Managing bribery and corruption risks in the life sciences industry
“Any competitive advantage gained through corruption is a mirage.”

Robert S. Khuzami, former Director of Enforcement, US Securities and Exchange Commission
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Managing bribery and corruption risks in the life sciences industry
Introduction

The current economic climate has meant that businesses need an even stronger corporate culture to monitor compliance and fight the risks of fraud, bribery and corruption. According to our 2016 Global Fraud Survey,1 11% of company executives across all industries believe that it is common practice to use bribery to win contracts. This figure increases to 15% in the life sciences sector, which is the highest across all the sectors.

Adding to the importance of managing bribery and corruption risk in the life sciences sector is the increasing volume of legislation and regulations, coupled with increased extraterritorial enforcement. Keeping compliance and monitoring programs up to date with the latest changes is a significant challenge, as demonstrated by just a few examples in recent years:

• The US Securities and Exchange Commission (SEC) noted a 20% increase in the number of whistleblower tips received in the first quarter of 2015 compared with the same period in 2014 under the 2010 US Dodd-Frank Act Whistleblower Program, incentivized by the combination of financial rewards and more stringent protections. Between 2011 and 2015, the SEC has awarded more than US$54m to 22 whistleblowers, of which US$37m was paid in 2015 alone.
• The UK Government released its UK Anti-Corruption Plan in December 2014, with the goal of providing a direction for the Government’s approach to international and domestic corruption, highlighting that this topic is a priority.
• Laws continue to be updated across many countries in this sector. In addition to the Russian legislation in 2012 that banned clinicians and pharmacists from accepting gifts from pharmaceutical companies, in 2015, Germany drafted a bill that extends its anti-corruption legislation to incorporate all health care professionals, including physiotherapists, pharmacists and self-employed practitioners (who were previously not considered “public officials” and thus exempt from enforcement), as well as all foreign public officials.
• Following the transparency requirements adopted in France in 2011, and in the US in 2013, from 2016, all European Federation of Pharmaceutical Industries and Associations (EFPIA) member companies will be required to disclose payments and transfers of value made to health care professionals and organizations. In this paper, we discuss why corruption problems persist, despite maturing anti-corruption and compliance programs, and set out some practical considerations for companies that face corruption risks.

1 EY’s 14th Global Fraud Survey 2016: Corporate misconduct – individual consequences.
Why life sciences?

In recent years, we have observed a variety of corruption cases that have covered a broad range of industries. In particular, such cases have involved companies in large infrastructure projects, where individual bribes and the business obtained from making those bribes can be quite significant. Not surprisingly, these are the industry sectors ranked lowest on Transparency International’s Bribe Payers Index. But why, then, is the life sciences sector ranked closely behind such a different industry group? What are the characteristics and pressure points of life sciences companies that seem to increase the risk of corruption?

**Characteristics that increase the risk of bribery and corruption**

**Customers and influencers of life sciences companies are often public officials.** In many countries, health care professionals (HCPs) or health fund administrators are employees of the government, or work at public institutions. They can be considered “public officials” under many bribery laws. By focusing on patient health, virtually all aspects of a life sciences company’s work – from R&D through manufacturing and promotion to distribution and pharmacovigilance – are highly regulated by government. So there are touch points with government officials every day, throughout the world. In some countries, especially in emerging markets, public officials are paid less than their private practice counterparts. So even gifts, meals or entertainment that involve sums that are small by other standards may be perceived as attempts to gain influence.

**Sponsored event objectives can be unclear.** Life sciences companies frequently provide travel, hospitality and other benefits to HCPs in the normal course of business. These benefits may be in connection with promotional activities, continuing medical education, scientific or medical research, clinical trials or post-marketing studies. Whether a sponsored event is related to scientific exchange or promotional activities is often unclear. This can lead to concerns about whether the sponsored interactions are appropriate. Fortunately, many countries have adopted industry codes that address these and other types of interaction. However, implementing and monitoring local compliance by subsidiaries remains a challenge for many global companies.
A heavy reliance on third parties. Another frequent feature of the life sciences sector is heavy reliance on sales intermediaries and other third parties. This is, once again, particularly prevalent in developing countries, where life sciences companies that are looking to sell directly often have insufficient language skills, business networks and logistics. But the risks extend beyond sales and cultural intermediaries. Other third parties, such as event organizers and travel agents, can be retained and sometimes serve as a conduit for transactions that are potentially inappropriate. Recent prosecutions have held companies liable for the unethical or illegal behavior of their agents or intermediaries as indirect actions of the contracting party. Exercising control over third parties and subcontractors is one of the major challenges facing the industry. Many companies have developed third-party due diligence programs, that include thorough understanding of the business purpose for engaging third parties, the precise services they perform and the compensation structure that they receive. In addition, many companies aim to monitor their third parties through a variety of programs, including on-site audits.

Loss of patent protection. Many “blockbuster” products are nearing the end of their patent protection. This results in increased pressure to keep market share and fend off competition, and may cause employees to engage in more aggressive activities to hold their company’s market position. Companies may also try to compensate for their new product pipelines through mergers and acquisitions (M&A) of other entities.

M&A activity. There has been an upsurge in the level of M&A activity as companies within the life sciences industry consolidate to cut costs, expand research pipelines and extend geographic reach. Such business transactions can increase compliance risks, depending on the strength of the acquired entity’s compliance practices. Successor liability has been a key focus of recent investigations, with acquirers assuming responsibility for the past or present actions of the acquired company’s employees and agents. Therefore, conducting thorough due diligence procedures is crucial before completing a business transaction and immediately after the transaction to manage the risks associated with corruption.

Proliferation of big data. Few industries compare to the life sciences sector in terms of the sheer volume, velocity and variety of data needed to run an organization effectively. With increased global competition and a stricter regulatory environment, effective management and monitoring of an anti-corruption program can become highly complex when dealing with such volumes of disparate data sources. From potentially improper vendor payments, speaker program documentation, HCP interactions, travel and entertainment, commissions, sales credits, grants, social media or email, the sources of electronically stored information that can put a life sciences company at risk are extensive. To address these risks, life sciences companies are rethinking how they leverage new innovations in technology to handle these big data challenges, including processing scalability, transaction monitoring and the integration of both structured (financial) and unstructured (text) data sources into a coherent analysis platform.
Why life sciences?

Compliance pressure points

Within the high-pressure environment of a life sciences company, a number of specific activities may pose substantial compliance risks on a day-to-day basis. Here are some of the most pressing examples:

Level of fees for services. It is a common business practice for life sciences companies to compensate HCPs for rendering professional services related to their field of expertise, such as speaking at medical conferences, consulting, training and participating in research studies. However, these legitimate programs can also be used as a means to provide benefits to HCPs in return for sales. To prevent such practices, companies must first establish a means of substantiating the general need for the service and how, from a medical or scientific perspective, the proposed HCP meets the need, independent of the HCP’s potential ability to purchase or influence the purchase of the company’s products.

Fair market value. To manage the risk that prosecutors may view services provided by HCPs to be thinly veiled bribes, there should be a clear and objective basis for establishing the compensation to be provided to a HCP. It is advisable to establish a methodology for calculating compensation, such as prevailing rates in the locality, general compensation of the HCP in their practice, level of relevant experience and scientific contributions of the HCP. This will help to establish a clear basis for the compensation, as well as increasing consistency of compensation.

Proof of service. Similarly to fair market value, if documentation confirming that the services that were performed cannot be provided, regulators may believe that payments related to alleged services were merely bribes. As a result, companies should ensure that adequate documentation is produced by an approval process. Such a process should require substantiation of the business case and estimated costs before a contract is entered into, and documentation to prove that the services were actually performed or expenses incurred prior to payment.

R&D data integrity. The importance of true and accurate preclinical data are the key factors for any medical product. Potential fraud or irregularity in the underlying data, including clinical trial or investigator misconduct through improper payments, may lead to investigations, fines, billions of dollars of lost revenue, and delay of market access, but, even more importantly, may cause potential harm to patients.

Value of scientific exchange. In the life sciences industry, a premium is placed on the value of scientific exchange of information to benefit patient health and outcomes. However, medical events designed to facilitate scientific exchange of information have often been in vacation destinations, and involve lavish entertainment and events unrelated to medical education. Moreover, companies may sponsor specific HCPs to attend the events, including payment of registration fees, travel costs and accommodation. These additional circumstances can give the impression to regulators that companies sponsoring HCPs, or the entertainment and other events, are making disguised attempts to influence the prescribing behavior of the HCPs, rather than supporting the exchange of scientific information.
The objectives of corporate citizenship initiatives. As in other industries, life sciences companies often want to be involved in their communities, and take an interest in public health and in research conducted on those topics. So it is not surprising that they may consider making charitable contributions to hospitals, nonprofit and educational institutions, medical societies and patient foundations. However, because these entities also employ, or are led by, the very HCPs that the companies want to persuade to use their products, there may be a blurred line between those donations and an attempt to influence individuals or institutions. The nature of the gift (for example, cash, products, other goods or equipment, unrestricted donations and disclosure of the form itself) may also raise concerns from a corruption perspective if the item could be converted for a use inconsistent with the stated purpose of the donation. As a result, additional problems could arise, which include the ability to determine the ownership, control and purpose of the charitable organizations, in order to ascertain whether they are bona fide charitable organizations, whether they are related to individual HCPs directly or indirectly, or if these HCPs have the power to influence government.

Tender requirements. Often, life sciences companies must participate in tenders to be listed on a formulary or approved for reimbursement. Tenders can be quite competitive, and losing a tender can damage a company’s business in the country. Tenders are often through government health systems, requiring additional direct interaction with government officials. Furthermore, some countries stipulate that the entity submitting the tender must be locally owned. This can necessitate the use of a third party, which may, as indicated above, create corruption risks. There have also been publicized instances of competitors colluding on bids, which creates additional risks.

Government austerity measures. In the current economic climate, many countries are struggling not only with the spiraling costs of health care, but also reduced tax incomes, rising deficits and increasing debt. As a result, some countries have been forced to make cuts to health programs. Such measures can result in increased pricing pressures on manufacturers, emphasis on patient outcomes, pressure to use less expensive bioequivalent, and removing coverage for certain medicines or conditions. Other possible implications are charges for access to state health care premises or compulsory licensing.

The ways in which life sciences products are developed, marketed, purchased, dispensed and paid for continue to evolve, often with little consistency or transparency. These changes can bring both risks and opportunities for companies in the sector. Companies with products losing patent protection may be anxious about maintaining their market share and revenue base, whereas generic manufacturers may have significant opportunities for market expansion.

At the same time, HCPs and government officials in certain countries may be subject to pay freezes or cuts, and may be looking for other means of income. Health care institutions may no longer be able to afford resources that they could in the past, leading them to request financial or other support directly as donations or under the guise of medical education, patient assistance or research. This combination of forces can create an environment that is conducive to bribes by company employees to HCPs, and in which government officials are willing to accept them.
Responding to the challenge

Companies in the life sciences sector need to address their corruption risks proactively. They should implement a robust and effective anti-corruption compliance program. Such a program will help companies reduce the risk of corruption and can help lessen the impact through more timely identification and investigation of a suspicious event. By adopting a program that is reviewed and monitored on an ongoing basis to assess that it remains relevant and proportionate, companies may be in a better position to demonstrate the measures that were taken to manage such risks, should a potential corruption breach be identified and scrutinized by authorities.

A step-by-step approach to evaluate and address corruption risks

EY has conducted numerous corruption risk assessments and has assisted companies with the development of anti-corruption compliance programs, including designing policies, financial controls, training, anti-corruption compliance internal audits and other monitoring mechanisms. Through our work, we have developed experience and knowledge of what companies should be doing to detect and deter corruption, and protect their shareholders.
Ten steps to an effective anti-corruption compliance program

1. **Conduct a corruption risk assessment**
   
   For a company acting in the life sciences sector, taking the time to identify and analyze its risks is essential to developing an effective anti-corruption compliance program. Companies need to allocate scarce compliance resources as efficiently as possible. Should unforeseen issues arise, a thorough risk assessment process puts a company in a position to demonstrate that it used due care in assessing its risk.

   The corruption risk assessment should focus on the actual risks posed by the nature of a company’s operations; the degree of business with governmental entities; its use of agents and other intermediaries; the countries where it conducts business; and the regulatory environment. It should identify what policies and controls the company has in place to mitigate its corruption risk, and analyze their effectiveness.

   The risk assessment should identify the nature and extent of interactions with HCPs, health administrations and regulators, and the policies and procedures applicable to those interactions. Reference should be given to local industry codes and regulations that provide guidance on topics such as government tenders, gifts, charitable donations, sponsorships, grants, meals and entertainment, and fee-for-service contracts. A plan for an effective anti-corruption compliance program, based on the present risk and current controls in place, should then be developed.

   The depth of the risk assessment will vary by company. The procedures involve information collection and analysis, generally through the assembly of documents, interviews and financial analysis. More robust risk assessments also involve transaction testing that can be performed at the corporate level and in high-risk locations.

2. **Develop a corporate anti-corruption policy**

   Companies should develop a company-wide anti-corruption policy, based on the requirements not only of the FCPA and the UK Bribery Act, but also local corruption standards and industry codes. The overall compliance policy should be a clear and unambiguous statement of the company’s position that both governmental and commercial bribery, on any scale or level, will not be tolerated. It should discuss the company’s commitment to accuracy in reporting and recording transactions, and to the establishment of internal systems ensuring proper control, accountability and safeguarding of shareholder assets.

   The policy should also encourage employees to report violations or seek guidance, and offer examples of “red flags” to help them recognize and avoid problem situations.
Retaining agents, consultants and other vendors, and the controls to monitor them on an ongoing basis. The vast majority of reported FCPA cases involved the use of third-party intermediaries, such as agents or consultants. Accordingly, this is a very important area and the central focus of many companies’ anti-corruption compliance programs. It is also perhaps the most expensive, in terms of the effort and resources required to address the risks.

Additional policies often include:

Gifts, entertainment, travel and expenses. Giving gifts or providing meals, entertainment or travel to government employees could, under certain circumstances, violate not only local industry codes, but also corruption laws. Such expenditure needs to be monitored carefully to avoid even the appearance of impropriety. This is an area of special concern in certain countries, where the culture of gift giving and business entertainment is firmly ingrained, and government and private sector officials at various levels expect such courtesies.

Facilitation payments. Facilitation payments are commonly thought of as “grease” payments, generally provided to lower-level government employees. While facilitation payments are prohibited by the UK Bribery Act, many payments that meet the FCPA’s narrow definition are also illegal in the local country where they are made. Given the different legal treatment accorded to such payments by the various authorities, and the inherent difficulties in enforcing a policy that prohibits bribery but allows facilitation payments, many companies are banning them altogether, with limited exceptions for situations involving potential imminent harm to life or property.

Charitable giving. Charitable giving guidelines should be designed to ensure that charitable donations are not being provided to organizations that act as conduits for bribes. Moreover, approval of charitable donations should be separate from the sales and marketing function.
Ten steps to an effective anti-corruption compliance program

Implement an effective whistle-blower hotline. An important element of an effective compliance program is ensuring that there are means of detecting potential violations and then addressing them. A whistle-blower hotline is imperative in this respect. It complements, rather than replaces, the need for compliance audits. At a minimum, an effective whistle-blower hotline should:

- Be easy to access
- Accommodate multiple languages and time zones
- Allow for anonymous submissions
- Offer a feedback mechanism for whistle-blowers on the status of their matter or additional required information
- Provide tracking of claims, including their status and duration
- Ensure complaints are routed to the proper resource within the company
- Summarize information for reporting purposes to responsible parties

In the light of the SEC whistle-blower reward program introduced under the Dodd-Frank Act, companies that wish to encourage individuals to report claims to the company, rather than the regulators, are strongly advised to establish an effective and timely whistle-blower hotline. Key steps include:

- Reviewing existing internal processes and ensuring that there is an effective, well-publicized way for potential whistle-blowers (both internal and external) to make claims to the company
- Analyzing the ability of the company's systems to respond to complaints and manage them
- Assessing whether internal practices can resolve matters quickly and thoroughly to satisfy whistle-blowers that their complaints have been taken seriously and investigated
Good management control is the first line of defense against corrupt payments. For example, strict enforcement of rules related to meals and entertainment, and the detailed reporting of the business purpose and people entertained, supports anti-corruption compliance. Reconciling bank accounts on a monthly basis is a key cash control that also protects against misappropriation and possible off-books payments. Increased financial controls in high-risk areas can be a critical way to avoid violations of FCPA books and records. Often, this means enhancing financial controls beyond what might normally be considered adequate to ensure accurate financial reporting under the Sarbanes-Oxley Act. This is because there is the additional purpose of deterring and detecting illicit or improper payments, regardless of value. Such controls include enhanced transaction review; augmented approval and accounting procedures; controls around bank accounts and petty cash; enhanced vendor approval and payment processes; and increased scrutiny of high-risk transactions. Life sciences companies should also consider ensuring that payments to health care professionals are properly approved through the compliance procedures prior to authorizing payment.

Life sciences companies may use a variety of third parties beyond distribution and other sales intermediaries. For example, clinical research organizations, travel agents, event planners, consultants or HCPs could be engaged as speakers, researchers or advisory board members. Acting on a company’s behalf, they can create vicarious liability. In today’s regulatory environment, it is important to know when a third party enters into business on behalf of the company, why they are used and what compliance and monitoring provisions are included in their contracts.

Companies should consider the following to mitigate the corruption risks posed by third parties:

- Precontract and recurring period due diligence and acceptance procedures
- Contracting provisions with anti-bribery representations and warranties
- Vendor certifications and anti-corruption training
- Ongoing monitoring of activity, including special payments review, approval for high-risk vendors periodic recertification and on-site audits

Companies can consider a four-stage approach to this challenge. First, identify the third parties; second, apply a risk-based approach; third, assess high-risk rated parties; and finally, develop a robust structure for the ongoing management of third parties and related risk.
Ten steps to an effective anti-corruption compliance program

6 Conduct anti-corruption compliance training

Anti-corruption training is imperative, especially for global organizations employing nationals in countries with a history of corruption. At a minimum, every person in a position to obtain business through bribery or other improper means should receive anti-corruption compliance training. Companies should also consider training all internal audit, accounting, financial and legal employees. Adequate training tools may include live and web-based training for senior employees, and web-based training for all other employees. Enhanced training may be considered for specific groups, such as senior management, accounting, sales and marketing, and finance. A company should have a process in place to ensure continual refreshment of the training materials. Many companies complement their training with a certification program. Training of third parties acting on behalf of the company must also be considered.

7 Monitor the program

Monitoring means continually evaluating your company’s anti-corruption compliance program for effectiveness. The purpose of anti-corruption compliance programs should be to both test for compliance with the policies, as well as test for potential violations or red flags. These activities often uncover new risks not previously seen or fully appreciated. In this way, they act as part of an ongoing corruption risk assessment process. This is one area where data analytics can play a key role.

However, the analytics required for effectively detecting bribery and corruption fraud schemes are fundamentally different from those used to identify traditional financial statement and accounting fraud schemes. Leading anti-corruption analytics should incorporate targeted, model-based mining and visual analytics tools that allow the data to “speak for itself” when it comes to identifying anomalies and unusual patterns. This is where the integration of big data processing capabilities and analytics that integrate text mining, data visualization, statistical analysis and external data sources can save time and money by focusing on high-risk vendors, employees or third parties.

Finally, anti-corruption procedures should stand alone and not be integrated into a larger set of processes. Generally, integrating anti-corruption procedures into larger audit programs is ineffective, as it often leads to situations where the auditor doing the testing lacks the necessary training, focus or supervision to do the work effectively.
Companies should develop a policy and specific procedures for anti-corruption due diligence in any contemplated merger, acquisition, or joint venture.

Many FCPA prosecutions have arisen in the context of M&A, where past actions of corruption came to light in the due diligence. The US Department of Justice (DoJ) has taken the position that companies must conduct thorough due diligence on the target company in order to avoid inheriting liability relating to potential past corrupt actions. It is common for the DoJ to pursue alleged FCPA violations on a “successor liability” basis, as evidenced by numerous public cases.

The amount of anti-corruption due diligence that can be performed in the context of a merger or acquisition is subject to negotiation between the buyer and the seller, and is often conducted under intense time pressure. Following the closing of the transaction, the acquiring company should put anti-corruption compliance high on its integration plan. It should conduct further risk assessment procedures as necessary to ensure that it has a good grasp of the corruption risks posed by the new organization and that it is addressing these risks.

Conducting anti-corruption due diligence makes good business sense, in order to address the risks it presents. These include:

- Potential impact on the future development and earnings of a target company (loss of business due to damage to image and reputation)
- Loss of contracts, licenses, or business opportunities that have been gained or kept through illegitimate payments or other
- Damage to reputation among authorities, public organizations, and business partners; sanctions from authorities and regulatory bodies
- Purchase price dispute, especially with long-term uncertainty regarding the result of law actions against the target company
- Potential high costs of investigations against the company and key management (internally and externally); fines after unlawful behavior is detected and made public
- Later pressure to dismiss key employees involved in past unlawful behavior, in order to demonstrate zero tolerance against corruption or violation of law to internal and external audiences
- Liability risks for management and controlling body of buyer company
- Risk of legal prosecution of “acquired” infringements against anti-corruption regulations
Ten steps to an effective anti-corruption compliance program

9 Periodically reassess risk and modify the program

Corruption risk assessments should be conducted periodically, to make sure that the anti-corruption program is evolving to meet new risks posed by the changing business, new markets, new partners and regulatory environment. If the business changes significantly, the reassessment process should be accelerated.

10 Engage a cross-functional team

In addition to a strong “tone at the top” from the board and C-suite management, effective anti-corruption programs generally collaborate across business functions. For example, legal and compliance will often team with internal audit to execute anti-corruption fieldwork. This trend is requiring internal auditors to retool and obtain specific training in the areas of FCPA and anti-corruption legislation or testing procedures. Another emerging pattern is legal and compliance and internal audit teaming with other business functions, including information technology, finance, human resources, procurement and the regional, divisional or operational business unit leaders, as they all have data sources or policies relevant to mitigating corruption risks.

Effective anti-corruption compliance programs that incorporate these 10 steps have a powerful deterrent effect. They send a message that senior management is committed to compliance and that they are checking to make sure compliance is achieved. Appropriate follow-up and disciplinary action is crucial to creating an anti-corruption culture.
Managing bribery and corruption risks in the life sciences industry
How EY can help

Through our experience advising a number of organizations in the life sciences sector and our global reach, we are ideally placed to help you reduce the risk of bribery and corruption in your business. Some recent case studies include:

**International compliance assessment.** We assessed compliance levels at over 50 international subsidiaries of a multinational medical device company. We focused on sales, marketing, financial controls, medical affairs activities and corporate governance, reviewing compliance with company and external standards. We presented our findings to senior management.

**Sales and marketing compliance testing.** We evaluated interactions between a pharmaceutical manufacturer and buyers and prescribers of its products, to assess sales and marketing compliance. Our review focused on fee-for-service arrangements, gifts and entertainment, pricing discounts, and free products and services. By testing key controls and developing comprehensive process maps, we were able to identify areas of concern and offer recommendations to address them.

**Government investigation.** A global pharmaceutical manufacturer sourced its investigation capabilities worldwide, requested support with the triage process, investigation strategy and execution process. We worked in collaboration with the companies’ in-house and external legal counsel, to investigate issues including off-label “promotions”, employee misconduct and anti-trust compliance activities to prevent bribery of government officials.

**Global compliance monitoring program.** We advised on the design of a risk-based compliance monitoring program for a multinational pharmaceutical company. This included a governance and reporting infrastructure to drive a consistent compliance monitoring approach across their global operations, increasing the transparency in findings and clarifying accountability for remediation. We used data analytics techniques to inform the testing program, allowing a focus on high-risk or unusual transactions to test for compliance monitoring.

**Fraud risk assessment.** We conducted a fraud risk assessment at a specialty hospital to help management understand the relevant fraud risks and identify measures to mitigate the threats identified. The EY team interviewed key personnel throughout the organization and conducted data analytics of claims, vendor and disbursement data. This identified risks related to asset misappropriation, improper payments, conflicts of interest and vendor management.

**Third-party monitoring.** We worked with a large multinational pharmaceuticals company to assist it with the implementation of its global distributor monitoring program, including: conducting due diligence procedures, on-site anti-corruption assessments and training of the company’s team to conduct these procedures going forward.

**Third-party compliance program.** We helped a global medical device company to develop a risk-based approach for third-party due diligence and then implemented dedicated programs for assessing third parties of a specific risk profile. For over 50 third parties classified as high-risk from more than 20 countries, we performed third-party audits which followed the same process and reporting structure.

**Internal investigation.** We assisted a law firm with an urgent internal investigation involving the process for assessing patient consent documents related to a clinical trial registry for a specialty hospital. We helped with data analytics, interviews of key personnel and the collection, organization and summarization of documentation related to the consent process.

**Due diligence.** We helped a private investment company to assess its potential acquisition of a third-party medical billing firm. We evaluated the billing operations and analyzed claims from seven separate offices. Our professionals conducted a walkthrough of the billing operations and tested the claims process, from data through to account resolution.
Anti-bribery and anti-corruption (ABAC) forensic data analytics.
We assisted a major pharmaceutical company with the design of an ABAC analytics work plan that encompassed customized, country-by-country analytics in support of its ABAC compliance program. Leveraging our library of anti-corruption tests and country-specific keyword terms around corrupt payment descriptions, our professionals teamed with compliance and internal audit to analyze vendor and procurement-related data, as well as employee and agent expense-related submissions. We developed interactive dashboards and risk-scoring models to assist the client with the identification of high-risk vendors, employees and agents for further substantive testing in the field.
Conclusion

In a climate of workforce lay-offs, industry consolidations, mergers and acquisitions, expiration of patent protection and uncertainty created by recession and market failures, the pressure on companies and their employees has intensified. These forces have combined with renewed enforcement efforts and the expansion of investment in emerging markets to heighten the risk of bribery and corruption faced by companies today.

Life sciences companies must remain flexible as they respond to these challenges. The complex network of laws evolving from the US, the UK and other jurisdictions will challenge the sector in many ways. The topic of managing third parties will be pushed to the fore, and the importance of setting the right tone at the top will remain. Key gaps in compliance and its perception need to be identified and addressed. Compliance officers working in life sciences companies will have the opportunity to assume an active, permanent and strategic role as they manage the compliance risks that prevail or arise in their companies.
## Contacts

For further help and information, please contact one of our industry sector or local area representatives, or log on to www.ey.com/fids.

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Managing bribery and corruption risks in the life sciences industry
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