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BRIBERY AND CORRUPTION IN THE LIFE SCIENCES SECTOR

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HOT TOPIC

BRIBERY AND CORRUPTION IN THE LIFE SCIENCES SECTOR

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Gary DiBianco represents corporations and their officers, directors and employees in criminal and civil investigations, regulatory matters and complex cross-border proceedings. He has extensive experience defending government inquiries and conducting internal investigations in anti-corruption, fraud, securities and related matters. Mr DiBianco has been involved in a number of significant matters representing US and international entities in a variety of industries and business sectors.

R&C: In your experience, how susceptible is the life sciences sector to bribery and corruption? Through what channels – such as government contracts – are instances of bribery and corruption likely to emerge?

Jezierski: The life sciences sector and the pharmaceutical industry have been under the anti-corruption regulatory spotlight and subject to increased scrutiny of late. The US Department of Justice (DOJ) and the Securities and Exchange Commission (SEC) have pursued pharmaceutical and life sciences companies for various US Foreign Corrupt Practices Act (FCPA) violations, including handing out kickbacks to obtain contracts with foreign health departments, payments to physicians in government-owned hospitals, unjustified fees and excessive hospitalities to influence government-run health system physicians to prescribe their products, as well as a wide range of inducements to healthcare professionals in the form of cash and gifts such as jewellery, meals, travel, entertainment and sponsorship for attending conferences.

Klinger: In our industry we work with a number of stakeholders, including healthcare professionals and government officials, to ensure that we are developing the right treatments and delivering them effectively to as many people as possible. Interactions with these stakeholders can pose compliance risks if not managed appropriately. Our industry is also highly regulated and we operate in an increasingly challenging environment where societal expectations are changing. To accommodate these changes, the life science sector must be agile and forward looking, working proactively to identify and mitigate new risks as they emerge. We must also continue to drive a culture of integrity in all that we do to meet the legitimate expectations of all our stakeholders.

Naviloff: Life sciences products are often sold into healthcare facilities such as hospitals and clinics, which may be government controlled, or directly to government institutions. Therefore, life sciences companies must interact with governmental entities and officials, exposing them to higher public corruption risks. In many countries, state controlled compensation and pressure on reimbursement rates have resulted in a strong incentive for medical institutions and medical professionals to administer excessive or unnecessary services to patients, as well as look towards other sources of revenues to maintain profitability. These same markets often contain widespread reports of healthcare corruption. The channels used to make improper payments vary widely, influenced in part by local customs, regulations and transparency laws, which makes completion of a risk assessment all the more necessary. The higher risk channels typically include transactions that involve third-party agents such as

regulatory agencies, sponsorships and conferences, travel and entertainment, travel agent payments, and so on.

DiBianco: The DOJ and SEC treat all employees of government healthcare systems as public officials within the meaning of the FCPA. Accordingly, those authorities have initiated investigations and brought actions not only for instances in which improper payments have been made to influence senior government officials on a tender committee or a Ministry of Health, but also to influence individual government-employed doctors in prescribing or purchasing decisions. As a result, there have been numerous and wide ranging anti-corruption investigations in the life sciences sector.

Grion: Judging by enforcement trends, the sector is quite susceptible to bribery and corruption, although significant progress has been made by both industry and governments. Corruption can occur at a couple of levels. First, not unlike other industries where significant public funds are at stake, government procurement processes in some parts of the world still lack adequate governance. Therefore, it is not uncommon to see enforcement cases related to bribery in exchange for the award of large government contracts. Second, corruption can also occur at a more granular level. Estimates put the number of healthcare professionals at 40 million globally. These dedicated professionals make daily decisions on what drugs to prescribe, what consumables to use or what small medical devices to recommend. At the same time, many of these professionals reside in remote parts of the world and are significantly underpaid government employees. This combination of factors creates an environment where relatively small payments, gifts or other favours can materially influence their choice of one brand versus another. This dynamic of significant public funds and a high number of decision makers is truly unique to the life sciences space.

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> *Rodrigo S. Grion, GE Healthcare*

R&C: What preventative steps can organisations take to deter bribery and corruption? Does the life sciences sector

pose any particular challenges when drafting these policies and procedures?

Klinger: Being a compliant and ethical company is not just about having the right systems and processes in place – it is also about nurturing shared values and helping employees to make the right decisions. For example, we are moving from a rules-based to a principles-based compliance approach, to make sure employees understand and can better assess the ethical implications of the activities they undertake. We support both senior and middle management to act as role models, setting a strong and consistent tone within their individual teams and across the organisation.

Naviloff: Much can be said with regard to implementing guidance detailed within the hallmarks of an effective compliance programme. However, from a life science lens, certain steps can be taken to deter and promptly detect corruption. First, make it real by developing detailed training with real-life industry-specific examples. Second, align incentives and reward employees for achievement of compliance metrics. Third, get out of harm's way. Establish sensible policies to limit high-risk interactions with healthcare providers, particularly those who have influence over medical bodies tied to regulatory approvals. Fourth, establish guard rails, such as adopting global procurement policies to capture and analyse data to establish acceptable compensation ranges. Fifth, monitor data and test transactions to spot corrupt intent. Take a deep analytical dive into data to identify ways to reduce risks. Finally, trust but verify. Deploy local compliance resources to develop trusted relationships and centralise the triage of issues.

"Life sciences companies have developed – and should continue to implement – detailed rules on the interactions with government employees and officials that are a part of their business."

Gary DiBianco, Skadden, Arps, Slate, Meagher

DiBianco: More than many other sectors, the life sciences sector depends on close collaboration between certain consumers – key physicians, scientists, professors and opinion leaders – and life sciences companies. Companies rely on specialists to assist in innovation, clinical research, product feedback and education. Accordingly, it is a part of

the business model of the sector that companies will support research, education, conferences and charitable giving, among other activities. US authorities have scrutinised such arrangements because of the inherent benefits they provide to the recipients, who also may be in a position to influence product purchase or registration. Life sciences companies therefore have developed – and should continue to implement – detailed rules on the interactions with government employees and officials that are a part of their business.

Grion: At a basic level, preventing bribery and corruption requires a strong culture of integrity and a robust compliance programme. This is ultimately true in every industry. But the challenges of creating an effective compliance programme in life sciences are exacerbated by the number and complexity of interactions between industry and healthcare professionals. Medicine today is an incredibly high-tech business and new drugs and medical devices hit the market at fast speed. Educating individual healthcare professionals on the patient benefits of these innovative products requires significant one-on-one interactions, training and very large sales forces. On the flip side, the life sciences industry relies on healthcare professionals to be expert consultants, as they are uniquely positioned from a clinical point of view to provide input into critical areas such as clinical trials and new product development. So, ultimately an effective compliance programme needs to be tailored to the highly decentralised nature of the selling process, the fact that most healthcare professionals are considered government officials, the wide range of interactions between industry and healthcare professionals, and the potential conflicts of interest these constant interactions may represent, if not structured correctly.

Jezierski: Any company should have an anti-bribery policy geared toward the specific risks facing that company. Life sciences companies should think about the various ways that bribery can manifest itself in their sector and develop local and global policies, as well as detailed procedures that cover gifts and hospitality, healthcare conferences, clinical trials, and marketing to healthcare professionals. Other relevant policies may include a policy on travel and related business expenses, a policy on purchasing goods and services from healthcare professionals, a policy on charitable donations, a policy on hiring healthcare professionals, a policy on promotional materials, and a policy on aggregate spending analysis of payments to healthcare professionals and key opinion leaders, and a third-party due diligence policy. Companies should periodically train employees on such policies and test their knowledge and ability to identify red flags. Compliance with such policies and procedures should also be tested periodically during internal audits. To deter bribery and corruption, a life sciences company should also establish an effective 'tone at the top', with companies' leaders emphasising

the importance of compliance at every opportunity. That tone at the top should be supported and demonstrated through conduct that clearly shows senior management's commitment to anti-corruption compliance.

R&C: How should life sciences companies go about implementing an effective anti-corruption compliance programmes? Should whistleblowing provisions, for example, play a key role?

Naviloff: Organisations should consider looking to the International Organization for Standardization's (ISO) new standard titled, Anti-bribery management systems, known as ISO 37001. This standard incorporates a global view of 'good practices' for use by organisations in all jurisdictions. While ISO 37001 should not be regarded as a silver bullet, it is a well-designed tool that can be applied by life science companies as a blueprint to improve or strengthen integrated prevention programmes already in place. ISO 37001 provides a sensible approach for "reasonable and proportionate" current-state evaluation and risk assessment. Companies such as Microsoft and Walmart have publicly committed to implementing and obtaining certification of their compliance with this new ISO standard. Given the fragmented framework of anti-corruption adoption in over 38 countries, and the business advantages of doing business with third parties which have obtained public certification, this consistent framework will likely continue to grow in acceptance and adoption in the life science industry in years to come.

DiBianco: The best company programmes are closely tailored to the activities that a company conducts and are reviewed and revised frequently as business practices evolve. A corporate culture should encourage employees to raise issues of concern that they may observe, and should provide a means to do so – such as a hotline – that allows candid and truthful reporting without fear of retaliation.

Jezierski: In addition to drafting and regularly updating policies governing interactions with healthcare professionals, companies should design appropriate internal controls to identify potential violations. They should conduct periodic risk assessments and audits to verify compliance, and promptly remediate identified gaps and weaknesses. Companies should make sure to include in their risk assessments the areas that have been targeted in recent pharma-related enforcement actions, such as joint ventures and relationships with state-owned medical centres and universities. It is also of critical importance to maintain and publicise communication channels to report potential violations, promptly investigate all reported violations, and take remedial steps including adjusting policies and controls based on findings. Companies should stay informed of FCPA cases involving other pharmaceutical and life sciences companies and benchmark their compliance efforts against peers.

Grion: The frameworks for an effective compliance programme are not new and serve as a good starting point. They start with a strong leadership commitment to integrity and cascade down to policies and employee training, auditing and corrective actions, among others. Each of these aspects is equally critical to a well-functioning programme and there is no doubt that an ombuds channel for employees to raise concerns without fear of retaliation is one of the most effect ways of detecting gaps. As far as implementing a new programme, industry codes of conduct and guidelines published by medical devices and pharma associations are incredibly helpful. One aspect that is often overlooked in the design of a new programme is seamless integration of compliance requirements and controls into operational processes such as quoting, servicing, contracting and disbursing. In other words, a compliance programme in life sciences needs to be practical to be effective. Another way to think about it is requirements need to be easy for employees to comply with, and difficult for them not to. This is particularly true in an industry with so many customer touch points.

Klinger: We use an integrated control framework, which includes compliance risk assessments, continuous monitoring and regular reporting to ensure standards of ethical business conduct are put into practice across the organisation. Enabling a culture of integrity is essential to improve decision making and also to support individuals seeking to raise concerns. We have a formalised system for dealing with complaints, providing a channel through which employees and external stakeholders can report actual or suspected cases of misconduct, anonymously if they wish. We also have integrity phone lines in 115 countries, which enable employees to report concerns in more than 40 different languages, and each report is investigated. We believe that the programme helps to address and also prevent misconduct. It gives employees

the confidence to speak up, without fear of reprisal, knowing that an investigation will be carried out and appropriate action taken. The cases reported and subsequent investigations give us an opportunity to learn and so reduce the chances of such incidents happening in future.

R&C: How can data analytics help to detect bribery and corruption in the life sciences sector? What insights can Big Data offer when it comes to identifying bribery and corruption that may otherwise be 'under the radar'?

DiBianco: Data analytics can be particularly useful in examining expense trends. At base, bribery and corruption require money to flow out of a company. Reviewing compilations of employee expenses, conference and travel expenses, speaker fee arrangements, grants and donations that expose trends can indicate whether there is a geographic business unit or line that may have a disproportionate spend in certain areas. Such spend could be an indication of potential corruption, fraud or theft concerns.

Grion: Data analytics is an area that has seen an immense amount of progress and continues to evolve quickly. Historically, to detect bribery, one relied primarily on scheduled audits and risk-based sampling. Detecting actual bribery through these methods can be inefficient, particularly in cases where transactions are small and sales forces are large and dispersed. This is where Big Data represents a quantum leap development. By systematically combining disparate datasets and implementing automated routines to flag unusual transactions or outlier trends, one can significantly expand the scope of what can be monitored. This approach also has the added benefit of allowing more real-time detection for 'surgical' follow ups. Early intervention, in turn, can significantly reduce the potential for issues to grow to more significant concerns. As a final thought, leveraging Big Data requires compliance professionals to 'ask the right questions'. Vast amounts of data can be overwhelming and mining the data for actionable insights is a mix of art and science.

Klinger: Data analytics can help organisations move from risk control to risk prevention. Analytics can help identify potentially high-risk activities and enable proactive monitoring. Better leveraging available data can also reveal trends in behaviour and help to pinpoint, and proactively address, specific issues before they mature into full-blown issues. For example, data analytics can be used to improve small meeting and event monitoring by providing detailed information on conferences and enabling a more effective detection of non-compliant behaviours.

Jezierski: Companies should collect data related to their interactions with healthcare professionals

and related providers, and analyse it for any abnormalities, such as excessive payments to a particular healthcare professional or key opinion leader in a particular market, or excessive cumulative gifts and hospitalities provided to a specific healthcare professional. While working with a data analytics software provider and creating algorithms to flag anomalies may require extra effort and time on the front end, it will pay off in the long run because violations that could have gone unnoticed and caused major problems will be caught in real time.

Naviloff: Data analytics is particularly useful to the life sciences industry where large volumes of information typically exist due to long supply and distribution chains involving fragmented pricing, with profits in some instances determined by the ultimate end customer. It is also useful given the growing body of transparency regulation requiring a precise capture of data. In essence, an effective compliance programme must include insights from 'structured' and 'unstructured' data to understand where risks reside and tailor procedures to monitor and root out potential issues at the transaction level. For example, data analytics can be used to report compliance with corporate pricing policies, identify unusual payment activity using fair value and other anti-corruption routines, and assess distributor product sales and return levels by type, such as expired product. These are but a few examples of the ways data analytics can assist organisations to identify potential improper transactions and missing controls.

"In today's environment, most healthcare companies rely on third-party service providers and the practice is growing."

Shannon Thyme Klinger, Novartis International AG

R&C: With more than 90 percent of reported FCPA cases involving third parties, how should these external risks factor into anti-corruption programme? What strategies can organisations deploy to mitigate or avoid liability linked to their business partners?

Klinger: In today's environment, most healthcare companies rely on third-party service providers and the practice is growing. While they provide many benefits, third parties also bring risks. It is vital that

due diligence is carried out before third parties are employed and that they are properly briefed on the company standards to which they will be expected to perform. We are strengthening third-party risk management, adopting a risk-based approach to assessing the third parties we use. We have also started to strengthen overall management of third parties and their associated risks, including how we engage new third parties, leverage IT systems to gain better visibility of existing third-party activities and better monitor third-party compliance.

Jezierski: Third parties involved in transactions, particularly those involving government interactions, should be carefully vetted. Life sciences and pharmaceutical companies should conduct focused due diligence on their distributors, agents, consultants and travel agencies. Companies should also include compliance clauses as well as audit and termination provisions in all third-party contracts, including contracts with healthcare professionals retained as speakers or other representatives of the company, and monitor third parties throughout the life of the contract. It is best practice to conduct a limited due diligence each time a contract is renewed, and follow up on all identified red flags.

Naviloff: First, have a documented fraud response strategy. The benefit of a written fraud response plan is powerful. Companies that have one in place are more likely to initiate follow-up investigations when illicit activity is suspected. Second, conduct rigorous background checks. Time and again, regulatory bodies look more favourably on companies that demonstrate solid due diligence in their efforts to combat fraud. Third, institute a sound procurement and contracting policy. It should address third-party capabilities, pricing and rights to audit, and so on. Fourth, identify organisations with more than a low level of risk. Steps should be taken to reduce risks, for example by utilising third parties recommended by government officials and organisations. Where risks cannot be satisfactorily reduced, organisations should be prepared to cease business relationships. Finally, use surprise audits. Using unscheduled audits with

"Where risks cannot be satisfactorily reduced, organisations should be prepared to cease business relationships."

Greg Naviloff, RSM US LLP

third-party intermediaries, where possible, can reduce fraud and corruption risk.

Grion: Organisations need to think critically about the value each third party brings to the table. At times, rationalising the number of partners or bringing certain activities in-house are the best alternatives to mitigating risk. By going through this strategic exercise, companies typically also identify financial benefits that go beyond risk mitigation. From a programmatic perspective, once it is determined that engaging a third-party is the most sensible approach, one needs to think beyond traditional due diligence and training. Ongoing monitoring of the relationship and the day-to-day transactions performed by the third parties is equally critical. It is important to think about third parties as an extension of the company, rather than an outsourcing of critical activities. Finally, there have been FCPA enforcement cases where bribes were paid through meeting organisers, law firms, subcontractors, and so on. A compliance programme needs to constantly evolve to risk assess non-traditional third parties and offer a customised risk mitigation approach to each.

DiBianco: The life sciences sector has developed diligence practices to review the background and integrity of potential distributors and external agents. The frameworks of such diligence have now been well established and should include ensuring that the third party is qualified for the tasks for which they will be paid, that they are free from integrity concerns or unmerited allegations, that they are being paid at fair market value for their services, and that they are being paid in a transparent, compliant and well documented manner.

R&C: How should organisations operating in the life sciences sector address the issue of 'facilitation payments', given that some countries advocate their use while others do not?

Grion: In general, any facilitation payments should be prohibited or severely restricted to situations where, for example, an employee of your company is in a potentially life-threatening situation. There are a couple of reasons for this. First, it is very difficult to explain to your employees the difference between a permissible facilitation payment and a payment that is potentially illegal. Second, while facilitation payments might be permitted under certain laws, these payments have the potential to become a slippery slope. Once they are made, there is an expectation on the part of the payment recipients than others will follow. This, in turn, becomes a vicious cycle with ever increasing demands for improper payments.

Naviloff: While there may be diversity in practice among organisations, many life science organisations have indicated that facilitation payments cannot be accepted, except in instances where there is concern

for an employee's safety, such as extortion. With that said, prohibiting facilitation payments can create challenges when dealing with certain administrative and permitting processes that involve government officials. These situations, in some instances, can be planned for in advance, but in practice avoiding facilitation payments entirely is difficult. An organisation may assess instances when the cost to the company of not making the payment is very high and when the foreseeable indirect consequences are low, as measured by factors such as the impact on culture from corruption in the company, and the impact of corruption among public officials. These decisions would presumably be made on a case-by-case basis and would be approved by an organisation's legal and compliance functions and well-documented in the organisation's books and records.

Jezierski: Facilitation payments – or 'grease payments' – are small payments to low-level public officials for basic administrative tasks that require no discretion on the official's part. Such payments are prohibited in most countries, but allowed in some such as the US, Australia and Canada. Life sciences companies may be pressured into making facilitation payments by licensing agents, customs officials and other low-ranked officials to process paperwork, clear goods and perform essential services, despite being entitled to such services in the course of conducting business. Qualifying payments as facilitation typically creates a lot of confusion among company employees. These payments are often not properly recorded on company books, which is a violation in itself. Therefore, the trend is now to prohibit facilitation payments of any kind under any circumstances, with very limited exceptions generally related to safety. However, recognising the challenges faced by companies doing business in jurisdictions where routine governmental processes are often slow and bureaucratic, some life sciences companies still allow their employees to make facilitation payments in certain circumstances, provided they are properly reported on the books. For example, a facilitation payment should not be recorded as a miscellaneous expense, local administrative fee or anything that masks its true nature of facilitating a transaction.

DiBianco: While the FCPA contains an exception for so-called facilitation payments, they are almost always illegal in the countries in which they are commonly demanded. Because permits, registrations and licences in the life sciences sector by definition frequently involve the health and safety of a product, most life sciences companies decide to ban facilitating payments in their policies.

Klinger: In my view, to truly foster a culture of integrity and compliance, organisations must set clear, global standards. We do not tolerate any form of bribery or corruption and facilitation payments are prohibited, irrespective of whether local law permits

them or not. This is clearly stated in policies which are renewed on a regular basis, and on which employees have been trained.

R&C: Are companies in the life sciences sector improving their approach to tackling bribery and corruption? What specific areas do they need to address going forward?

Naviloff: Significant progress has been made in terms of the robustness of programmes that life sciences companies have developed to reduce corruption risks. This includes increased third-party due diligence, more robust data collection, increased use of technology and increased diversity of training. Going forward, life science organisations must focus on continually improving their compliance programmes and the resulting controls to identify new and emerging risks and to prioritise limited compliance resources. As life science companies evolve, so do regulatory landscapes and risks; employees will continue to look for and exploit weaknesses in controls. Specifically, the proliferation of transparency laws, requiring detailed reporting, will challenge many decentralised companies with disparate technology platforms. Complex supply and distribution chains, joint research and marketing arrangements will also need to be continually addressed. The goal of all life science organisations should be to create a self-sustaining programme that is efficient and devotes the right resources to higher-risk areas, and which also becomes incrementally better over time through resource allocation, process and technology to mitigate new and emerging risks.

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Jezierski: Companies in the life sciences sector are improving their approach to tackling bribery and corruption. Many global companies have already developed an elaborate set of compliance policies to mitigate corruption risks throughout their organisations. Life sciences companies should take special care to consider anti-corruption exposure during the M&A process. Any merger or acquisition should include a careful pre- and post-transaction review for anti-corruption liability and a plan for

updating and standardising anti-corruption policies across corporate platforms.

DiBianco: The life sciences sector has seen a disproportionate share of anti-corruption investigations and hence has been a leader in the proactive development of compliance policies, procedures and training. Several settlements have included express terms to ensure anti-corruption diligence in corporate acquisition transactions, sufficient control over joint venture partners and third parties, and regular reviews of a company's compliance programmes. Companies should continue to actively update their compliance policies and procedures as their business practices change or as they expand into new business lines or geographic markets. Companies should strive to keep their policies current and relevant, and their training programmes practical, interesting and understandable to employees.

Klinger: As an industry, we continue to focus on ensuring a sustainable approach to anti-bribery and anti-corruption compliance efforts. An effective compliance programme in these areas must go beyond having the right policies, process and interactive training programmes, although these are important. We must better leverage technology, analytics and machine-learning to enhance our detection efforts and enable not just early risk identification, but ultimately risk prediction. Strengthening the culture of integrity at all levels of an organisation is also critically important. It takes time to truly and deeply embed that culture across a very large, complex and multinational organisation, but I strongly believe such actions are the right ones.

Grion: Most mid to large companies operating in the life sciences space have had compliance programmes for several years and the level of maturity of these programmes is high. In part, challenges ahead are less about building significant new infrastructure and more about pivoting to continue to stay effective and relevant. For example, customers are starting to look to life sciences companies to provide highly integrated solutions to address complex problems such as how to efficiently run a hospital or how to reduce the incidence of diabetes. These multi-year and customised partnerships between governments and companies represent a significant change from the historical approach of selling medical devices or promoting new drugs, and require adjustments to a compliance programme. At a more basic level, evolution also entails rethinking communications and training programmes to be more in line with how the new generation of employees prefers to engage. R&C