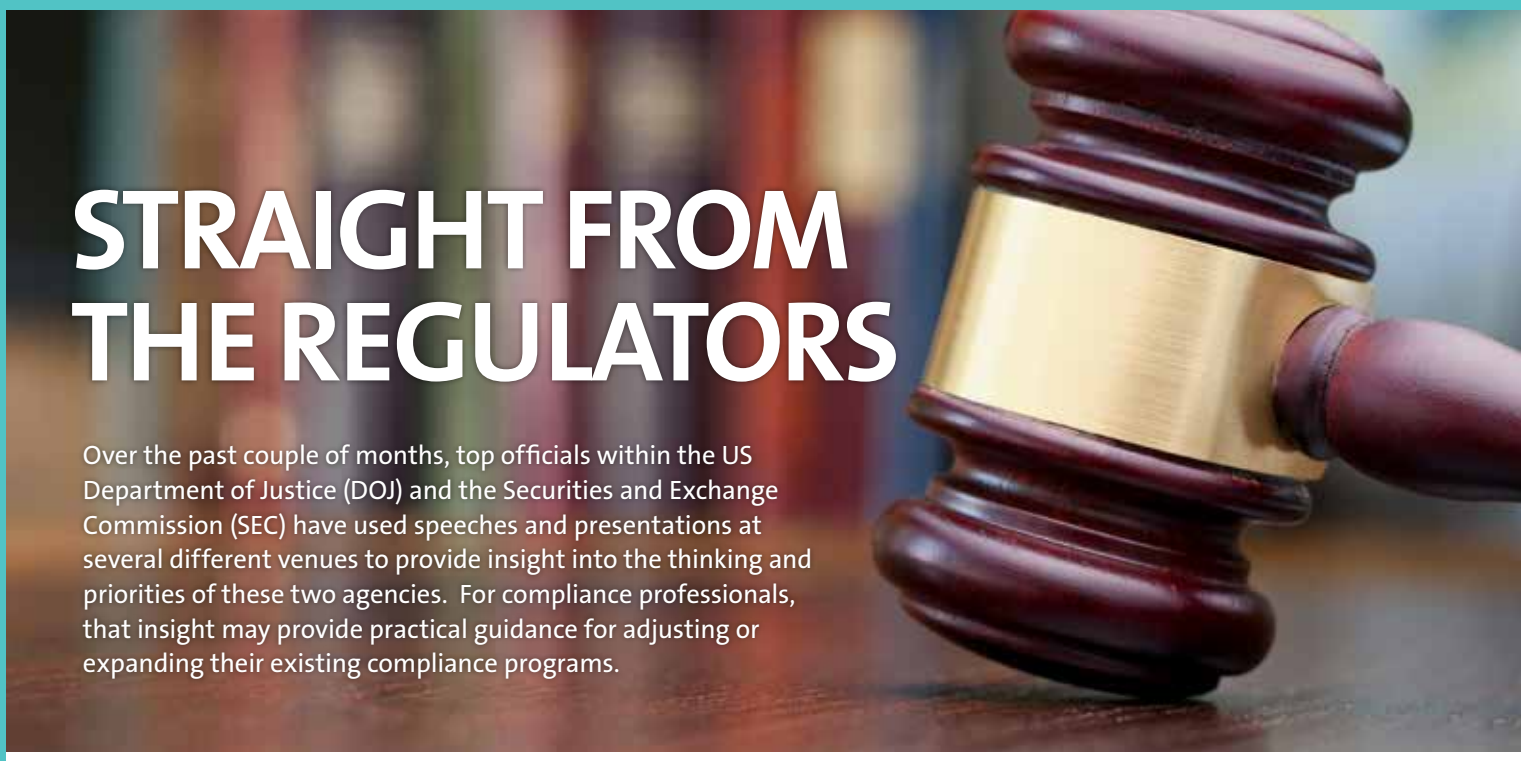
Life & Health

Health Care Compliance Communiqué

Q2 2015



STRAIGHT FROM THE REGULATORS

Over the past couple of months, top officials within the US Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) have used speeches and presentations at several different venues to provide insight into the thinking and priorities of these two agencies. For compliance professionals, that insight may provide practical guidance for adjusting or expanding their existing compliance programs.

Common Compliance Issues for the Pharmaceutical Industry

For pharmaceutical companies, the most important information may have been provided at CBI's Pharmaceutical Compliance Congress by Andrew Ceresney, Director of SEC's Division of Enforcement. Ceresney spoke on three major topics: FCPA, internal controls, and disclosure. Here is a brief breakdown of the Commission's recent achievements and its ongoing focus on the industry.

- Acknowledging SEC's broad area of enforcement activity, Ceresney quickly zoned in on the pharmaceutical industry, saying, "... the pharma industry is one on which we have been particularly focused in recent years." Three specific types of misconduct were identified as the most common in the Commission's FCPA enforcement cases: "pay-to-prescribe" bribes; bribery to get drugs on approved formulary lists; and bribes disguised as charitable contributions.
  - **Pay-to-prescribe** cases center on bribes paid to public official doctors and hospitals for prescribing specific medications or medical devices. Ceresney breezed past the predictable, simple payments of cash to doctors or medical officials to what he called more innovative schemes to reward prescribing physicians for their illegal actions. Among the innovative schemes: a "point program" under which government doctors accumulated points for the number of prescriptions written for the company's products. The points were then redeemable for gifts ranging from medical books to cell phones. In

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STRAIGHT FROM THE REGULATORS *(Continued)*

other countries, doctors in senior positions in government health care institutions who agreed to use the company's products were awarded a percentage of the medication's value as cash, free products or expensive travel.

- **Formularies:** Bribery also rears its head when it comes to having your company's products included in formularies. One company's subsidiary made payments to a small foundation created by a regional government health official. The official placed the company's drugs on the government's reimbursement list. When combined with other FCPA violations, the company settled charges against it for $29 million.
- **Charitable Contributions:** Charitable contributions represent an all-too-common form of bribery. They also represent a type of bribery popping up on SEC's radar. In one case, a medical device company made a substantial contribution to fund a library at a public university. The lab was strongly supported by a public hospital physician. In another case, a company made a contribution to a foundation headed by the director of the governmental body funding the purchase of pharmaceutical products.

It is important to note that in each of these cases, the violations were committed by subsidiaries of the companies – but it was the companies that faced SEC's enforcement actions and, eventually, settled their allegations for far more than the original bribe.

Ceresney moved to a discussion about how a robust FCPA compliance program might have avoided some of the described violations. "I can't emphasize enough the importance of such programs," he said, "This is a message that I think has started to get through in the past five years."

Chief compliance officers in the pharmaceutical industry have been well-aware of the importance of robust compliance programs, but Ceresney offered reminders about some important elements of those programs. "The best companies," he explained, "have adopted strong FCPA compliance programs that include compliance personnel, extensive policies and procedures, training, vendor reviews, due diligence on third-party agents, expense controls, escalation of red flags, and internal audits to review compliance." He then went on to emphasize the importance of risk assessments based on the factors listed in the DOJ/SEC Resource Guide on the FCPA. An area of particular interest to him (and, as noted, something that appears in each of the cases described during his presentation), was third-party due diligence. He focused strongly on distributors, explaining that the use of distributors can create "... the risk that the distributor will use their margin or spread to create a slush fund of cash that will be used to pay bribes to foreign officials."

Internal Controls

We often hear about the importance of internal controls, but Ceresney focused specifically on financial controls, saying, "I am pleased to report that we have recently seen an increase in enforcement actions brought in the financial reporting area, plus significant new investigations underway." Enforcement actions increased more than 40% between 2013 and 2014 and new investigations during the same period increased 30%. Ceresney described one recent case in which SEC charged a company for having inadequate controls. The company's recorded revenue in a particular segment lacked sufficient proof of customer acceptance of the orders in question. The company's internal controls failed miserably to meet the standard expected by SEC: inadequate written accounting policies and procedures, failure to properly train personnel on how to evaluate orders; and insufficient formal review of the judgment calls made by a small group of people.

"Instead of a check-the-box mentality, it is important to use careful thought at the outset to how controls should be designed in light of a firm's business operations," said Ceresney. In many cases, the SEC and even the DOJ will pursue enforcement actions against companies for internal control violations even in the absence of fraud allegations. Whether in the pharmaceutical industry or not, public companies are held to a standard of financial responsibility and compliance; the inability to meet those standards puts the company at substantial risk of enforcement under various laws including the FCPA and Sarbanes-Oxley.

STRAIGHT FROM THE REGULATORS *(Continued)*

Disclosure

"Now, financial reporting is not just about financials. It is also about disclosure ... "Ceserney emphasized. He continued, "One significant type of key event we see causing problems with disclosure in our industry is disclosures on your dealings with the FDA." In a recent case, the SEC charged a medical technology company, its CEO and its CFO with deficiencies in disclosures related to its FDA filings. The deficiencies were eight misleading public filings stating that the company intended to file a Premarket Approval application with the FDA while, in reality, the CEO and CFO knew that the company was unable to meet its publicly stated deadlines.

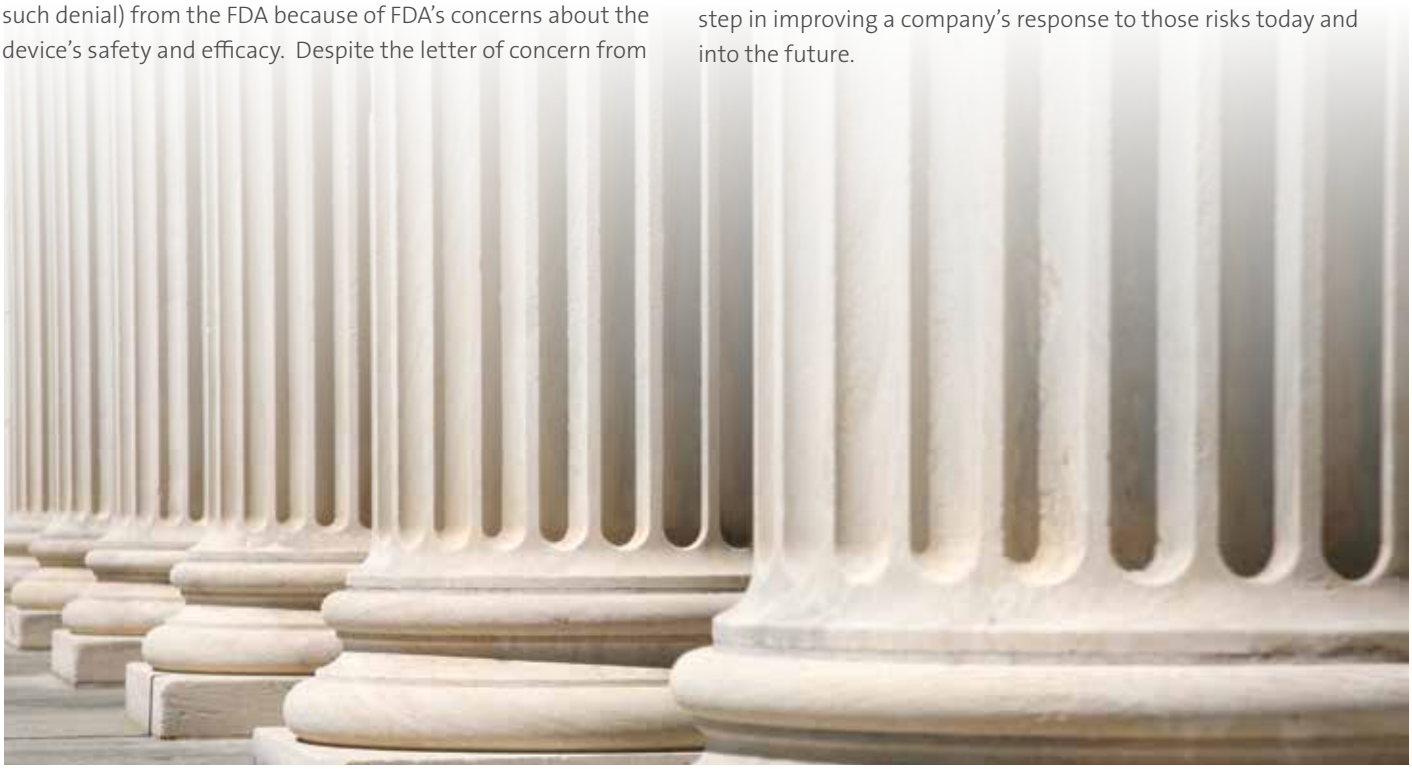
In another case, a biopharmaceutical company and related entities and individuals were charged with misleading investors about the regulatory status of the company's drug product. The FDA had placed a full hold on the company's application to begin Phase 1 clinical trials, but an officer of the company informed potential investors that Phase 2 would begin in 60-90 days and that FDA approval should come within the year.

In a final case, a medical imaging company and its CEO were charged with fraud for misleading shareholders about the FDA's opinion of a device under development. The SEC alleged that the company had received a denial of clearance (the third such denial) from the FDA because of FDA's concerns about the device's safety and efficacy. Despite the letter of concern from the FDA, the company's CEO downplayed the concerns, calling them "not substantive" and that the FDA did not really question the technology.

When companies in our industry think about "disclosure," it is often related to disclosures to governmental agencies about potential fraud. However, in the last case cited by Ceresney, the settlement with the company required exceptional transparency of the company's interaction with the FDA. Among the provisions of the settlement, the company agreed to promptly share FDA correspondence on its website or in a form 8-K and to require all officers and directors participate in training regarding compliance with securities laws.

Fraud and Beyond

Regulatory and legal compliance is a challenge for companies in any industry, but the risks facing firms in the Life Sciences industry are particularly thorny. A company's compliance with the FPCA, securities law and transparency about its interactions with the FDA create a complex challenge that requires the attention of multiple members of any corporate organization – from directors to CEOs, CFOs and CCOs. Those challenges will only intensify. Fraud under the FCPA is only one aspect of the risks companies face. Understanding the broader range of what the SEC views as particular risk areas and tracking recent enforcement actions is one step in improving a company's response to those risks today and into the future.



PUBLIC ANGER, BUSINESS RISK

Public unrest and societal instability have always been concerning factors for companies in decisions about establishing operations in individual countries. In the past several years, social unrest has become even more of an issue as demonstrators around the world have demanded an end to corruption in government.

Major demonstrations have not been limited to one nation, one economic profile or even one continent. In South America, governments including those of Venezuela, Brazil and Peru have been shaken. In Europe, Hungary, Spain and Ukraine are only three of the countries that have faced recent demonstrations demanding an end to real – or perceived – corruption in their governments. Other countries with notable and growing public outrage directly linked to corruption in government include India, Kenya and Kuwait.

Tightened Regulations

Public demonstrations have not been without consequence. In some cases, senior government officials including national presidents, vice presidents and ministers have been forced from office, either through "voluntary" resignation or strong public "encouragement." In other cases, from Germany to China, new or expanded anti-corruption legislation has been proposed or enacted, seemingly aimed at preventing or controlling the escalation of anti-government sentiment.

Although these national laws are unique to their countries and economies, there are several trends that deserve to be noted by global companies. Consider the following:

- Companies are expanding requirements for comprehensive compliance programs. Spain is one of several countries that now requires and regulates the content of company compliance programs. Among the requirements are standards and controls capable of mitigating any detected criminal activities and financial controls to prevent crimes. In Ukraine, a new law recently became effective requiring most companies to have compliance programs.

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PUBLIC ANGER, BUSINESS RISK *(Continued)*

- Some countries have proposed or enacted legislation that will hold companies liable for the corrupt actions of their employees. Vietnam, for example, has proposed replacing its former penal code with one that criminalizes companies for criminal behavior by employees. Conversely, Germany criminalizes the behaviors of individuals, not companies, but the country has a solid track record of cooperating with government agencies including the US Department of Justice to prosecute companies under US laws such as the FCPA.
- Increasingly, companies are prosecuting their own government officials for accepting bribes. The US FCPA makes it illegal to solicit, offer or give bribes to foreign government officials. In contrast, the UK's Bribery Act criminalizes the acceptance of bribes as well, opening up a much broader liability for companies. Although the FCPA does not make accepting bribes as a violation of the FCPA, it is important to remember that other US laws, including anti-trust and fraud laws, may come into effect for accepting bribes, not only from foreign government officials but also from private companies and US government officials.
- The cooperation among national governments and international law agencies is intensifying rapidly. Interpol has increased its use of global warrants on corrupt officials around the world, giving all local governments authority to detain listed individuals. While GMP violations are not immediately viewed as potential anti-corruption violations, the dramatic growth of counterfeit drugs has led countries to reconsider the connection between drug production and potential corruption.

Recognizing Risk

Traditionally, the FCPA was the primary international anti-corruption law and represented the greatest compliance risk for global companies. The FCPA focused directly on the actions of individuals and companies that offered or paid bribes to foreign government officials. Since then, the UK Bribery Act set a new standard of corporate liability by making both the acceptance and provision of bribes illegal; in addition, it expanded the criminality of bribes to include corporate entities with any presence in the UK. As countries follow suit in criminalizing the giving or receiving of bribes, companies are increasingly caught in the crosshairs of global operations, particularly as the prosecution of government officials for corruption traces back to the individuals or corporate entities at the other end of the transaction.

Anti-corruption compliance programs have long formed an important component in global business operations. Similarly, risk has been an essential element of those programs. Now, risk is evolving into a much more complex challenge. Top-performing companies recognize those added risks and respond with expanded, targeted education for employees likely to encounter those risks.

EMPLOYEE SUPPORT OR EMPLOYEE FATIGUE?

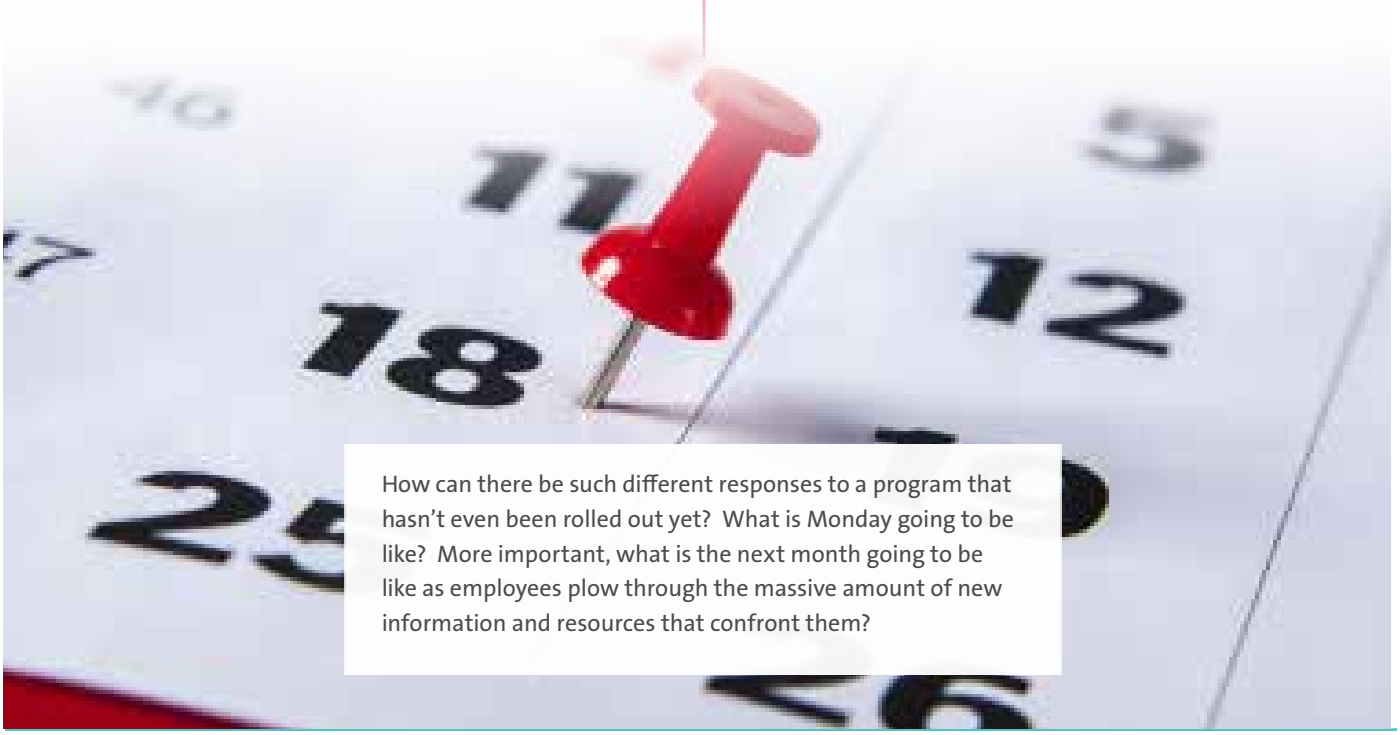
Imagine this familiar scenario...

On a Friday, after months of grueling work to develop a new, enterprise-wide training program, a CO looks over the program one last time before the planned rollout on Monday. The most engaging instructional designs have integrated creativity and interactivity into a new generation of training resources; a cutting-edge infrastructure has been installed to help employees design their own curricula of "required, recommended and opportunity" resources; new training modules have been added to provide employees with pathways to advancement; and, for the CO, new tracking and monitoring capabilities have been designed to measure employee competency and regulatory compliance.

Now, imagine two separate responses to the same scenario:

The CO looks at the program with satisfaction, anticipating that employees will embrace the technology-driven program that allows each employee to complete required training as well as pursue courses for long-term learning and advancement. The system has been designed, from beginning to end, to streamline the training function and the CO is looking forward to improved monitoring capabilities. After many months of work, the CO enthusiastically announces the rollout on Friday, promising employees a better, more advanced training program that incorporates new designs and better technology. Monday can't come some soon enough!

On Friday afternoon, as they look forward to the weekend, employees receive a corporate communication informing them about a "new, better" training program. Young, technology devotees zoom in on the new infrastructure. Older workers look at the same prospect of a new, advanced technology infrastructure and shudder, worried that they will be left behind. Both groups suspect that the new program is designed to make management's job easier while plopping new work and responsibilities on them, all without giving them more company-paid time to complete that work. Monday is not anticipated with enthusiasm, but with dread.



How can there be such different responses to a program that hasn't even been rolled out yet? What is Monday going to be like? More important, what is the next month going to be like as employees plow through the massive amount of new information and resources that confront them?

EMPLOYEE SUPPORT OR EMPLOYEE FATIGUE? *(Continued)*

In his substantial effort to create a cohesive, comprehensive training program that integrates three goals -- compliance, competency, and employee support for advancement – he has overlooked the power of the rollout on employee understanding and acceptance. From the vantage point of 20/20 vision, the responses of the CO and employees are predicable. Yet, the responsibility for the employees' responses lies on the shoulders of the CO. In the end, the point is not how good the program looks on paper; the goal is how well it is accepted and used by employees.

Creating a Successful Rollout

There are a number of elements COs can employ to build a training program roll-out that encourages employee acceptance and meets corporate objectives. Answering a few key questions can set up important signposts to that initial rollout and short-term implementation.

- **Why?** Several months before the planned rollout (when the rumors swirl about new responsibilities for every employee) it is important to answer the basic question of "Why?" Why are you working on a new program? Why are we going to have these new courses? Why are we going to be loaded with a pile of new work? In short, why are you doing this? The suspicion among employees is likely to be that the program is being designed to make life easier for management. It is important to emphasize that the program is being designed to support employees by reducing redundant coursework, improving the targeting of courses to job functions, implementing technology that allows employees to complete courses anywhere and at any time, and giving employees easily-accessible learning resources for career advancement. The underlying theme should be, "This is part of our commitment to you. We want to make your learning more relevant to what you need, more interesting, and less repetitive. We believe it will make your jobs more satisfying and your career advancement more accessible."
- **When?** Few things are more overwhelming than being greeted by a pile of information that you are expected to read, digest and translate into behavior – all on your time and according to schedule. That's what some employees face and that's the common perception of a "new" training program. Instead, spend time introducing the rollout process. Yes, you'll be starting up the new program on Monday with two courses that are required for everyone (FCPA, for example, or What Does FDA Do?) Those courses are required for regulatory compliance but more important, their content is already familiar to employees. The first step in the rollout should be designed to allow employees to become accustomed to the infrastructure. More technology-savvy employees will appreciate the accessibility of interactive, scenario-based or game-related courses on their mobile devices. Other employees will appreciate dedicated on-site training about the infrastructure, how it works and, most important, how it will make their lives easier and less stressful.
- **What happens next?** Once the initial courses have been rolled out, give employees a reasonable timeline for the rollout of additional resources. Make sure they are rolled out slowly and in small "clumps." Begin to sprinkle in courses that are not part of the "required list" or even the "recommended list." Introduce the third resource as "We want to make it easier for you to advance in your careers so we've included advanced learning resources." A separate area for these resources should be considered to minimize the potential for employee fatigue just looking at the list of courses.
- **What if the courses are too difficult or incomprehensible to particular employee segments?** Your improved monitoring capabilities will enable you to see which employees are completing which courses. As a result, gaps in understanding or response are quickly identifiable. Is the content too complex for a particular group? Might language be a problem for some employees in completing the courses? Do some employees seem to have problems with the infrastructure? It is important that employees feel confident in complaining about – or complimenting the new program. Does it work better than the former program? Great. Is it worse, more cumbersome, less understandable? Okay, then employees might need more preliminary training on how to use the system, understanding the subject matter, or understanding what the new program has to offer them.

EMPLOYEE SUPPORT OR EMPLOYEE FATIGUE? *(Continued)*

Training Doesn't Have to Be Miserable!

Why is training always so miserable? It doesn't have to be, even though there is a familiar groan heard around the corporate world as new programs are rolled out. Instead of using a stick, try carrots. For example, create competition among different departments in a specific location: Which group can complete four courses with the highest grades and least time? Winners get pizza on the company. Or, which employee can achieve the highest, most consistent completion scores over a three-week period? The winner gets two tickets to a good steakhouse in town. Or, which department has the best suggestions for improving the program? The winning department receives an afternoon barbeque – on two hours of company time. In each case, both company and employees win. The company gains enthusiasm for the program, high completion rates and strong test scores. Employees receive corporate recognition, "winning" in competition with their peers, and often, a willingness to help co-workers learn the infrastructure or subject matter.

Corporate training is inevitable and most companies undergo a constant process of upgrading, expanding, revising and restructuring their training programs. Making sure the rollout and early implementation are successful is a critical step in making sure the program is successful over the long term – and, even more important, employees view the company as responsive to their needs and supportive of their learning goals.

About UL EduNeering

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UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council, and the Duke Clinical Research Institute.