Health Care Compliance Communiqué

YEAR-END 2015

NEW RULES FOR INDIVIDUAL ACCOUNTABILITY

The US Department of Justice (DOJ) and, more recently, the Securities and Exchange Commission (SEC), are credited with setting a global standard for anti-corruption enforcement. The two agencies have returned billions of dollars to the US treasury through multi-million dollar settlements with companies to resolve allegations of corporate misconduct. Even though the size of the settlements keeps growing, with some reaching hundreds of millions of dollars, the two agencies are often berated for not focusing more attention on the prosecution of individual corporate leaders. Some legislators, including members of Congress, as well as the public in general, are demanding to know why more corporate officers are not held accountable for the actions of the companies under their watch. Critics of the agencies' emphasis on corporate financial penalties ask, "Why aren't more leaders of major global corporations in prison for criminal violations of anti-corruption laws?"

The DOJ Responds to Critics

Deputy Attorney General Sally Quillian Yates addressed that question in remarks at New York University School of Law by announcing a new policy on individual liability in corporate wrongdoing. Yates set the stage quickly, noting the inherent difficulty in prosecuting cases against individuals. "These

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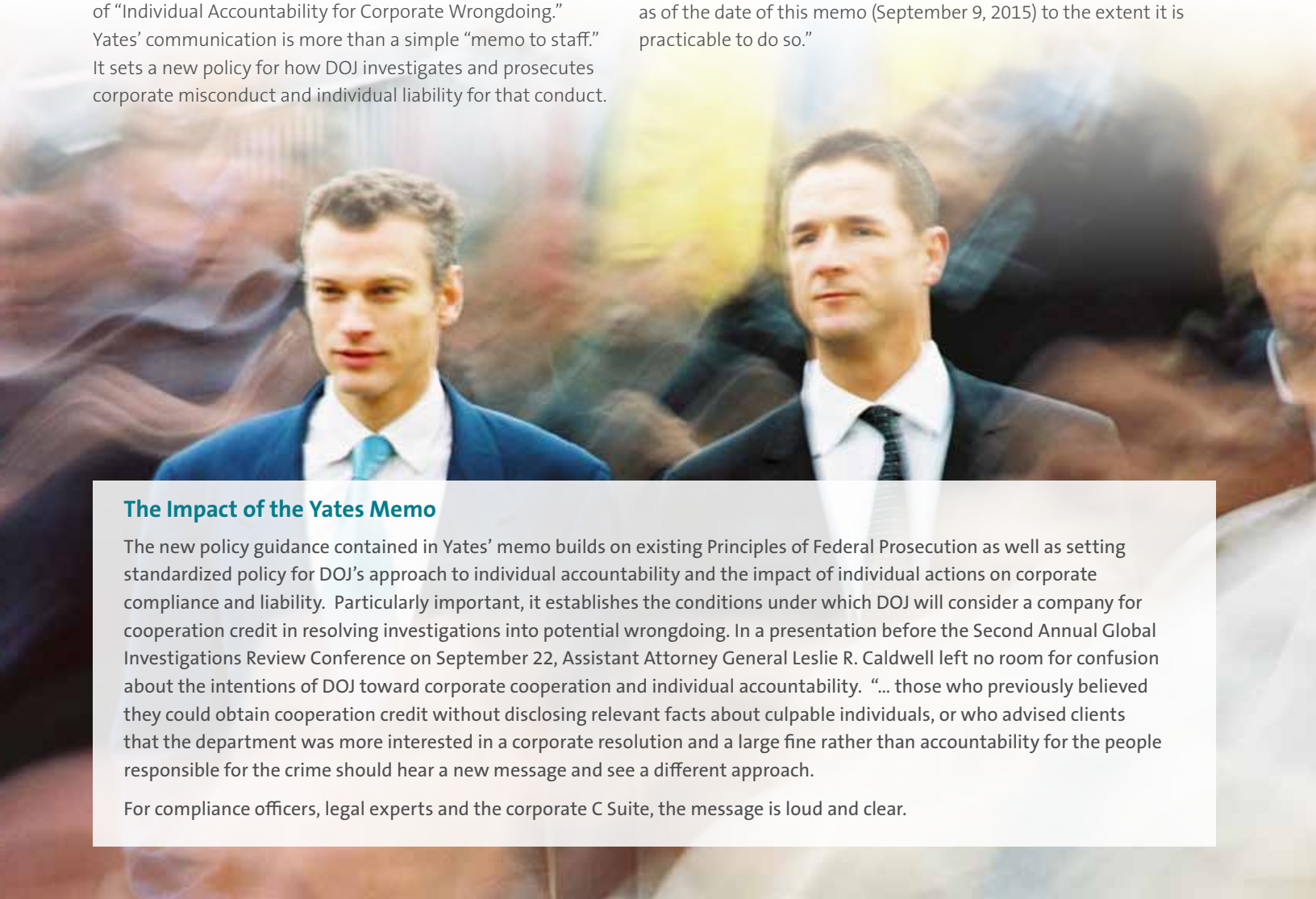
cases," she explained, "can present unique challenges for DOJ's agents and attorneys: there are complex corporate hierarchies, enormous volumes of electronic documents and a variety of legal and practical challenges that can limit access to the evidence we need." She followed by drawing a line in the sand, noting that corporate misconduct was not much different from the other work DOJ does. "Crime is crime," Yates stated. "And it is our obligation at the Justice Department to ensure that we are holding lawbreakers accountable regardless of whether they commit their crimes on the street corner or in the boardroom."

DOJ now has a new tool in meeting that obligation. On September 9th, Deputy Attorney General Yates issued a memo to the Assistant Attorney Generals of DOJ's various divisions, the Director of the FBI, the Director of the Executive Office of the US Trustees and all United States Attorneys on the subject of "Individual Accountability for Corporate Wrongdoing." Yates' communication is more than a simple "memo to staff." It sets a new policy for how DOJ investigates and prosecutes corporate misconduct and individual liability for that conduct.

"One of the most effective ways to combat corporate misconduct is by seeking accountability from the individuals who perpetrated the wrongdoing," Yates stated in her memo. Notwithstanding the difficulties of identifying culpable individuals during a corporate investigation, Yates' memo sets out "... steps that should be taken in any investigation of corporate misconduct." Those six steps, which apply to both criminal and civil investigations, were crafted to ensure that "... all attorneys across the Department are consistent in our best efforts to hold to account the individuals responsible for illegal corporate conduct."

Yates directed that certain criminal and civil provisions of the United States Attorney's Manual and the commercial litigation provisions in Title 4 be revised to reflect the changes embodied in the six steps outlined in her memo. (These steps are illustrated on the next page) "The guidance in this memo will apply to all future investigations of corporate wrongdoing. It will also apply to those matters pending as of the date of this memo (September 9, 2015) to the extent it is practicable to do so."



The Impact of the Yates Memo

The new policy guidance contained in Yates' memo builds on existing Principles of Federal Prosecution as well as setting standardized policy for DOJ's approach to individual accountability and the impact of individual actions on corporate compliance and liability. Particularly important, it establishes the conditions under which DOJ will consider a company for cooperation credit in resolving investigations into potential wrongdoing. In a presentation before the Second Annual Global Investigations Review Conference on September 22, Assistant Attorney General Leslie R. Caldwell left no room for confusion about the intentions of DOJ toward corporate cooperation and individual accountability. "... those who previously believed they could obtain cooperation credit without disclosing relevant facts about culpable individuals, or who advised clients that the department was more interested in a corporate resolution and a large fine rather than accountability for the people responsible for the crime should hear a new message and see a different approach.

For compliance officers, legal experts and the corporate C Suite, the message is loud and clear.

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STEP 1 **To be eligible for any cooperation credit, corporations must provide to the department all relevant facts about the individuals involved in corporate misconduct.** Yates was specific in her remarks discussing the policy the next day. About this first step, "It's all or nothing. No more picking and choosing what gets disclosed. No more partial credit for cooperation that doesn't include information about individuals." She continued in the same vein, "The rules have just changed. Effective today, if a company wants any consideration for its cooperation, it must give up the individuals, no matter where they sit in the company. And we're not going to let corporations plead ignorance. If they don't know who is responsible, they will need to find out." This policy change is likely to affect a company's decisions about how to respond to allegations of wrongdoing. Significantly, the policy applies to both criminal and civil investigations. Equally significant, "... a company should not assume that its cooperation ends as soon as it settles its case with the government. Going forward, corporate plea agreements and settlement agreements will include a provision that requires the companies to continue providing relevant information to the government about any individuals implicated in the wrongdoing. *A company's failure to continue cooperating against individuals will be considered a material breach of the agreement and grounds for revocation or stipulated penalties."*

STEP 2 **Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.** Explaining this policy, Yates added, "Moreover, once a case is underway, the inquiry into individual misconduct can and should proceed in tandem with the broader corporate investigations. Delays in the corporate case will no longer suffice as a reason to delay pursuit of the individuals involved."

STEP 3 **Criminal and civil attorneys handling corporate investigations should be in routine communication with one another.** The memo eliminates any confusion about why this cooperative investigation is an important policy. "Consultation between the Department's civil and criminal attorneys, together with agency attorneys, permits consideration of the full range of the government's potential remedies (including incarceration, fines, penalties, damages, restitution to victims, asset seizure, civil and criminal forfeiture, and exclusion, suspension and debarment) ..." Department attorneys are reminded to be alert for circumstances where concurrent criminal and civil investigations of individual misconduct should be pursued.

STEP 4 **Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individual.** As part of this policy Yates said, "We are instructing our attorneys that they should not release individuals from civil or criminal liability when resolving a matter with corporation except under the rarest of circumstances."

STEP 5 **Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.** The policy notes, "Delays in the corporate investigation should not affect the Department's ability to pursue potentially culpable individuals." If a decision is made at the end of an investigation not to bring civil claims or criminal charges against individuals who committed the misconduct, the reasons "... for the determination must be memorialized and approved by the United States Attorney or Assistant Attorney General whose office handled the investigation, or their designees."

STEP 6 **Civil attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond the individual's ability to pay.** Yates emphasized, "Going forward we will be pursuing civil actions against corporate wrongdoers even if those wrongdoers don't have the financial resources to satisfy a significant monetary judgment." She said, "There is real value ... in bringing civil cases against individuals who engage in corporate misconduct, even if that value cannot always be measured in dollars and cents. Civil enforcement actions, like criminal prosecutions, hold wrongdoers accountable for their actions ..." Then, explaining the potential consequences of that accountability beyond the ability to pay large fines and penalties, Yates said, "... if the individual is liable, we can take what they have and ensure they don't benefit from their wrongdoing. These individual civil judgments will also become part of corporate wrongdoers' resumes that will follow them throughout their careers."

NEW RULES FOR DONATIONS IN CHINA

Most global companies are aware of the responsibilities and risks related to anti-corruption laws including the Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act. Although both laws seek to prevent or prosecute bribery by companies, there are critical differences between the two including the definition of what is allowed, how the law is enforced, and in what context it is prohibited. The US' FCPA, for example, focuses on bribing foreign government officials in order to gain or keep business. The UK Bribery Act has a broader scope, prohibiting the giving and receiving of bribes to or from any individual or organization, whether commercial or government.

Due to their extraordinarily long supply chains and their reliance on international customers – often government-sponsored or controlled healthcare facilities – Life Science companies face particularly significant risks under the FCPA and UK Bribery Act. However, those are not the only risks confronting global companies. A growing number of nation-specific anti-bribery laws with different requirements and standards are complicating the compliance function of global companies. Countries from Canada to Brazil, India and China are enacting stringent anti-bribery laws.

China in particular has enacted strict anti-corruption laws. Those laws pose particular risk for global Life Science companies that rely heavily on suppliers in China as well as government-controlled healthcare facilities.

In October 2015, China's National Health & Family Planning Commission issued Provisional Rules on Receiving Donations for Public Welfare that revised the Interim Measures for the Administration of the Acceptance of Social Donations and Financial Aid by Healthcare and Health Institutions. Those measures were enacted in 2007 and had not been revised since then. The new measures, *Administrative Measures on Accepting Donations for Public Welfare by Healthcare Entities*, is also known as the New Donations Rule or the Donations Measures. The New Donations Rule has multiple components that collectively establish a comprehensive set of requirements for companies involved in China's healthcare industry. As with other anti-corruption, anti-bribery and anti-competition laws, corporate compliance depends on a clear understanding of the Rule's definitions, restrictions and requirements, especially those related to "donations," "healthcare entities," and prohibitions.

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NEW RULES FOR DONATIONS IN CHINA *(Continued)*

What is a Donation?

The new Rule defines "donation" as support and assistance in the form of funds, goods, etc. provided voluntarily and for free to healthcare providers. Donations may also take the form of grants and sponsorships though these are less tightly defined in the Rule. Donations which can be accepted by healthcare organizations must be used for the following purposes:

- Public health services and health education;
- Training and education of healthcare personnel;
- Academic activities and scientific research in the healthcare field (donors cannot designate specific recipients but must contribute only to the healthcare organization itself.);
- Public facilities and equipment for healthcare institutions;
- Other not-for-profit public welfare activities including fee reductions for medical treatment.

"Healthcare Organization" and Restrictions

Since the vast majority of healthcare institutions in China are government-affiliated, global companies will almost certainly be regulated by the new law in addition to such anti-bribery laws as the FCPA and UK Bribery Act. The new Rule defines "healthcare organizations" broadly as hospitals as well as foundations and other civil societies or organizations under the jurisdiction of China's National Health and Family Planning Commission.

Healthcare organizations may NOT accept a defined group of donations. Among the most notable are those that involve for-profit commercial activities; appear to be commercial bribes or raise suspicions of unfair competition; support political or other "ideological" purposes; relate to the procurement or purchase of goods and services; or involve the economic interests of the donor including scientific research or intellectual property rights. Two other, obvious, conditions are prohibited: if the donation violates the law or is the response to extortion. Hospitals are prohibited from using any part of the donation for their personnel's management fees, salaries or stipends. Civil societies are given more leeway in how they may use the donations, but only if those actions are contained in a donation agreement.

Additional Provisions

China's new Donations Rule includes other provisions for healthcare organizations relating to transparency, contracts and recordkeeping. Healthcare organizations must set up a pre-acceptance system that allows for the evaluation of each donation for necessity and compliance with the Rule's provisions. Based on the evaluation, healthcare entities and donors must have a written agreement that complies with specific requirements for all contracts. Healthcare entities must provide formal receipts to the donor for the donation. When the project is completed, the healthcare organization should provide the donor with feedback about how the donation was used and managed. Absent those provisions, the healthcare entity should work with the donor on a use for the surplus.

An important element of the Rule applies to transparency of the donation process. Healthcare organizations must publicly disclose, either through their own websites or through local media, information about the donations. Among the elements to be disclosed are how the healthcare organization used the donation and managed its use of the donation through internal management systems, periodic audits and performance reviews.

Impact on Life Science Companies

The new Rule applies directly to healthcare organizations, not Life Science companies, but it sets forth specific restrictions and vital compliance information. The Rule is intended to prevent or expose bribery and other anti-competition actions by either for-profit companies or government-related healthcare organizations. It might be helpful if CCOs of global pharmaceutical and medical device companies share knowledge about the Rule to operating units that do business in China.

PROCUREMENT FRAUD AND SUPPLY CHAIN RISK

According to a recent poll by Deloitte Financial Advisory Services, more than a quarter of surveyed professionals reported supply chain fraud, waste or abuse during the previous year. The results are both disturbing and predictable since nearly as many poll participants admitted that they had no existing program to prevent and detect the risks of supply chain fraud, waste and abuse. (The poll was conducted during a webcast hosted by Deloitte in early 2015.) Often comprising scores or even hundreds of organizations, the supply chain is one of the most significant financial, compliance and reputational risks facing today's global life science company. Even the results of the Deloitte survey dwarf the size of the risk. If we assume that only a percentage of fraud was detected, the true size of the fraud problem is likely to be much higher.

Even though chief compliance officers regularly rank the supply chain as one of their most serious compliance risks, their efforts to establish effective supply chain management programs are often thwarted by insufficient funds – unless or until a serious supply chain problem emerges. Then, attention and resources snap to the constantly changing chain of organizations that provide goods and services to global pharmaceutical and Life Science companies.

In attempting to balance the need to manage compliance inside the organization and compliance outside the company in the supply chain, too often an area of particular vulnerability is passed over. In our experience working with companies in the global Life Science industry, we have found that an area of particular compliance, financial and reputational risk is the link between the "inside" and the "outside." That bridge between inside and outside is the procurement process.

Where is the Risk of Procurement Fraud?

The idea that their employees represent a major supply chain risk is disturbing to many corporate officers. "We trust our people," is a common response, "And they receive the best possible anti-fraud, anti-bribery and anti-corruption training." Certainly, employees receive the bulk of compliance training while some companies still lack effective supplier training. Yet, according to the Deloitte poll, 22.9% of respondents identified employees as the top source of supply chain fraud risk compared to 17.4% for vendors and 20.1% for other third parties including subcontractors and other vendors.

The attraction for employees to commit fraud in the procurement process is understandable, however disturbing, because of the many types of fraud possible in the process, the size of the potential return, and the relative low risk of detection. We see some employees commit fraud regardless of the amount or quality or training. Others, however, commit procurement fraud unintentionally or with inadequate appreciation of the seriousness of their offense. This second group can benefit from additional training targeted to the risks they may face in the procurement process.

Types of Procurement Fraud

The impact of procurement fraud does not stop with the selection of a vendor or other third party. Rather, it filters into the supply chain itself, supporting performance that is illegal and financially negative to the company. There are multiple types of procurement fraud, some perpetrated solely by one or more "insiders" and some resulting from collusion between employee and supplier.

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PROCUREMENT FRAUD AND SUPPLY CHAIN RISK *(Continued)*

Common types of procurement fraud include the following:

- **Bribes and kickbacks.** Bribes and kickbacks to procure new or expanded business can start small – a gift, cash, free travel – and quickly escalate to include more costly and less visible payments such as fees for services that are not performed or interest in business transactions commissions. Because they are so high profile and have been the subject of so much enforcement, bribes and kickbacks are likely to be the most obvious form of procurement fraud – and the most likely to be reported by whistleblowers.
- **Favored treatment.** Procurement officers may be influenced to make illegal decisions in procuring goods and services. Examples include: Qualifying a vendor that has not been properly vetted, paying excessively or buying unneeded, non-compliant goods or services. In the most egregious cases, vendors may simply not exist; dishonest procurement personnel can submit "bills" from these non-existent vendors, who typically provide services that are not as easily tracked as goods that would be inventoried and stored.
- **Contract management.** Procurement managers may collude with contractors in many different areas including change orders and invoice payments. Dishonest procurement personnel may accept inflated change requests, for example, or multiple invoices for similar work given to the same contractor. A "red flag" for compliance officers should include repeated change orders that increase or extend the contract, multiple billings from the same contractor for one-time services, and multiple awards for similar work to the same contractor. False invoices can also be submitted for goods that are never delivered.
- **Poor quality goods or services.** Corrupt procurement officers may solicit, purchase and accept goods that are of inadequate quality. This area of procurement fraud is of particular concern for pharmaceutical and medical device companies. The goods may be of inadequate quality, the supplier may be unqualified to deliver goods of the required quality, or the supplier may have demonstrated a pattern of non-compliance and poor quality. The "fraud" occurs when the procurement officer knows about these issues but awards the contract and enables acceptance of counterfeit or poor-quality goods.

Many other opportunities for procurement fraud exist, either by a corporate employee alone or in collusion with the contractor. These opportunities can include bid-rigging, bid manipulation such as rigged specifications in a contract, sole source awards that avoid fair competition, and even purchasing products for an employee's personal use.

Responding to the Risk

What can global companies with large, often diffused procurement functions do to prevent or detect procurement fraud in its early stages, before it becomes a massive financial, compliance and operational problem? First, corporate officers must accept the procurement risks from their own employees. Second, training must target those areas to which procurement personnel are most exposed. Targeted training accomplishes two essential purposes: it reminds those individuals who may be tempted to "bend the rules" that there are serious consequences and it reinforces the positive behavior of compliant personnel.

The corporate hot line represents one of the most effective deterrents to long-term fraud. A simple report of "I don't know if this means anything but we seem to be getting a lot of invoices from Company A lately" can signal potential fraud and enable a rapid corporate response.

Finally, expand the corporate view of "procurement" and "supply chain." The procurement function also stretches into recordkeeping, accounting and contract management. In the opposite direction, the supply chain begins with the procurement of goods and services, not with management of suppliers of goods and services.

Effective supply chain management is impossible without compliant procurement. By acknowledging their inescapable connection and training all relevant employees in the "red flags" of possible procurement fraud, companies can focus on the challenge of ensuring the compliance of their own organizations and those of their third parties.

UL EduNeering's Detecting and Preventing Fraud Course (Code: Ethics13)

This 30-minute eLearning course explains what constitutes fraud, how to recognize and report potential or actual fraud, and when and how you should report it. After completing the course, learners will recognize internal fraud, computer fraud, social engineering, and money laundering.

The course explains that fraud comes in many forms, such as falsification or alteration of records or reports, and dishonest use of information for personal gain.

For example, embezzlement, the most blatant type of fraud, can include actions such as conversion of assets or improper use of credit.

The course also lists the seven warning signs of fraudulent activity. Designed for a global workforce, this course can be taken via a mobile-friendly device, and is available in six languages.

To review the Detecting and Preventing Fraud course, contact pat.thunell@ul.com.

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.