Life & Health

Health Care Compliance Communiqué

Q3 2014

THE CHANGING PHARMA WORKFORCE

Compliance Officers know that an essential element of effective communication and training is understanding their company's workforce. For years, COs and training directors have worked to accommodate the unique language and cultural challenges presented by a global workforce but a recent study by George Mason University's Institute for Immigration Research suggests that the US Pharmaceutical workforce may require a closer look.

Shaun Michel and Dr. James Witte of the Institute recently released, *Immigrants Working for US: Pharmaceuticals*, which sheds new light on the makeup of the US workforce in the Pharmaceutical industry – and may highlight topics that should be considered by COs and training professionals.

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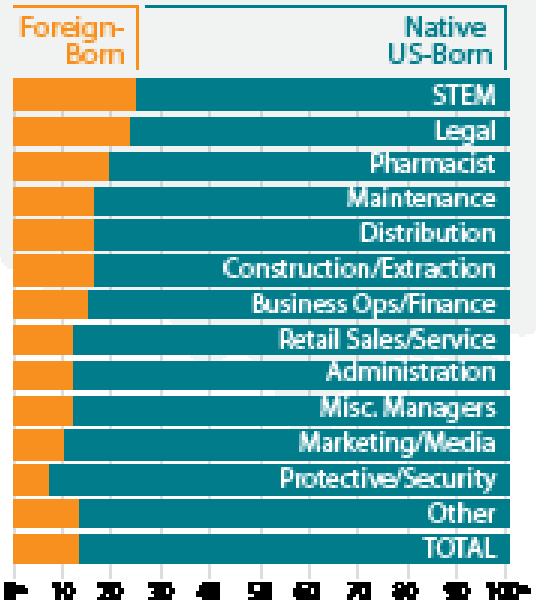
THE CHANGING PHARMA WORKFORCE *(Continued)*



Although the study was released in 2014, some of the numbers date back a couple of years, since they are the most recent available. Nevertheless, the numbers paint a picture worth seeing. In 2011, immigrants to the US represented 17% of the employed labor force in the Pharmaceutical industry (compared to 13% of the US population). Most of those immigrants are from the world's fastest growing Pharmaceutical markets. Retail represents the vast majority of Pharmaceutical employees. When that retail sector is broken down, diagnostic and treatment, supervisors of retail sales and cashiers represent the largest sub-group of employees.

Manufacturing accounts for 30% of the industry's immigrant employees, with the largest occupational category comprising R&D, and production and distribution as the second largest in the industry.

Compliance and training personnel carry responsibility for ensuring that their company's corporate compliance training and reinforcement are understood by all employees and relevant third parties. While the vast majority of the industry's immigrant employees are fluent in English – in fact, many immigrants earn advanced degrees in US or other English-speaking institutions of higher learning – there is little risk that immigrant employees would be disadvantaged in learning and applying compliance-mandated information from standard materials distributed across the US. Nevertheless, the growing number of immigrant employees in the US Pharmaceutical industry should remind COs and training personnel of the importance of knowing their workforces and ensuring that all employees have equal access to the compliance knowledge disseminated by the company.

LEARN MORE in ***Managing the Risks of Third Party Intermediaries***. Download our white paper for an in-depth look at assessing and managing TPI risk, anti-corruption training, monitoring and reinforcement, and the cost of noncompliance.

FAILURE TO FOLLOW UP LEADS TO WHISTLEBLOWER AWARDS

Two small press releases on the website of the US Securities and Exchange Commission serve as large reminders of the risk associated with ignoring internal reports of possible wrongdoing.

In July, 2014 the SEC awarded more than $400,000 to a whistleblower who reported fraud to the SEC after the company failed to address the issue internally. According to Sean McKessy, chief of the SEC's Office of the Whistleblower, "The whistleblower did everything feasible to correct the issue internally. When it became apparent that the company would not address the issue, the whistleblower came to the SEC in a final effort to correct the fraud and prevent investors from being harmed."

A month later, the SEC awarded $300,000 to a company employee who performed audit and compliance functions. As in the previous case, the employee reported wrongdoing to the SEC after the company failed to respond. In fact, the employee did everything right, reporting concerns of wrongdoing to appropriate personnel, including a supervisor. When the company failed to take action within the required 120 days, the whistleblower reported the same information to the SEC, leading directly to an SEC enforcement action.

Although the two cases appear similar, there is one important distinction that should be noted by companies. In the second case, the employee had performed audit and compliance functions at the company. According to SEC's McKessy, "Individuals who perform internal audit, compliance, and legal functions for companies are on the front lines in the battle against fraud and corruption. They often are privy to the very kinds of specific, timely and credible information that can prevent an imminent fraud or stop an ongoing one."

Companies routinely credit employees with being their "eyes and ears" in the fight against fraud and corruption, just as compliance programs routinely highlight the importance of reporting possible wrongdoing through hotlines or to appropriate personnel. When companies refuse to listen to employees who are doing all the right things and following their employers' Code of Conduct, the companies risk turning their "eyes and ears" into whistleblowers.

SUNSHINE AND PARTLY CLOUDY ON OPEN PAYMENTS WEBSITE

Which companies are paying how much to which doctors? ProPublica has tracked payments from Pharmaceutical companies to physicians in its "Dollars for Docs" website feature. Although all payments are not included in the listing, ProPublica lists those that are publicly disclosed, often as part of settlements with the US government to resolve allegations of illegal marketing activities. According to the organization, payments listed on its website total a staggering $2.5 billion from 2010 to 2012 from just 15 companies that represent 43 percent of all drug sales in the US. Most notable about the website feature is that it is publicly accessible.

In 2010, another effort was launched to create transparency of payments from Pharmaceutical companies to Health Care Professionals (HCPs) as a way of inducing them to prescribe or use the company's products. That effort, this time by the US Congress, resulted in the Physician Payment Sunshine Act (Sunshine Act), which was included as part of the 2010 Affordable Care Act. The Sunshine Act was designed to shine light on payments that could compromise the integrity of the physician/patient relationship by influencing HCPs about the medical treatments they prescribed to patients.

None of that is news for compliance professionals. Nor is it news that the Centers for Medicare and Medicaid was developing its own website that would list payments from Pharmaceutical and Medical Device companies to physicians. When the website was open to the public, planned for September 2014, the initial list of payments would cover the period from August to December 2013, with future coverage showing payments for January-December of each year.

The planned launch didn't work out as hoped. In July, physicians were given access to the site to check on payments that companies claimed to have provided to them. Physicians who believed the material was incorrect could contest it. Good idea, but glitches in the beta system caused CMS to close the website down temporarily. It seems that there was at least one instance of a physician finding inaccurate information when he logged on (a time-consuming process in itself, according to reports) and discovered that information for a physician in another state had been attributed to him. The Open Payments website suffered other glitches according to published reports including those from ProPublica, including "error" messages for physicians without established relationships with Life Science companies and excessively long log-on procedures.

The registration of payments from Pharmaceutical and Medical Device companies isn't just an exercise in voluntary transparency; it is a compliance requirement under the federal Sunshine Act. State laws may be more stringent than those included under the federal statute. Regardless of the glitches in the Open Payments website, Pharmaceutical and Medical Device companies must have their information ready for entry onto the site.

FACING CREDENTIALING REQUIREMENTS FOR HCIRs

Many Medical Device companies struggle to help their reps and service personnel present the "training" credentials they need to enter a Health Care facility.

One of the issues that contributes to this struggle is the division among hospitals around "National Patient Safety Goal" training. While all parties involved understand the importance of the Joint Commission's National Patient Safety Goals, the question is often asked by sales operations and compliance teams: to what extent does a sales or service representative need to understand the medical issues that involve treatment and care for an actual patient?

For this reason, some states, including Indiana, have noted that much of the "National Patient Safety Goals" are caregiver standards, and some topics are not applicable to Medical Device sales reps and service personnel. And many leading Health Care organizations have agreed with these states. Both the Mayo Clinic and the HCIR Coalition (http://www.hcirbestpractice.org) have stated that National Patient Safety Goals are "intended for healthcare professionals who are direct caregivers, not for HCIRs."

All parties agree that certain "patient safety goal" topics can be appropriate for an HCIR to act on, such as hand washing, and in fact, the HCIR Coalition has developed a specific patient safety online program focused on the role of a non-care giver in a Health Care setting.

However, despite these recommendations and guidelines, Medical Device companies continue to face hospital credentialing requirements that include a training program on National Patient Safety Goals. Some of this training can be very patient-centric and even delve into medical issues, which may fall outside of the reasonable duties of the HCIR.

In response to these challenges, UL has introduced a new "***National Patient Safety Goals***" course that focuses on what HCIRs need to know.

NEW PATIENT SAFETY GOALS COURSE:

Part of UL EduNeering's HCIR Curriculum

Our new National Patient Safety course, written by Berkeley Research Group, a leading consulting firm for health care clients, and a subject matter expert for most of the courses within the UL EduNeering Sales and Marketing Library, can be added to an HCIR credentialing program that already includes our existing courses on HIPAA, Operating Room Conduct, AdvaMed Code, etc., and it should serve to fulfill those healthcare facilities that require "Patient Safety Goal" training from their HCIRs.

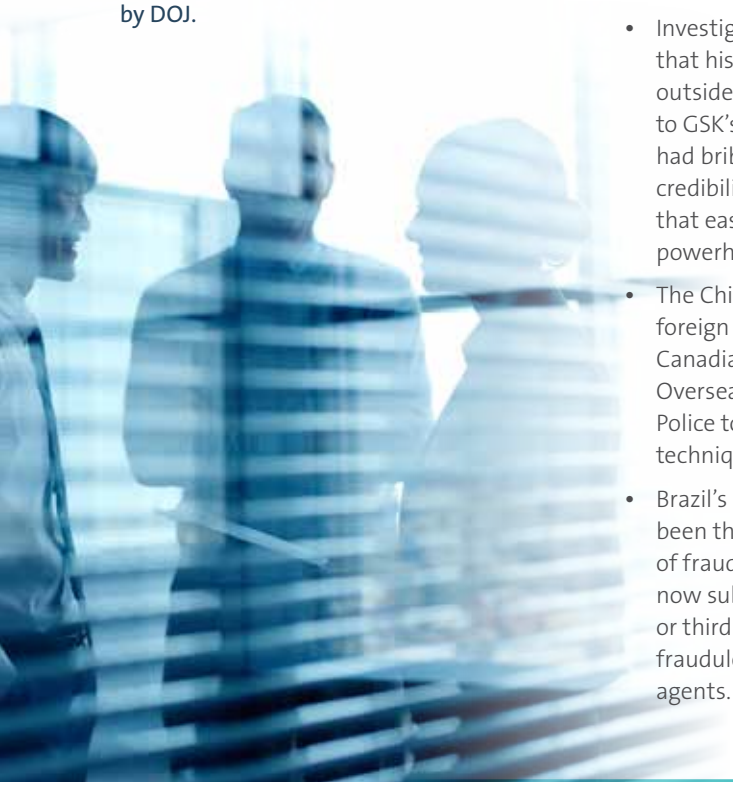
Learners will understand how standardized credentialing training advances the goals of safety, quality of care, confidentiality and compliance with applicable regulatory guidelines:

- Bloodborne Pathogens
- Operating Room Protocols (Sterile/Aseptic Controls)
- Health Insurance Portability and Accountability Act (HIPAA)
- Product Compliance and Medical Device Reporting (MDR) Requirements
- Ethics/Conduct Policies and Procedures

Subscribers of our Medical Device Sales and Marketing Library will receive this course as part of their subscription. If you would like more information about the course, please contact your Account Director or contact our Client Services team at prn.technologysupport@ul.com.

MOVE OVER, FCPA: YOU HAVE COMPANY

Not so long ago, the US Department of Justice (DOJ) was the top cop in anti-corruption enforcement and the Foreign Corrupt Practices Act (FCPA) was the biggest weapon in the fight. Things change and in the increasingly heated global battle against corruption, things change quickly. The DOJ still wields powerful weapons including the FCPA and laws against money-laundering, trade and sanction violations, wire and mail fraud, and kickbacks. Enforcing those laws is no longer the sole responsibility of DOJ. Today, DOJ's international counterparts may take the lead in anti-corruption investigations, non-US laws may exceed US laws in scope and severity, and enforcement actions by other countries may dwarf the penalties imposed by DOJ.



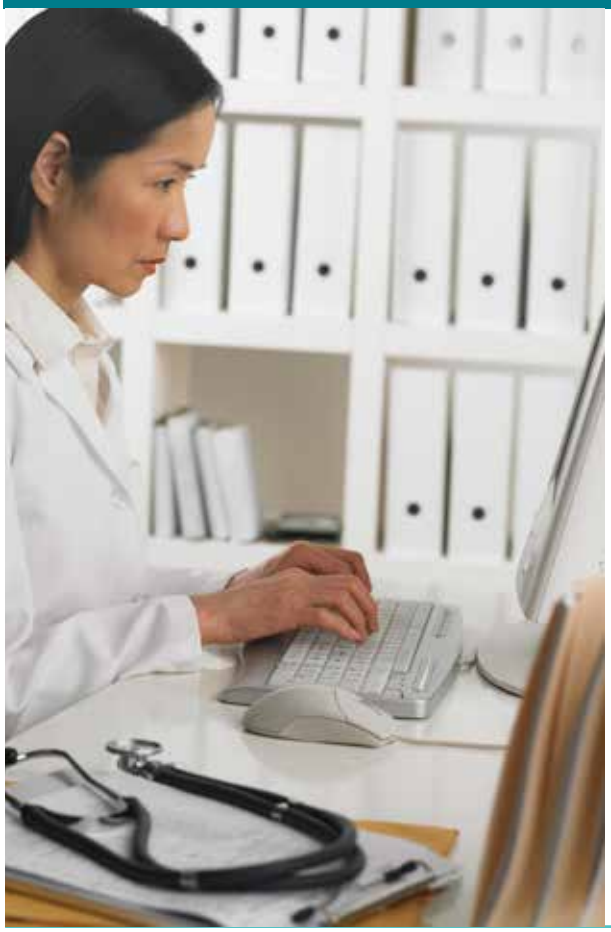
Staying abreast of international anti-corruption regulatory and enforcement activities can be the stuff of nightmares but here are just a few of the actions underway.

- China has made reform of its Health Care industry a top priority, putting both domestic and global Life Science companies squarely at the center of the bulls-eye. GSK's China division is alleged to have funneled bribes to physicians and government officials in China. And, China is not alone in its investigation of GSK. A report on July 30 in Compliance Week by Roberta Holland describes cooperation between UK and Chinese anti-corruption officials. Holland's article references a Reuters interview with David Green, director of the UK's Serious Fraud Office (SFO), who said this was the first example of such cooperation of which he is aware. The cooperation makes sense for both governments. The SFO launched its own investigation into GSK's activities shortly after China brought charges against the company. While GSK's activities in China have attracted the lion's share of global attention, it's worth remembering that China has undertaken investigations into the actions of other Pharmaceutical giants. It's equally significant that China has taken the same tough stance against corruption by members of its own government, domestic Life Science companies and global companies outside the Life Science industry. In short, China has signaled – and continues to confirm – its intention to attack corruption.
- Investigations don't stop at national borders. SFO's Green explained to Reuters that his office was investigating allegations of corruption in multiple jurisdictions outside China, including the Middle East. In mid-August, an anonymous email sent to GSK's top managers and viewed by Reuters made allegations that the company had bribed doctors and officials in Syria. Whether an anonymous email deserves credibility or the allegations prove true, the report illustrates the snowball effect that easily occurs when corruption investigations are leveled against a global powerhouse with operations in many countries around the world.
- The China/UK cooperation is being repeated in other places. An international foreign bribery task force links the US Federal Bureau of Investigation, the Royal Canadian Mounted Police, the Australian Federal Police and the City of London Overseas Anti-Corruption Unit. The unit was launched by the City of London Police to allow police from all four countries to share knowledge and investigative techniques.
- Brazil's Clean Companies Act now makes companies – not just individuals, as had been the case earlier – liable for bribing public officials or committing other types of fraud related to public procurement. Both Brazilian and foreign companies are now subject to civil sanctions for giving "an improper benefit" to a public agent or third party related to him. Specifically, the new law prohibits bid rigging, other fraudulent actions and efforts to hinder investigations by public bodies, entities or agents.

MOVE OVER, FCPA: YOU HAVE COMPANY *(Continued)*

- The World Bank has intensified its willingness to debar companies found guilty of corruption and bribery. In 2013, the Bank imposed its longest debarment on SNC-Lavalin based on allegations of improper payments by the Canadian engineering company to officials in Bangladesh. For ten years, SNC and 100 of its subsidiaries are prohibited from bidding on projects funded by the World Bank. The company also is prohibited from bidding on projects funded by other international development banks.

Many other countries are intensifying their anti-corruption enforcement actions, by enacting new legislation, expanding existing legislation, establishing discrete anti-corruption enforcement units and entering into cooperative agreements with counterparts in other countries. As a result, companies with global operations are confronted by a growing list of anti-corruption laws but also with the potential "snowball" of enforcement actions extending from one country to another. Establishing, maintaining and continually updating a comprehensive anti-corruption program – one that goes beyond the FCPA to include other types of fraud, bribery and corruption as well as the unique requirements of individual countries – has never been more important or more challenging.



About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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.