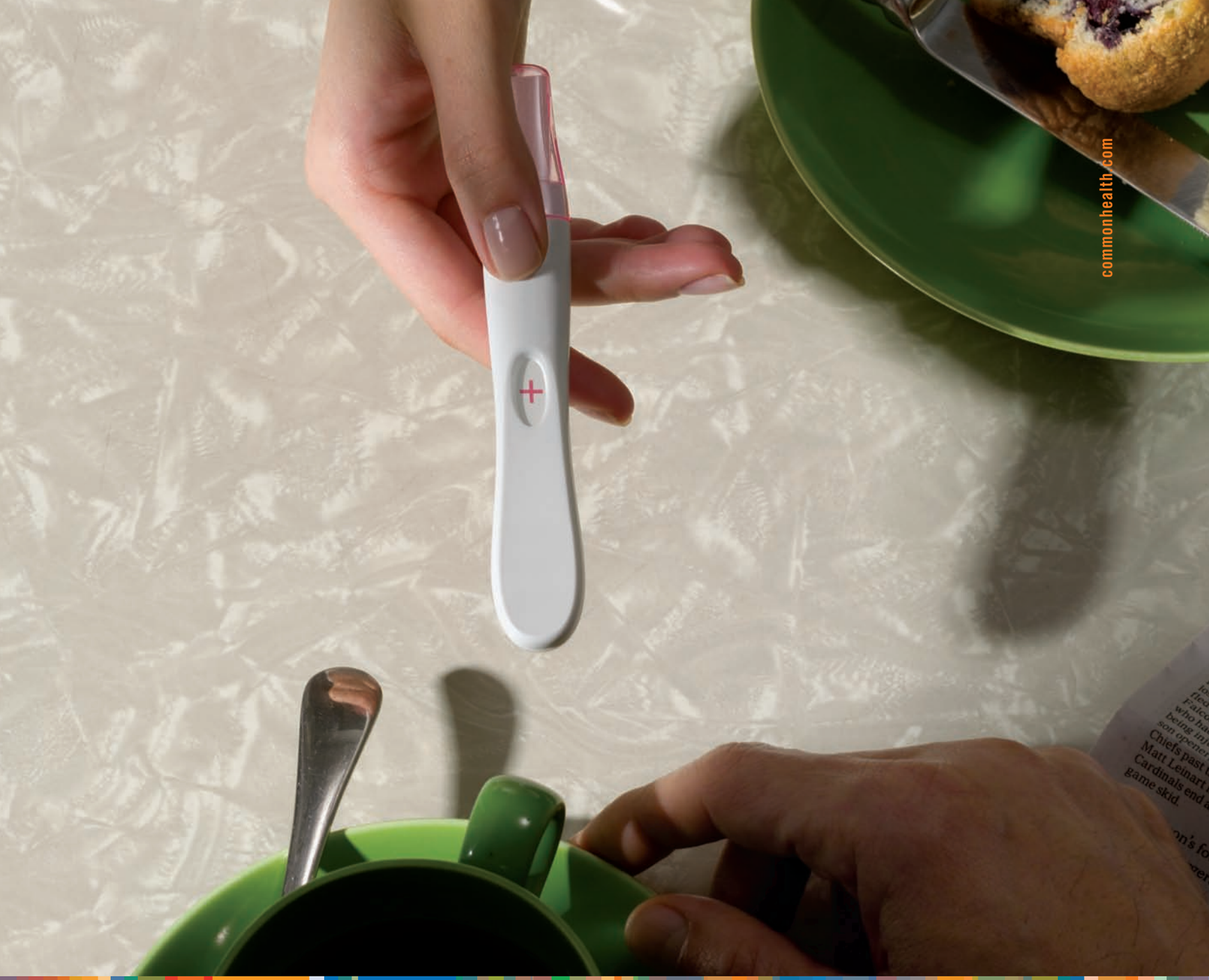
If more states disallow the sale of prescription data to pharma companies, such as New Hampshire has done, pharma companies can no longer rely on armies of young sales reps using prescription data to get their messages across to the right physicians. And the industry is shaking in its boots because other states are looking into this restriction.

up-to-date information on which laws have been passed, what the laws require, and which laws are close to passing.

KANOVSKY. SANOFI-AVENTIS. The first step is to understand what the state regulations are and what the changing environment is going to bring in terms of new requirements, new reporting, and new restrictions. We work closely with our government relations group to get information about new and pending legislation and with various industry and legal forums to keep on top of and track state regulations. It is also important to recognize that Vermont, Minnesota, and California each have regulations but they are very different in terms of scope and requirements. For example, there is an absolute dollar restriction on gifts to practitioners in Minnesota with reporting obligations regarding other activities; there are obligations in Vermont requiring the reporting of certain activities to the state attorney general's office; and in California there is a requirement that companies must have a compliance program and certain self-imposed limitations. We work with our sales and marketing and medical colleagues, as well as with our information systems and technical people, to understand the mechanics of where data are and how the information can be brought together to meet the requirements.

WALLACH. HEALTH MARKET SCIENCE. There are states that require companies to aggregate what is spent on each physician. I would deem this to be a three-fold challenge. The first challenge is a systems and process problem; the disparate data sets in systems being used today were not set up to be aggregated in a data warehouse, so companies can't report back to the state — this is a business process problem. The second challenge is a data matching and identification problem; companies have to figure out if a Dr. J. Smith in a sales representative's reporting system is the same as a Dr. J. Smith in each of the company's other systems. The last challenge is actually the easiest to solve, the arithmetic of adding up the numbers and sending them to the state. However, because pharma companies tend not to do data matching well, this makes the reporting very difficult. If data matching is done correctly, then to comply with state regulations companies don't have to change their business process. They just have to provide an alert to the field when they are getting close to the spending limit on a particular physician.

FREEMAN. SERONO. The most challenging times are to come. To date, meeting the requirements of those states that have had compliance rules — Minnesota, Vermont, and California — has been been very manageable. And the California mandate has had more of a leveling effect than being a compliance chal-



Real. Unexpected.

New opportunities can come along at any time. To keep your brand going strong, you have to be ready to seize them.

We'll make sure you're well equipped. We record hundreds of real physician-patient visits, then analyze their wants and needs through our proprietary methodology. Our library is the largest of its kind, because we've been doing this longer than anyone. We leverage this inside information to create reality-based, results-driven campaigns, maximizing every stage of your brand's life.

You want real results? We'll exceed your expectations.

CommonHealth® Collaborative Velocity℠

A WPP Company

There's nothing common about us.

Sound Bites from the Field

PHARMAVOICE ASKED COMPLIANCE EXPERTS IF THE INCREASE IN MARKETING REGULATIONS DURING THE PAST FIVE YEARS IS HAVING A POSITIVE OR NEGATIVE IMPACT ON THE INDUSTRY.

JANN TORRANCE BALMER, RN, PH.D., is Director of Continuing Medical Education at the University of Virginia School of Medicine, Charlottesville, Va., an ACCME-accredited school of medicine. For more information, visit healthsystem.virginia.edu.

"I don't believe that the regulations alone have a negative impact on marketing but the combination of these new regulations, the cost of developing systems to address the guidelines, coupled with the continued public scrutiny of the costs of pharmaceutical products and medical devices can have significant implications for these companies. The marketing guidelines outlined by the federal government, specifically the FDA and the OIG, provide clearly defined parameters designed to protect the interest of the public. These federal guidelines are consistent with the PhRMA and AdvaMed guidelines, as well as the AMA Resolutions on Ethics and Gifts to Physicians.

There is significant pressure and attention from all sectors to ensure that the pharmaceutical and medical-device industries are embracing the best interest of the public in their efforts to market products.

Specifically, the OIG requirement for a compliance program mandates that these companies develop a structure that separates education and promotion and that fosters patterns of behavior that promote the public trust.

The attention from the media and large dollar amounts of settlements between the federal government and the pharmaceutical industry have created a heightened level of public awareness of the challenges faced by these companies as they balance public trust with the business of medicine."

GARY FINGERHUT is Executive VP (responsible for the global life-sciences practice) at Axentis Inc., Warrensville Heights, Ohio, a provider of enterprise governance, risk, and compliance management software. For more information, visit axentis.com.

"From a financial viewpoint, increased regulation has shifted resources away from research and development. This diversion of resources negatively impacts the identification of new and novel compounds, as well as the appetite for taking on the risks associated with research into new therapies and classes of compounds. This heightened regulation also has the potential to negatively impact mortality and the quality of life. At the same time, however, increased regulation and scrutiny have led to improvements in access to all company-sponsored study data. This access benefits the healthcare practitioner and removes any bias commonly associated with such published information. This, in turn, improves the decision-making process of the practitioner.

Pharmaceutical companies want to get the most return on investment they can from their regulatory compliance programs by leveraging the process and technology investments across multiple areas."

DARREN JONES, CIA, is Senior Manager, Healthcare Risk Consulting, Protiviti Inc., Menlo Park, Calif., a provider of independent internal audit and business and technology risk-consulting services. For more information, visit protiviti.com.

"The regulatory changes in guidelines and enforcement have been a positive adjustment, bringing integrity back to the pharmaceutical industry, and ensuring the objectivity of physicians, and ultimately enhancing patient care. The way pharmaceutical companies implement their commercial compliance programs, however, has often been overly restrictive. Some companies have implemented intrusive controls on top of their existing business practices. Similar to other compliance programs, for example Sarbanes-Oxley, commercial compliance programs need to be tailored to an organization's corporate culture and business practices with sustainable, efficient, and compliant sales and marketing processes. Commercial compliance controls should be embedded within those processes in a manner that enhances the innovative nature on which the industry was built. The industry needs to strike a balance between compliance and innovation in its marketing and brand-awareness efforts."

PETER SANDFORD is Executive VP of NXLevel Inc., Hopewell, N.J., a learning company that specializes in engaging technology-based learning programs, including custom and off-the-shelf compliance programs. For more information, visit nxlevel.com.

"Marketing regulation plays a major role in prompting companies to establish cultures that value ethics and compliance. As a result, the average consumer, for the first time, is being presented with detailed product information, including risks, through the mainstream media. Over time, this level of communication will foster an environment of trust and public good will. As the industry moves to being a source of unbiased clinical information, the public will recognize companies as advocates for better public health, and positive life-long relationships with consumers will follow."

WENDY H. SCHWARTZ, ESQ., is a Partner at Reed Smith LLP, New York, a top-25 international law firm with 1,100 lawyers located in 13 U.S. and four European cities. For more information, visit reedsmith.com.

"The increase in regulatory scrutiny of marketing practices has had the positive effect of forcing the industry to take a hard look at long-standing practices that benefit from periodic re-examination, which can be open to abuses. The issue is finding the right balance. There needs to be enough regulation to encourage self-examination and correction without complicated, multilevel strictures that overburden and confuse the marketing process."

To access a FREE Podcast on this topic, featuring Peter Sandford, go to pharmavoice.com/podcasts.

lenge. But some of the specifics in the legislations that are expected to take effect in 2007 by Maine, West Virginia, and Washington, D.C., are going to be quite challenging for us and for many other companies.

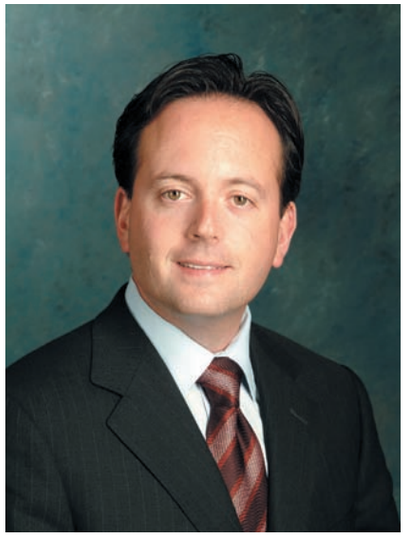
Proactive Prevention

Training employees is a key component of any compliance program. Providing instruction and protocols through a number of communications channels is important for reinforcing the corporate mission and message.

BERTRAND. MEDIMMUNE. We pride ourselves on being responsible entrepreneurs, so the mainstay of our program is to conduct proactive compliance training. While we have the standard approaches that most pharmaceutical and biotech companies have, such as a committee with representatives from medical affairs, legal, regulatory, sales and marketing, public affairs, and other groups to review materials, we try to go a level deeper. Members of our compliance team ride with sales representatives, go to regional meetings, and spend time with folks in the field. Communication is the best medicine; we make sure people understand why we create a new policy and why we have to make changes as opposed to mandating processes from the home office.

FREEMAN. SERONO. We use a Web-based training program to provide compliance education to all employees. We supplement that with live sessions, Webcasts, and other types of communications that are more tailored to particular functions. We add periodic updates and messages that go out by e-mail, via our Intranet, and through other channels that continue to raise awareness around the specific compliance issues and objectives. In addition, we carefully monitor the activities of our sales and marketing personnel to ensure that their activities are in compliance with the established policies and procedures.

SIEGEL. CEPHALON. The crux of my job as a compliance officer is to develop programs that prevent and deter noncompliance. We spend the bulk of our time training in the areas where we believe the company is at greatest risk, such as sales and marketing practices. The medical and clinical fields are beginning to receive more attention, so we are increasing our efforts in those areas as well.



BRENT SAUNDERS
Schering-Plough

Compliance is a verb, not a noun. We can't become complacent and think we have reached a state of compliance. Compliance is something that we strive to make part of our operational DNA.

Rules and Regulations

Compliance executives agree that the varying regulations placed on the industry during the past five years have made their mark, however, opinions differ as to which regulation has had the most impact.

SAUNDERS. SCHERING-PLOUGH. In the short term, the regulatory environment will continue to become more complex and the enforcement environment, particularly in Europe, will become much more active. Another big challenge is the broadening scope of the enforcement environment. Many of the enforcement actions today in the United States are around sales and marketing practices, and in the future those enforcements will likely look at practices, such as clinical trials, publications, and medical affairs. To be proactive, compliance officers need to start thinking beyond just sales and marketing compliance.

FREEMAN. SERONO. The PhRMA code was a signal event in the evolution of compliance efforts in the sales and marketing area. Before that there were significantly more perspectives among companies. The code changed the direction of the industry as a whole; today most companies view compliance issues fairly similarly.

STEVE KANOVSKY
Sanofi-Aventis

With changing legislation and enforcement, as well as changes in each state, we can expect that there will be more oversight and increased burdens in terms of documenting and reporting, but not necessarily new restrictions.

SIEGEL. CEPHALON. I believe the FDA Promotion and Advertising Regulations have had the most impact on the industry as a whole. These regulations are at the core of what pharmaceutical marketing is all about. We have spent a significant amount of time focusing on this area in our organization. Much of what we see in the headlines about our industry is relat-

A Positive Look at Compliance

ERIC SIEGEL
Cephalon

As the industry works to remain compliant with sales and marketing regulations, compliance executives are charged with enforcing processes throughout their companies. Eric Siegel, VP, Deputy General Counsel, and Chief Compliance Officer at Cephalon Inc., shared with PharmaVOICE why compliance can be a positive experience for companies and their employees.

Compliance brings a number of benefits, and despite the fact that the rules imposed may at times make people feel a bit restricted, we remind employees of these benefits and the message becomes more palatable.

Contrary to what people may think, compliance programs do not prevent businesses from achieving their goals. Very often compliance dovetails nicely with a company's business goals and can result in the company spending money wisely by carefully planning its marketing initiatives and activities. Compliance in sales and marketing is resulting in initiatives that have been well-thought out and well planned; this is one way in which companies are not only implementing compliant programs but ensuring that the programs fit their goals.

LEVELING THE PLAYING FIELD

Most pharmaceutical and biotech companies have developed compliance programs that contain very similar types of rules because everyone is starting from the same vantage point in terms of the PhRMA code, OIG guidance documents, and so on. This has leveled the playing field. Previously, companies were escalating their spending on dinners, sporting events, and similar activities. Today, since companies are all working within similar guidelines, marketing and sales executives are free to focus on the programs that are going to work for the company and those activities that are truly going to drive the business.

THE SALES PERSPECTIVE

There has been a great deal of positive feedback from sales representatives regarding compliance programs because they no longer have to be entertainment directors who have to spend their time taking doctors to shows and sporting events. Sales reps are serious, knowledgeable professionals. Working within the compliance framework allows them to do what they do best: impart their knowledge to customers about products and provide education to physicians. Compliance programs allow sales representatives to take much more pride in what they do. In the recent past, activities such as dine-and-dash programs and gas-and-go initiatives, which were common in the industry, made it difficult for representatives to take their jobs seriously.

REPUTATION ENHANCEMENT

Perhaps most importantly, compliance programs help to protect the company's reputation. Next to its employees, the company's reputation is probably its single most important asset. With all of the negative press these days, anything that companies can do to help protect their names and the names of their products is absolutely critical. Compliance programs and the employees who support them go a long way to help to build a positive image for the industry.

FEEL-GOOD COMPLIANCE

Virtually all employees want to work for a company that they can feel good about and that they think is committed to doing the right thing. By having a compliance program and advertising it to employees, people understand that their company is committed to doing the right thing. People feel good about working for a company that cares about its employees, its customers, and patients. In an industry such as ours that is somewhat under siege, these positives should not be discounted.

ed to settlements with large components that deal with off-label promotion, which stems directly from companies that allegedly have not been following these promotional and advertising regulations.

BERTRAND. MEDIMMUNE. The California compliance law had a big impact, and it drove home the fact that throughout the entire organization we were going to need to make certain changes, such as adopting the PhRMA code and ensuring that we are fully compliant with the OIG guidance document. We have been doing things the right way since the inception of the company, so many of these changes simply meant documenting and formalizing certain aspects of the compliance program.

WALLACH. HEALTH MARKET SCIENCE. The regulation that has had the most expense put against it is the PDMA and the need to validate physicians before they can be given a sample. Because of this regulation, companies tried to move away from paper sample cards and toward PDAs so they could capture an electronic signature, which meant that the entire salesforce automation system had to be validated. A validated system is twice as expensive to implement as a nonvalidated system because of all the additional documentation, testing, and training required.

KANOVSKY. SANOFI-AVENTIS. The OIG guidance and the various corporate integrity agreements have established what the government's expectations are and the framework for effective compliance. This is probably one of the biggest changes in the last five years versus the previous five to 20 years.

SRIVATSAN. COGNIZANT. The regulatory environment is expected to become even more stringent. In the United States, there is an expectation that an increasing number of states will adopt marketing and price disclosure legislations based on the PhRMA code of conduct and other state actions. This could potentially lead to a scenario where organizations will have to comply not only with federal mandates but also cater to individual requirements from each of the states. ✦

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