

HEALTH CARE COMPLIANCE COMMUNIQUÉ

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WHO, WHERE AND HOW OF GLOBAL ANTI-CORRUPTION

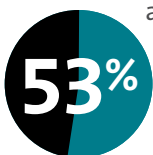
The underlying assumptions of many companies in building their anti-corruption programs may not be serving them well...

In fact, what we have thought we knew about global anti-corruption risks, players and actions may be interfering with our ability to prevent corrupt behaviors in our organizations. That, at least, is one of the conclusions one can draw from the recently released OECD Foreign Bribery Report. A closer look at some of the key findings of the report points to the need for compliance officers to take a fresh look at the assumptions that underlie many compliance programs.

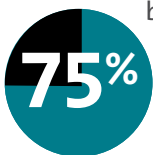
Our own experience with clients on the ground confirms the importance of this “fresh look” and highlights changes that can lead to greater returns on compliance investments. On the following page are four of the most important findings from the OECD survey, how those findings may contradict traditional thinking and what you can do to respond to the gap.

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WHO, WHERE AND HOW OF GLOBAL ANTI-CORRUPTION *(Continued)*



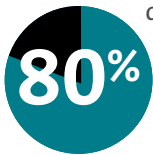
- a. **53%** of global corruption cases involved corporate management (41%) or Chief Executive Officers (12%). A traditional compliance approach focuses on the role of CEOs as setting the “tone at the top” that informs the organization’s compliance approach and filters through every aspect of the compliance program. If we accept the report’s findings that management-level employees and CEOs are directly involved or aware of corruption within the organization, we are left with several potential questions: Are managers and officers receiving necessary training to educate them on their compliance responsibilities, anti-corruption laws and corruption risks? Are training requirements applied at the organization’s highest levels or focused primarily on employees below the management level? Too often, training for corporate officers and senior managers is overlooked or minimized. Ironically, corporate officers and senior managers represent a segment of the company in the greatest need for specialized anticorruption training since they carry unique responsibilities and are most likely to be individually prosecuted by law enforcement agencies for corrupt activities.



- b. **75%** of foreign bribery cases involved third-party intermediaries. In recent years, companies have boosted their emphasis on training agents, brokers, employees of business service companies and subcontractors. The supply chain, however, especially for highly regulated global organizations such as pharmaceutical and medical device companies, stretches across multiple jurisdictions and invariably includes multiple “subcontractors to subcontractors.” While compliance training may be provided – or certified by the intermediary – there is typically little oversight aimed at the end of the supply chain or the business services sector. Training for third-party intermediaries must be appropriate for the audience in language, literacy, culture and job function. Oversight must be aggressive, not just of subcontractors but also of their subcontractors, agents and suppliers.



- c. The common assumption that foreign bribery occurs primarily in developing economies is not only false but risky. According to the OECD report, **two thirds** of bribes were paid to officials in countries in the top half of the UN Human Development Index. In our experience, the majority of risk management focuses on developing economies rather than developed nations including those in Europe. Given the numbers illustrated by the OECD survey, it is worth rethinking the potential risk of geographic locations and the compliance training/oversight that should be focused in each area.



- d. The majority of foreign bribes were paid to officials of state-owned enterprises. The individuals in those organizations who received bribes ranged from CEOs and presidents to lower-level employees. Overall, SOEs represented **80%** of the foreign bribes covered in the OECD report, followed by the heads of state, ministers, defense officials and customs officials. Most bribes were given as a way of obtaining public procurement contracts, which is not surprising, but expanded training may be warranted for any employee – CEO or salesman – who is involved in the business of interacting with current and potential clients.

Taking Action

Global companies have spent billions of dollars, literally, on compliance training, communication, auditing and oversight. Yet, many of the compliance training programs we see are dated, based on assumptions that do not match the findings of the OECD study and other recent reports. The increased regulation and cooperation among national law enforcement agencies to enforce anti-corruption laws adds risk to the challenge of compliance but simply adding another layer of training atop a traditional foundation is unlikely to address that risk.

Compliance professionals are being called on to do more, often with fewer resources. Often, they are victims to the same “this is the way it’s always been” assumptions from above, limiting the ability to adjust existing, costly compliance strategies to address newer realities. Nevertheless, our work with global clients clearly shows the need to take a fresh look at the traditional approach that underlies most of today’s compliance programs and consider how newer surveys and findings should influence the where, who and how of future compliance training.

Source: OECD (2014), *OECD Foreign Bribery Report: An Analysis of the Crime of Bribery of Foreign Public Officials*, OECD Publishing <http://dx.doi.org/10.1787/9789264226616-en>



THE GLOBAL ANTI-CORRUPTION WINDS ARE SHIFTING

Global anti-corruption laws, standards and enforcement strategies are all in flux, leading to some uncertainty in the compliance community about what to expect or how to plan for compliance.

Individual countries are rapidly enacting new anti-corruption laws, some based on established standards such as those contained in the US' Foreign Corrupt Practices Act (FCPA) but many with unique provisions that pose unfamiliar challenges to companies familiar with FCPA compliance requirements. Equally important, international organizations such as the World Bank and ISO are taking a more active role in guiding the global fight against corruption, potentially leading to a global standard that sets an even playing field regardless of location.

While compliance professionals keep a close eye on changes in anti-corruption laws and enforcement policy in those countries in which they do business or plan on establishing business footholds, it is worthwhile to be aware of the movement underway in international organizations. Here are two of the most significant activities and plans that could change the international anti-corruption landscape and affect corporate compliance for global organizations in 2015 and beyond:

- Last December, World Bank Group president Jim Yong Kim spoke at the International Corruption Hunters Alliance. He commented on the United Nations Convention Against Corruption signed by 45 countries eleven years earlier before focusing on the Alliance, created with support from Australia, Denmark and Norway three years ago to foster multilateral cooperation in fighting corruption and supporting improvements in national governance. Although his remarks focused on plans, ideas and cooperation, the World Bank has increased use of its sanctioning and debarment authority. Those sanctions and debarments, some lasting as long as ten years, are imposed on companies that have been found guilty of corruption under various national jurisdictions. In the past year alone, companies representing countries around the world have been prohibited from participating on any project that receives funding by the World Bank. Although the companies and projects most commonly represented are in the infrastructure, environmental and construction industries, it's worth remembering that the life sciences sector has been targeted for scrutiny by regulators in countries around the world and is vulnerable to World Bank actions.

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THE GLOBAL ANTI-CORRUPTION WINDS ARE SHIFTING *(Continued)*

- The International Organization for Standardization (ISO) is moving forward with ISO 37001, which will create internationally accepted best practices for anti-bribery and anti-corruption compliance. The proposed standard is being designed to be applicable for companies of any size, organizational structure or business sector. According to reports, the ISO standard will be modeled on the existing British Standard Institute (BS) 10500 standard. The ISO standard is still in the early stages of development; even so, it is far from universally applauded. Among the points of contention is a certification provision that would be used to document a company's compliance with accepted anti-bribery compliance practices. Even though the standard is far from completion, it reflects a growing movement toward a single standard for anti-bribery compliance programs.

National Initiatives

New anti-bribery laws and regulations seem to be enacted by countries on a monthly basis, creating a bewildering compliance challenge for global companies. Although the US is no longer the sole driver of anti-corruption legislation and enforcement, the US remains a powerful player in the global anti-corruption world, continuing its work with global partners including those in the Open Government Partnership, the G-7, the G-20 and the OECD Working Group on Bribery. The Obama Administration is working in a number of areas to promote transparency and stamp out corruption worldwide. Some of those initiatives:

- Continuing to apply the FCA to prosecute individuals and companies that pay bribes to foreign officials to obtain business benefits. The US works with partner governments to pursue recovery of proceeds of corruption and use visa authorities to deter those engaged in corruption or their beneficiaries and enablers from using the US as a safe haven. As part of that effort, the Administration advocates legislation that closes gaps in US money laundering laws.
- Developing a National Action Plan to promote and incentivize responsible business conduct, including with respect to transparency and anti-corruption consistent with the UN Guiding Principles on Business and Human Rights and the OECD Guidelines on Multinational Enterprises.
- Taking several actions to prevent corrupt entities from using anonymous shell companies to launder the proceeds of corruption. Among those actions is proposed rulemaking issued by the Department of the Treasury to clarify and strengthen customer due diligence obligations for US financial institutions including a requirement to identify beneficial owners of certain customers that are legal entities.
- Working with other countries to promote anti-corruption, transparency and open government through cooperation and resources including approximately \$1 billion annually from the Department of State and US Agency for International Development for anti-corruption and related good governance programs.
- Continuing the US' leadership role in the Open Government Partnership, launched in 2011 as a voluntary, multi-stakeholder initiative of 8 countries that agreed to concrete commitments to promote transparency, fight corruption and harness new technologies. The Partnership now numbers 64 countries and has resulted in the passage of anticorruption legislation around the world, new freedom of information laws and initiatives to publish information on government spending.

Risks for Health Care Companies

The Health Care industry is not directly mentioned in the US anticorruption agenda nor does it appear as one of the "most corrupt" industries in international surveys and reports. That is a small consolation for the scores of companies that have coughed up multi-million dollar fines in one country, only to be faced with fresh rounds of prosecution under related charges in other jurisdictions. Pharmaceutical, Medical Device and Biologics companies will continue to be under scrutiny by regulators and law enforcement agencies in the US and abroad. They will continue to be especially vulnerable to corruption because of their inherent interaction with state-owned enterprises and their reliance on third parties, whether suppliers of products or services. While compliance professionals in the Health Care industries understandably focus their attention on regulations, laws and enforcement actions within their own industry, there are important developments outside the industry that may not seem to apply today – but that will inevitably affect the future compliance actions of Life Science companies.

COMBATTING TRAINING FATIGUE

One of the most significant compliance challenges facing many companies has been brewing for years inside the organization itself: training fatigue. The prospect of employees ignoring or “going through the motions” of compliance training is disheartening to employers that have poured huge amounts of time and money into developing and implementing a strong compliance training program.

Now, consider how disheartened many employees have become about the whole training process. In one month, an employee of a global pharmaceutical company might be hit by general training on the FCPA, revised policies for interactions with healthcare providers, three new SOPs related to new equipment or processes and 13 SOP revisions, new employee benefit explanations and forms, a letter from the CEO and a list of 16 additional training sessions available but not yet required. Worse yet, consider the new hire; within 24 hours of hiring, he or she may be overloaded with Codes, policies, HR and legal forms, dozens of job-specific SOPs and lists of training sessions or modules waiting to be completed.

Certainly, each training element was designed to perform an essential function. They provide the knowledge to ensure regulatory compliance, workplace safety, product quality, good employee relations and strong corporate culture. The challenge: how to achieve the company’s knowledge goals without fueling the training fatigue that afflicts so many employees at every level of an organization.

The problem of fatigue overload isn’t reserved for any individual industry or company. We have worked with global companies with well-established training programs and organizational structures and with medium-sized companies struggling to establish a working infrastructure for compliance training. On the following page are some of the key points we share with them in their efforts to prevent and combat training fatigue in their organizations.

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COMBATTING TRAINING FATIGUE *(Continued)*

1. **Get rid of the silos.** There are a number of business functions that are responsible for training or communication, yet they often fail to communicate with one another about the content, schedules and expectations of their training programs. Collaboration is essential among these various functions – compliance, quality, human resources, corporate communications and counterparts in foreign subsidiaries or dispersed corporate operations. Even senior officers should be represented since their buy-in and ongoing support will determine the effectiveness of a new, multi-center approach.
2. **Schedule distribution from multiple departments.** As a first step, identify what training and communication materials are flowing from which departments, how they are being scheduled and who is slated to receive them. Then, organize the distribution of materials so there are few multi-sided “dumps” that can easily overwhelm even the hardest employee.
3. **Establish education as the goal.** The content of each training segment may be different but the underlying message should be consistent: we are investing in our employees’ knowledge and advancement as well as ensuring that our company produces the best quality and maintains consistent compliance.
4. **Understand your learners.** The same message falls on different ears every time it is heard. Understand the learners in your organization: language, literacy, location, culture, familiarity with technology, typical “tools” of communication. A 25-year-old technician considers email an outdated form of communication and sees video games as a learning resource; a 55-year-old manager may have a very different perspective – and less tolerance for what may appear to be “games” instead of “serious training.”
5. **Who needs what – and who is receiving what?** Everyone doesn’t need every training resource available from the company. Drilling through the layers of the company to identify job functions and related knowledge needs is the first step in streamlining the training process. Second, identify the training resources that are currently in use, how they are being distributed and how completion and competency are measured. Third, do some spring cleaning, eliminating outdated regulatory training materials; consolidating courses from separate departments or locations into fewer, more effective tools; and planning to fill in the gaps between what exists and what is needed.
6. **Make sure there’s adequate time and access for training.** Many companies use on-demand online training because it allows employees to access their training programs whenever they wish. That works for an employee population with access to computers and the internet; it may not work for employees who use only cellphones at home, and it certainly doesn’t work if there are too few computers available in the workplace for employees who need to complete their training at work because of confidentiality or security issues. For too many employees, “training” simply takes time away from their normal job duties. Too often, the result is an employee who races through the training in order to check off a box signifying completion – not an employee who actually focuses on learning the content, thinking about its applications, and retains the new knowledge.
7. **Advertise your program.** The Super Bowl is a football game but it is also a product showcase. Companies compete for having the best, most creative ads. Take a page from the advertising industry to market your own compliance program. Think “out of the box,” using non-traditional methods that might include competition between different departments. The department that successfully completes two training sessions in a set period of time “wins” a free lunch at a local restaurant. Competition is strong motivation but remember that the operative words are “successfully completing” the courses – and that should include being able to demonstrate understanding of the material.

A Fact of Business Life

Training is a fact of business life but it doesn’t have to lead to training fatigue and the resulting problems of inadequate knowledge, noncompliance, inefficient operations and even quality problems. Many companies find that an outside advisor is best equipped to identify the problems and recommend workable, company-specific solutions that address both effectiveness and cost-efficiency.

For more information about UL’s Advisory Services and our experience working with companies to improve training compliance, knowledge retention and employee performance, email Pat.Thunell@UL.com or call 609-627-5302.



DELIVERING TRAINING THAT'S GLOBAL – AND MOBILE

Today's corporate compliance teams need to incorporate the latest technology into their training and communication programs. And compliance teams are challenged to reach global employees, who have regional language requirements, and also prefer a mobile device to take compliance training.

That's why UL EduNeering has launched eight of our most popular ethics courses into our innovative EduFlex format. EduFlex supports both mobile friendly formats and multiple languages from a single course, so LMS administrators don't have to make multiple assignments to a global audience. The mobile-ready courses include:

- Detecting and Preventing Fraud Code: ETHICS13
- Doing the Right Thing: Anti-Bribery Code: ETHICS09
- Global Anti-Bribery Code: ETHICS14
- Handling Confidential Information Code: ETHICS10
- Making Ethical Decisions Code: ETHICS17
- Privacy and Data Protection Code: ETHICS15
- Recognizing and Avoiding Conflicts of Interest Code: ETHICS11
- Safeguarding Intellectual Property Code: ETHICS12

Our 50+ Course Ethics and Corporate Responsibility Library

These eight courses replace our existing courses with the same name, and are now available to subscribers of our Ethics and Corporate Responsibility library, which covers Global Fair Competition Laws, Insider Trading and many other critical topics. Clients can also work with our Learning Services team to customize these courses to reflect their own policies.

Our Ethics and Compliance courses are designed to engage employees in an active learning experience using state-of-the-art adult education technologies and techniques. Courses contain realistic business scenarios to help learners apply what they've learned in real-world business situations, leveraging content from experienced ethics and compliance practitioners.



Over the next two years, we are planning to upgrade all of our Ethics courses to the visually rich, mobile-friendly format, in which learners will be able to tap, swipe, pinch or zoom in on objects on the screen. In addition, learners can employ automatic screen rotation to display the course in either portrait or landscape.

[Download our brochure to learn more.](#)



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.