Life & Health

Health Care Compliance Communiqué

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HOW DOJ SEES "EFFECTIVE" COMPLIANCE

The point of compliance with anti-corruption laws, including the FCPA, is to prevent corrupt behaviors. DOJ offers insight on building a compliance and training program that can help protect companies from corrupt behaviors and criminal prosecution.

In late 2014, a senior official with the US Department of Justice spoke before the Advanced Compliance and Ethics Workshop. In that presentation, Marshall L. Miller, Principal Deputy Assistant Attorney General for DOJ's Criminal Division, spoke about "... a few primary strengths and weaknesses that we have observed in corporate compliance programs of late." Focusing first on the weaknesses, he said, "As an overarching theme, the failure to expand compliance programs to meet the needs of growing corporations – particularly global corporations – drives many of the compliance problems we have seen." Then, he turned to the other side of the coin, noting that compliance programs that have proved to be the most effective were those with widespread prophylactic and training mechanisms in addition to procedures designed to uncover wrongdoings and expose individuals responsible for criminal behavior.

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HOW DOJ SEES "EFFECTIVE" COMPLIANCE *(Continued)*

How important is having an effective compliance training program for companies caught in the crosshairs of a DOJ investigation?

Speaking about the direction given to DOJ by the Principles of Federal Prosecution of Business Organizations, Miller noted, "One of those factors expressly directs us to consider the existence and effectiveness of the corporation's pre-existing compliance program in deciding whether to charge a corporation with a crime." He continued, "The existence of an effective compliance program can make all the difference when a corporation is in the Justice Department's sights."

Miller describes the experience of several different companies with vastly different outcomes. The highlighted examples point to challenges confronting the entire Life Science community, not just a handful of companies. Miller's observations, cautions and recommendations correlate with what we have learned through our work with Life Science companies, regardless of size, location, product type or corporate structure.

Growth and Risk

Miller set the stage when he said, "As an overarching theme, the failure to expand compliance programs to meet the needs of growing corporations – particularly global corporations – drives many of the compliance problems we have seen." He pointed to the experience of a global company that had pleaded guilty to FCPA for export control violations. According to Miller, the most glaring failures occurred in its overseas offices and subsidiaries. As an example, Miller noted that despite the company's global presence, it "... did not even bother to translate its compliance policy into languages other than English." Miller continued to aim hard hits at a company with operations in more than 100 countries, saying incredulously that the company, "... didn't even bother to make its compliance program intelligible to many of its employees ..."

Miller pointed to another example of a rapidly-expanding global company that entered a Latin American market but failed to translate its compliance policy into Spanish, failed to implement its compliance policy at the Latin American subsidiary, failed to train its personnel and failed to regularly test or audit transactions for illicit payments.

Culture of Compliance vs. Profit

Effective compliance requires training and testing for proficiency but it also requires a "culture of compliance" that begins at the top and filters through to every level of the organization. Citing two examples in which compliance policies existed but were circumvented in favor of profits, Miller said, "Both cases reflect failures in global enforcement of compliance programs. But perhaps more starkly, they illustrate a failure of any 'culture of compliance' to extend beyond US borders. In fact, that culture so clearly favored the promotion of profits that compliance policies were viewed as mere speed bumps, rather than barriers to illegal conduct."

In our experience, few companies show blatant disregard of the requirements and intent of domestic and international anti-corruption laws. There are, however, many companies that have invested millions of dollars into their compliance initiatives but continue to fall short of "effective compliance."

It is worth remembering Miller's comment about DOJ taking into account the effectiveness of a company's pre-existing compliance program when deciding how or if to move forward with criminal prosecution. Consideration of an existing compliance program was on display when DOJ and SEC declined to prosecute Morgan Stanley for criminal violations of the FCPA. Both government agencies went to great lengths to praise the company's compliance program, yet some observers have suggested that Morgan Stanley's compliance program "failed" because Garth Peterson engaged in criminal activity. Consider this: Morgan Stanley has more than 60,000 employees working at 1300 offices in 42 countries. No company, particularly one with the size and scope of Morgan Stanley, can guarantee complete compliance by all of its employees. Garth Peterson understood the company's policies and the FCPA yet chose to engage in criminal activity by circumventing the compliance policies and procedures set in place by Morgan Stanley. His criminal behavior was identified and stopped, not by law enforcement agencies but by Morgan Stanley, which voluntarily reported his illegal activities.

Preventing Bad Behavior

Notwithstanding the massive global commitment to preventing and prosecuting business corruption, headlines continue to show that corruption has not been eradicated. Miller's presentation to a room of compliance professionals acknowledged that corruption was all too common, but he sought to put that reality into an important context.

"While the Justice Department is often the last line of defense against fraud and corruption, all of you who work in compliance are the first," said Miller. "Criminal prosecutions can and do deter future bad behavior, but your work can prevent that conduct before it happens."

...It is that commitment to prevent bad behavior before it happens that drives compliance professionals in developing robust, resilient and effective compliance training programs.

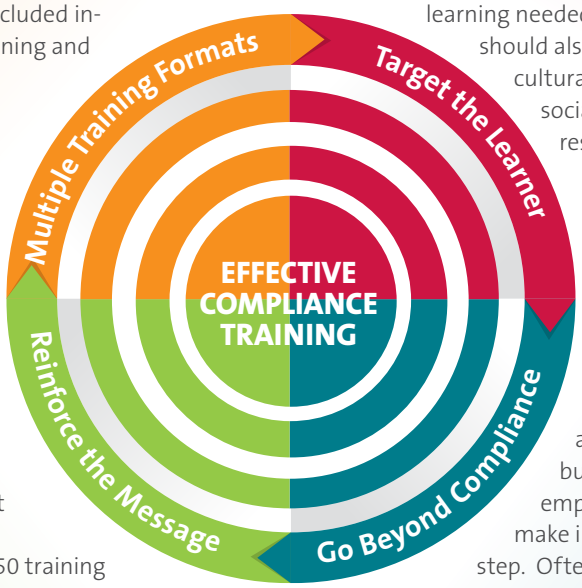
HOW DOJ SEES "EFFECTIVE" COMPLIANCE *(Continued)*

Best Practices for Effective Compliance Training

Both DOJ and SEC considered Morgan Stanley's compliance training program to be especially praiseworthy. The Morgan Stanley program included several "best practices" that we recommend to our clients, including the following:

Multiple Training Formats: We emphasize the importance of using multiple learning techniques to stimulate engagement and drive comprehension among diverse groups of learners. Training formats may include online learning, live presentations, newsletters and various technology-based messaging. Younger employees, in particular, are more open to technology-based learning techniques, such as text messages and even social networking. According to reports, Morgan Stanley's training program included in-person presentations, web-based training and reminder messaging.

Target the Learner: Effective training is defined by the learner, not the number of hours or specific format used to distribute materials. Training should not only target the learning needs of the learner, but also the knowledge needs of the learner. Employees outside of the US may require more thorough knowledge about the FCPA than would employees with limited or no contact with foreign government officials. But at the same time, training must be tailored to the learning needs of the learner. Language is the most obvious learning needed to be considered, but training should also take into account the learner's cultural expectations, literacy levels, social conventions and even religious restrictions.



Reinforce the Message: Training is not a one-time event. A comprehensive training program on FCPA, for example, should be followed by ongoing reminders that reinforce the company's commitment to compliance. According to reports, Morgan Stanley provided more than 50 training sessions on FCPA and anti-corruption topics for Asia-based employees. Equally important, the company regularly distributed "reminders." According to DOJ and SEC, reminder messages addressed topics, including the FCPA, gift-giving and receiving, contact with regulators and government officials, guidelines for engaging consultants, global anti-bribery, Code of Conduct, travel and expense policy and even a specific reminder about gifts and entertainment related to the Beijing and Hong Kong Olympic Games.

Go Beyond Compliance: No training program can answer every individual situation in which an employee may be involved – but well-designed training can help employees identify potential risks and make informed decisions about the next step. Often that "next step" is reaching out to the Corporate Compliance Officer for guidance. It may also be reporting a suspected violation. An effective compliance program continually reinforces a corporate culture in which mutual support and trust among employees promote the right actions at the right time.

APEC MOVES FORWARD ON ANTI-CORRUPTION

This past November, President Barack Obama and Asia-Pacific Economic Cooperation (APEC) leaders agreed to intensify their anti-corruption efforts across the Pacific region. A key aspect of that elevated effort, according to information released by the White House, is that leaders "... encouraged APEC Member Economies to enhance cross-border cooperation in combating public corruption, business bribery, money laundering and illicit trade. The creation of a new network of anti-corruption authorities and law enforcement agencies ... will support these actions and reinforce APEC's overall efforts to spur economic growth and greater investment and trade across all economies."

The meeting of APEC leaders produced several tangible actions that are likely to affect compliance officers of global companies, particularly those with significant operations in Asia. APEC leaders adopted the APEC Principles on the Prevention of Bribery and Enforcement of Anti-Bribery Laws as well as the APEC General Elements of Effective Voluntary Corporate Compliance Programs.

Of particular interest to the Life Sciences community, APEC Ministers endorsed three sets of APEC principles for voluntary codes of ethics in sectors where Subject Matter Experts (SMEs) are the major stakeholders. The first SME Business Ethics forum had been held in Nanjing, China in September 2014, during which participants issued the Nanjing Declaration to Promote Ethical Business Environments in the Medical Device and Biopharmaceutical Sectors for SMEs.

The Nanjing Declaration

The Nanjing Declaration was not developed overnight, nor was it crafted by one representative from any one group of interested parties. The Declaration begins by defining the various participants: "... representatives from healthcare providers and professional organizations, anti-corruption agencies, health ministries, health regulatory agencies, economic ministries, medical device and biopharmaceutical associations, industry and patient organizations from across the APEC region." The numbers represented by those groups are impressive. According to the Declaration, "... nearly 1,000 stakeholder representatives have engaged in this initiative from all 21 APEC member economies to strengthen ethical business practices for the medical device and biopharmaceutical sectors, including more than 10,000 SMEs ..."

Global Life Science companies rely on lengthy supply chains that invariably include small- and medium-sized businesses that are likely to feel the impact of the Nanjing Declaration. So, what are the areas of focus contained in the Nanjing Declaration and related Principles adopted by APEC over the past several years? The Declaration set out several goals that provide insight into where APEC's priorities stand:

- Double the number of Medical Device and Biopharmaceutical industry associations that have adopted codes of ethics from 33 in 2012 to 66 or more

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APEC MOVES FORWARD ON ANTI-CORRUPTION *(Continued)*

by 2015, and work toward the universal adoption and implementation of the APEC Principles by 2020;

- Implementation of association codes by a majority of member companies by 2017;
- For APEC member governments, support and endorse local partnerships in APEC economies between relevant government ministries/agencies and the Medical Device and pharmaceutical industries to advance industry's voluntary efforts to strengthen ethical business practices;
- For governments, support and endorse local partnerships in APEC economies between relevant government ministries/agencies and healthcare professional organizations;
- For Healthcare Professionals, support the development and implementation of codes of conduct consistent with the APEC Principles, working toward regional alignment by 2020;
- For non-government organizations, in particular patient organizations, promote ethical environments in the Medical Device and bBiopharmaceutical sectors.

Heads-Up for CCOs

APEC has taken on the task of aligning anti-corruption laws, regulations and policies among member states across the Asia Pacific region. There are a number of Declarations (including the Beijing Declaration on Fighting Corruption) and Principles that have been endorsed and are at various stages of implementation by member countries.

Compliance challenges for global companies have historically come from the US, the European Union and international organizations, such as the World Bank, the UN and ISO. That is changing – and changing dramatically – as the countries of Asia take on a much larger role in the production and use of medical products. Individual countries, including China, have been particularly aggressive in pursuing international companies suspected of corrupt activities and in enacting stringent laws related to anti-corruption.

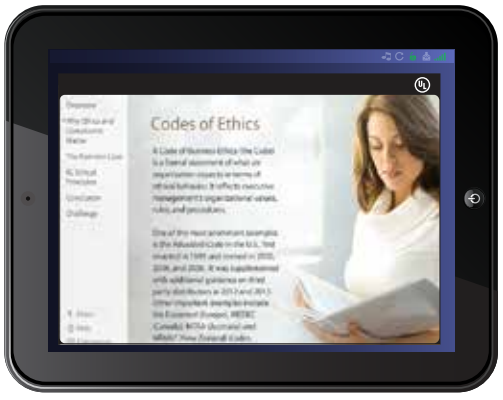
CCOs of global companies can be hard-pressed to stay current in a rapidly evolving landscape of new laws, often with shared anti-corruption goals but with vastly different requirements for achieving those goals. APEC's efforts to create a common infrastructure across the member countries may help CCOs as the Declarations and Principles take effect. Until the implementation of those initiatives, it is important for CCOs to understand the general framework underlying APEC's various policy initiatives while digging deep into the specific regulations and requirements of the countries in which the company operates.

AdvaMed Compliance Course Focuses on Kuala Lumpur Principles

Compliance teams in the Medical Device industry now have a convenient way to learn about global codes and principles.

A new UL eLearning course authored by experts at AdvaMed, entitled *Compliance Improves Business Performance*, outlines the Kuala Lumpur (KL) Principles, which are focused on improving the quality of Health Care throughout the Asia Pacific region. These principles were presented at the 2011 Asia Pacific Economic Cooperation's (APEC) SME Ministerial Meeting and endorsed by APEC ministers the same year.

This self-paced course, which should take about 30 minutes to complete, can help Medical Device compliance teams and executives recognize the costs of corruption worldwide, the major milestones in anti-corruption legislation and the codes and principles that can ensure not only compliance with the law but also a stronger competitive edge for a global business.



How to Register for this Course

AdvaMed members can receive complimentary access to this course. Simply visit uleduneering.com/partnerships/advamed. Complete the brief form to register, and we'll send you an e-mail with complete login instructions to take the course online.

GLOBAL ANTI-CORRUPTION LAWS: DIFFERENT RISKS AND REQUIREMENTS

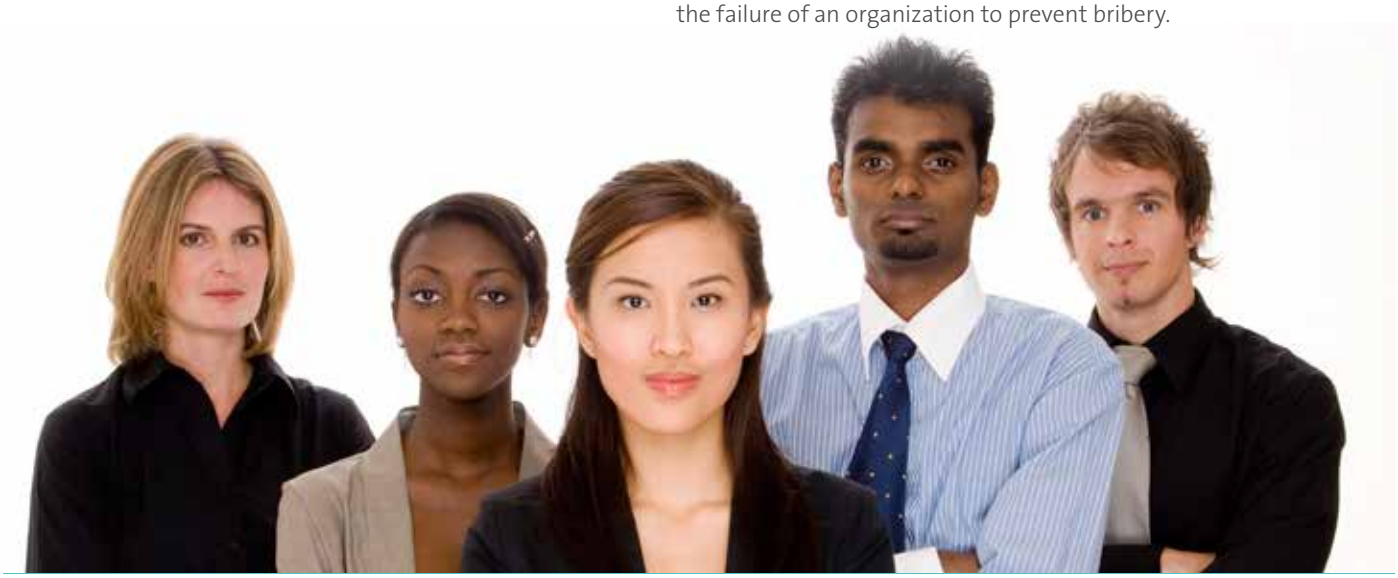
When it was enacted in 2010, the UK Bribery Act put global companies on notice that their anti-corruption compliance responsibilities were no longer limited to those imposed by the US' Foreign Corrupt Practices Act (FCPA). Since then, countries stretching from Canada to Brazil, Germany and China have approved new or expanded anti-corruption laws. As a result, companies with operations or suppliers in multiple countries face the challenge of complying with a diverse set of laws with different provisions that require different compliance responses.

Despite the growing number of national anti-corruption laws, enforcement across the globe has not been applied with equal enthusiasm. According to Transparency International's, Progress Report 2014: Assessing Enforcement of the OECD Convention on Combating Foreign Bribery, only four countries were ranked as having active enforcement of their anti-corruption laws. Germany and Switzerland rounded out the "active" group. The ranking is likely to change in the next year. Already, countries including Canada and China have intensified their anti-corruption efforts through expanded legislation and enforcement activities while countries including Brazil are setting strong standards for ethical business conduct with new laws.

The FCPA and Anti-Bribery Act

The FCPA is the world's most well-established anti-corruption law and has set the foundation for many other countries' laws. Despite the FCPA's long-standing status as the world's most stringent anti-corruption law, the UK's Bribery Act of 2010 gives the US law a run for the title. Both laws have a broad reach, potentially impacting companies and individuals across the globe. But, while the two laws are frequently lumped together, they are not identical. In fact, there are key differences between the two – and those distinctions could pose very different compliance challenges. Here are some of the most significant distinctions between the two laws:

- The FCPA prohibits bribes (defined as "anything of value") that are offered, approved or paid to a foreign government official for the purpose of obtaining or retaining business. The Bribery Act prohibits the payment of a bribe to any person as a way of inducing them to act improperly; the prohibition is not limited to foreign government officials.
- Under the FCPA, receiving or accepting a bribe is not prohibited; only offering or paying a bribe is prohibited. The Bribery Act prohibits bribing a person and accepting a bribe.
- The FCPA imposes strict liability only under its books and records provision (there is no strict liability under the bribery provision), which requires companies to maintain adequate systems of "books and records." The Bribery Act created a new strict liability offense for the failure of an organization to prevent bribery.



GLOBAL ANTI-CORRUPTION LAWS: DIFFERENT RISKS AND REQUIREMENTS *(Continued)*

- The FCPA applies to any company headquartered in the US, all US citizens regardless of their location, any person acting in violation of the law while in the US and any foreign company listed on a US stock exchange. The Bribery Act applies to any company that conducts any part of its business in the UK, to UK citizens and to individuals who reside in the UK. Both the FCPA and Bribery Act apply to activities of regulated companies and individuals regardless of the location of the violation. In early 2014, David Green, head of the Serious Fraud Office, proposed an amendment to the Bribery Act that would make companies and banks that fail to prevent financial crime by employees liable to bans from European contracts. The proposal is opposed by many groups but, according to a speech by Green in October 2014 at the Pinsent Masons Regulatory Conference, it is still moving forward. According to statements by Green, if approved, the amendment would "... greatly increase the SFO's reach over corporates in appropriate cases."
- The FCPA allows "facilitating payments" in specific situations. The Bribery Act makes no allowance for facilitating payments.
- The FCPA is enforced by the US Department of Justice and the US Securities and Exchange Commission. The Bribery Act is enforced by the Serious Fraud Office. Enforcement agencies for both laws routinely are assisted by other law enforcement agencies, both in their own countries and under cooperative agreements with other governments.

Beyond the US and UK

Companies with dispersed operations or suppliers do not have the luxury of complying with only one nation's laws. The reach of the FCPA and Bribery Act may affect a company regardless of its location; similarly, new laws, such as Brazil's commonly called Clean Companies Act, applies to any company with a presence in Brazil. Although the Act has no provision for prosecuting individuals, regulated organizations carry strict liability for prohibited actions committed for their benefit or in their interest.

It is important to recognize that international cooperation in investigating and enforcing anti-corruption laws is now the norm. That cooperation has already led to some of the largest global settlements by companies alleged to have violated anti-corruption laws, regardless of the country. Countries may also initiate "follow-on" prosecutions based on information uncovered in an investigation by another government. Finally, shareholders and investors have stepped into the arena by launching lawsuits based on information identified during a governmental investigation.

There is no "easy" pathway to anti-corruption compliance by a company with operations, agents and suppliers in multiple countries. Training should be pushed out from the corporate walls to third parties who may expose the company to liabilities. Similarly, as recent enforcement actions demonstrate the risks posed by corporate subsidiaries, companies will be called on to exert greater education and oversight of subsidiary officers, employees and third parties. With multiple countries enacting their own anti-corruption laws, the complexity of the CCO's job will only increase.

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