Debevoise & Plimpton

FCPA Update
September 2018
Volume 10
Number 2

FCPA Update

A Global Anti-Corruption Newsletter

Also in this issue:

16 Sanofi Settlement Highlights Risk in the Life Sciences Industries

Click here for an index of all FCPA Update articles

If there are additional individuals within your organization who would like to receive *FCPA Update*, please email prohlik@debevoise.com, eogrosz@debevoise.com, or pferenz@debevoise.com

Focus on the Construction Industry: Identifying and Mitigating Construction-Related Corruption Risks

The global construction industry is rife with corruption risks. From project planning to land acquisition to project completion and dedication, almost every stage of a large project involves interaction with government authorities. In large infrastructure projects, governments often are the sponsors, and, in private development, environmental and regulatory clearances present clear opportunities for corrupt demands. It is therefore unsurprising that numerous FCPA investigations and some of the biggest FCPA settlements have involved construction projects. Over the last decade alone, the SEC and DOJ – sometimes together and other times independently – have resolved more than twenty enforcement actions in this sector. Monetary penalties collected by U.S. authorities

Continued on page 2

Focus on the Construction Industry: Identifying and Mitigating Construction-Related Corruption Risks
Continued from page 1

in these cases have ranged from $337,000 to over $800 million. And other authorities worldwide have become actively engaged in reviewing such projects and prosecuting corrupt activities.

Many construction projects, particularly those involving extractive industries and infrastructure projects, begin with tenders involving government instrumentalities. Such tenders can generate high-dollar demands for bribes. In fact, the largest construction-related FCPA penalties to date have involved conduct associated with such tenders. Of these cases, Alstrom's $772 million penalty is the fourth biggest monetary settlement with the U.S. government in an FCPA case.[1] If expanded to include total global recovery, then Odebrecht's $2.6 billion dollar penalties[2] would top the list. In addition, one of the World Bank's largest settlements – the $100 million resolution with Siemens AG – involved a large infrastructure project in Russia.[3]

The risks do not end at the tender stage. Throughout the life cycle of large projects, owners, developers, and builders have numerous interactions with government officials, many of whom possess the discretion to veto or delay projects and increase costs. This means that government officials have the leverage to demand improper payments, and by all accounts they do so with some regularity. The involvement of third parties, including logistics contractors, subcontractors, suppliers, vendors, and others, only serves to increase these corruption concerns. The FCPA imposes liability on owners, developers, general contractors, and others who fail to properly manage such third-party risks. For example, seven companies involved in oil and gas projects – Parker Drilling, Pride International, Tidewater Marine, Transocean, Global SantaFe, Noble Corp., and Royal Dutch Shell – paid a combined $173 million in fines relating to dealings with the freight-forwarder Panalpina, which had used corrupt payments to avoid customs and excise duties for rigs and other project-related equipment in Nigeria.[4]

Continued on page 3

1. U.S. Dep't of Justice Press Release, *Alstom Pleads Guilty and Agrees to Pay $772 Million Criminal Penalty to Resolve Foreign Bribery Charges* (Dec. 22, 2014), https://www.justice.gov/opa/pr/alstom-pleads-guilty-and-agrees-pay-772-million-criminal-penalty-resolve-foreign-bribery.
2. The DOJ initially announced that it would receive 10% of this recovery, amounting to $260 million, but later reduced Odebrecht's U.S. criminal penalty to $93 million on the basis of an inability-to-pay analysis. *United States v. Odebrecht S.A.*, Sentencing Memorandum, No. 13-643 (RJD) (Apr. 11, 2017).
3. World Bank Press Release, *Siemens to Pay $100 Million to Fight Fraud and Corruption as Part of World Bank Group Settlement* (July 2, 2009), http://worldbank.org/en/news/press-release/2009/07/02/siemens-pay-million-fight-fraud-corruption-part-world-bank-group-settlement. The Siemens settlement with the U.S. government – resulting in $800 million in penalties paid to the United States Treasury – also involved construction-related elements. *SEC Litigation Release No. 20829, SEC Files Settled Foreign Corrupt Practices Act Charges Against Siemens AG for Engaging in Worldwide Bribery with Total Disgorgement and Criminal Fines of Over $1.6 Billion* (Dec. 15, 2008), https://www.sec.gov/litigation/litreleases/2008/lr20829.htm.
4. SEC Press Release 2010-214, *SEC Charges Seven Oil Services and Freight Forwarding Companies for Widespread Bribery of Customs Officials* (Nov. 4, 2010), https://www.sec.gov/news/press/2010/2010-214.htm; SEC Litigation Release No. 22672, *Charges Parker Drilling Company with Violating the Foreign Corrupt Practices Act* (Apr. 16, 2013), https://www.sec.gov/litigation/litreleases/2013/lr22672.htm.

Focus on the Construction Industry: Identifying and Mitigating Construction-Related Corruption Risks

Continued from page 2

Large projects also often involve consortia or joint ventures, which can present a host of other corruption risks and compliance challenges. The Halliburton/KBR matter, for example, included three other companies – Technip S.A., ENI, S.p.A./Snamprogetti Netherlands B.V., and JGC Corporation – which were alleged to have conspired to make corrupt payments.[5] Collectively, those three entities paid an *additional* $921 million in penalties.[6]

Given the continued growth of the construction industry, and the global emphasis on infrastructure projects, particularly in developing economies, obtaining a better understanding of the exposure to corruption risks is increasingly important. The international construction market is expected to grow to $15.5 trillion worldwide by 2030.[7] The largest share of this growth is likely to be in developing and

"Over the last decade alone, the SEC and DOJ – sometimes together and other times independently – have resolved more than twenty enforcement actions in [the construction] sector."

expanding economies, where business growth and an emerging middle class are likely to give rise to increasing infrastructure needs. The Asia-Pacific region, and China in particular, are likely to be a hub for such growth – and corruption risk – for many years to come.[8] China has announced its so-called "belt and road" initiative, with plans to underwrite billions of dollars of infrastructure investment in countries along the old Silk Road, linking it with Europe.[9] The Hong Kong Independent

Continued on page 4

5. For some non-U.S. companies, the risks of involvement in joint ventures may be somewhat mitigated by the Second Circuit's recent ruling in *United States v. Hoskins*, No. 16-1010-cr, 2018 WL 4038192 (2d Cir. Aug. 24, 2018). *See* Kara Brockmeyer *et al.*, "Second Circuit Curbs FCPA Application to Some Foreign Participants in Bribery," FCPA Update, Vol. 10, No. 1 at 1-7 (August 2018), https://www.debevoise.com/insights/publications/2018/08/20180830-fcpa-update-august-2018.

6. U.S. Dep't of Justice Press Release, *JGC Corporation Resolves Foreign Corrupt Practices Act Investigation and Agrees to Pay a $218.8 Million Criminal Penalty* (Apr. 6, 2011), https://www.justice.gov/opa/pr/jgc-corporation-resolves-foreign-corrupt-practices-act-investigation-and-agrees-pay-2188; SEC Press Release No. 2010-119, *SEC Charges Italian Company and Dutch Subsidiary in Scheme Bribing Nigerian Officials with Carloads of Cash* (July 7, 2010), https://www.sec.gov/news/press/2010/2010-119.htm; SEC Press Release No. 2010-110, *SEC Charges Technip with FCPA Violations* (June 28, 2010), https://www.sec.gov/news/press/2010/2010-110.htm.

7. *See Global Construction 2030: A Global Forecast for the Construction Industry to 2030*, Global Construction Perspective (2018), https://www.pwc.com/vn/en/industries/engineering-and-construction/pwc-global-construction-2030.html.

8. *See Managing Bribery and Corruptions Risks: The Real Estate, Construction and Infrastructure Industry*, Ernst & Young (2017), https://www.ey.com/Publication/vwLUAssets/Managing_bribery_and_corruption_risks_in_the_construction_and_infrastructure_industry/%24FILE/Assurance_%20FIDS_sector_paper_Construction.pdf.

9. *See* J.P., *What is China's belt and road initiative?*, The Economist (May 15, 2017), https://www.economist.com/the-economist-explains/2017/05/14/what-is-chinas-belt-and-road-initiative.

Focus on the Construction Industry: Identifying and Mitigating Construction-Related Corruption Risks
Continued from page 3

Commission Against Corruption has warned about "corruption . . . beyond our imagination" resulting from those projects.[10]

This article examines some of the most significant and common corruption risks confronted by those operating in the construction industry and offers practical considerations for better mitigating those risks.

Specific Corruption Risks Facing the Construction Industry

The "construction industry" is not only extremely large, but also many-faceted and very complex. It includes large and versatile engineering, procurement, and construction ("EPC") contractors, as well as small subcontractors and suppliers, architects, developers, engineers, and others. The construction industry is not limited to traditional commercial or residential developments and building projects. It also covers onshore and offshore oil and gas facilities, factories, port facilities, power generation facilities, highways, bridges, tunnels, ports, airports, and many other complex structures and facilities that must be built on site.

Construction projects are traditionally divided into different phases, each of which presents unique corruption challenges. The critical phases of any project are: (1) design, engineering, and development; (2) site acquisition; (3) tendering; (4) procurement and construction; and (5) completion and occupancy. The risks associated with each phase differ from project to project, depending on size and complexity, and on whether the project is government sponsored, private, or facilitated by an international development bank.

The Design, Engineering, and Development Phase

The earliest stage of any construction project involves planning and development. During this stage, the project is conceptualized and designed, and a budget is prepared. The conceptual nature of the work often minimizes corruption risks, but, in many jurisdictions, architectural plans may require specific approvals. This is especially true in China, where "design institutes" must be consulted, and designs and plans must be approved before further steps can be taken. These institutes and their personnel often have government ties or can influence government decision-makers, giving rise to FCPA and other corruption risks.

FCPA cases involving design institutes have generally arisen among suppliers to larger projects. In 2011, Watts Water Technologies, Inc. agreed to the entry of an administrative cease and desist order by the SEC arising from payments made by a

Continued on page 5

10. Christy Leung, *Hong Kong's ICAC chief warns of corruption in Belt and Road countries, South China Morning Post*, South China Morning Post (July 3, 2018), https://www.scmp.com/news/hong-kong/hong-kong-law-and-crime/article/2153483/hong-kongs-icac-chief-warns-corruption-belt.

Continued from page 4

Chinese subsidiary to a design institute in order to "influence the design institute to recommend [the subsidiary's] valve products to [state owned enterprises] and to create design specifications that favored [its] valve products."[11] These activities allegedly related to infrastructure projects in China. Watts Water and its subsidiary paid a total of $3,801,606 in disgorgement, interest, and penalties to resolve the matter based on violations of the books and records and internal controls provisions of the FCPA.

In a similar case, also in 2011, Rockwell Automation, Inc. and its Chinese subsidiary RAPS-China, were fined by the SEC for having used design institutes because of their "influence on the Chinese government-owned mining companies to which RAPS-China sought to sell its . . . product."[12] Although Rockwell Automation's resolution with the SEC also was limited to a cease and desist order based upon violations of the FCPA's books and records and internal controls provisions, and required the payment of a $2,761,091 in disgorgement, interest, and penalties, the description of facts in the case made clear that the improper conduct arose from the influence the design institute could bring to bear to help the subsidiary place its products in large mining projects.

Although the functioning of design institutes is unique to China, similar government-mandated reviews and approvals at the design and development stage – ranging from architectural review to historical preservation mandates – are common in the construction industry and create significant corruption risks.

The Site Acquisition Phase

An adjunct to the development phase of any project is the acquisition of the building site. This is a phase where many potential corruption risks may be present. In some cases, the land itself may be controlled by the government, or the property may be located in a special economic zone the government has set aside for favorable tax treatment or for other economic advantages. Although no FCPA cases involving settlements with the DOJ or SEC have focused on land acquisition issues, private litigation currently pending against Cognizant Technology Services Corp. ("CTS") alleges corrupt payments in connection with CTS's acquisition of rights to locate facilities in India in Special Economic Zones controlled by the Indian government

Continued on page 6

11. *In the Matter of Watts Water Technologies, Inc. and Leesen Chang*, Securities Exchange Act of 1934 Rel. No. 65555, Accounting and Auditing Enforcement Rel. No. 3328, Administrative Proceeding File No. 3-14585 (Oct. 13, 2011) at 2, https://www.sec.gov/litigation/admin/2011/34-65555.pdf.

12. *In the Matter of Rockwell Automation, Inc.*, Securities Exchange Act of 1934 Rel. No. 64380, Accounting and Auditing Enforcement Rel. No. 3274, Administrative Proceeding File No. 3-14364 (May 3, 2011), https://www.sec.gov/litigation/admin/2011/34-64380.pdf.

Continued from page 5

and that grant occupants special rights that can mitigate taxation, customs duties, and other costs.[13]

Although this civil litigation is still in process, and CTS is "vigorously" defending against the allegations, CTS has acknowledged in quarterly filings with the SEC that it has self-reported issues to U.S. authorities involving potential corrupt payments related to its facilities in India.[14] CTS already has reclassified $4 million in project expenses (from capital costs to ordinary expense) as improper payments and claims that an additional $2 million in payments were potentially improper. CTS's disclosures, however, do not describe the particular nature of the issues, and the litigation of the securities class action case is ongoing.

Similar corruption risks also may be presented by the need to obtain zoning approvals or changes for a particular project. Large infrastructure projects also often require environmental clearances or other approvals by government agencies before the project can be undertaken. Such approvals can often be controversial, politically sensitive, and spark public controversy, making corruption risks that much more pronounced.

The Tendering Phase

Major infrastructure projects – ranging from bridges, highways, and tunnels to airports, ports, other transportation facilities, water projects, and a host of others – may present the most significant corruption risks in the construction industry. In connection with most of these projects, the sponsor will be a government authority. Public tendering processes are a widely used means of awarding contracts for such projects and are a particularly ripe opportunity for corruption to infect the process. In fact, most FCPA enforcement actions from the past ten years involving construction projects have focused on the tendering stage.

The history of FCPA enforcement arising from this stage of construction projects reveals that companies have sought to hide improper payments as part of the contract price, perhaps assuming that the size of the projects would make it harder to detect the misconduct. For example, in connection with the bid to construct a major natural gas pipeline system through the Niger Delta, Bilfinger and its

Continued on page 7

13. According to the Amended Class Action Complaint for Violations of the Federal Securities Laws ("Amended Complaint"), by operating in designated "Special Economic Zones" (SEZs), the company received various benefits, including exemption from minimum alternate tax, 100% income tax exemption on export income, and single window clearance for central and state level approvals. *Shane Park et al. v. Cognizant Technologies Solutions Corporation*, Am. Compl., No. 16-CV-06509-WHW-CLW, ¶ 30 (D.N.J. Oct. 5, 2016). The Amended Complaint argues that "payments related to procuring SEZ licensing were being made to government personnel." *Id.* ¶ 10.

14. *See* Cognizant Technology Solutions Corp., Form 10-Q for the Quarter Ended June 30, 2018 (October 2, 2018) at 29-30, https://www.sec.gov/Archives/edgar/data/1058290/000105829018000028/ctsh2018630-10q.htm.

Continued from page 6

coconspirators allegedly agreed to inflate the price of its bid by 3% to cover the cost of paying bribes to Nigerian officials.[15]

Additionally, a number of the enforcement actions have involved companies paying bribes to third-party agents that appear to have done no work on the project itself and were being used to pass along corrupt payments to foreign officials. For example, Siemens allegedly relied on "business consultants" to funnel improper payments to foreign government officials responsible for awarding business.[16] The PBSJ Corporation allegedly authorized bribes disguised as "agency fees" for a local company owned and controlled by a foreign official.[17] Most recently, Elbit Imaging was charged with books and records and internal controls violations in connection with payments to a third party associated with a shopping mall development in Romania, even in the absence of evidence that the funds were paid on to foreign officials.[18]

"[A] number of the enforcement actions have involved companies paying bribes to third-party agents that appear to have done no work on the project itself and were being used to pass along corrupt payments to foreign officials."

In addition to "agents" and third parties that merely serve to disguise bribe payments, recent enforcement actions against Hitachi, Ltd. and Halliburton highlight the risks involved with local content regulations, where local laws require partnering with a specific subset of third parties.[19] Such regulations, which are common in developing countries, typically require foreign companies to partner with or retain local third parties in an effort to ensure that local companies and

Continued on page 8

15. *United States v. Bilfinger SE, Information*, No. 13-CR-745, ¶ 21 (S.D. Tex. Dec. 9, 2013); U.S. Dep't of Justice Press Release, *Willbros Group Inc. Enters Deferred Prosecution Agreement and Agrees to Pay $22 Million for FCPA Violations* (May 14, 2008), https://www.justice.gov/archive/opa/pr/2008/May/08-crm-417.html.
16. *United States v. Siemens Aktiengesellschaft*, Information, No. 1:08-cr-367 (D.D.C. Dec. 12, 2008).
17. SEC Press Release, *SEC Charges Former Executive at Tampa-Based Engineering Firm with FCPA Violations* (Jan. 22, 2015), https://www.sec.gov/news/pressrelease/2015-13.html.
18. *In the Matter of Elbit Imaging, Ltd.*, Securities Exchange Act of 1934 Rel. No. 82849, Accounting and Auditing Enforcement Rel. No. 3925, Admin. Proc. File. No. 3-18397 (Mar. 9, 2018), https://www.sec.gov/litigation/admin/2018/34-82849.pdf.
19. *Securities and Exchange Comm'n v. Hitachi, Ltd.*, Complaint, Case 1:15-cv-01573 (D.D.C. Sept. 28, 2015), https://www.sec.gov/litigation/complaints/2015/comp-pr2015-212.pdf (the "Hitachi Order"); *In the Matter of Halliburton Company and Jeannot Lorenz*, Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing Remedial Sanctions and a Cease-and-Desist Order, Securities Exchange Act Rel. No. 81222, Accounting and Auditing Enforcement Rel. No. 3884, Admin. Proc. File No. 3-18080 (July 27, 2017), https://www.sec.gov/litigation/admin/2017/34-81222.pdf (the "2017 Halliburton Order").

Continued from page 7

communities receive some of the work and benefits from the construction projects.[20] These requirements, however, may increase bribery and corruption risks by limiting the potential pool of partners to well-connected, local businesses.

In the Hitachi case, for example, the company allegedly tried, through a local partner, to qualify for preferential status in government procurements under a South African affirmative action statute, South Africa's Black Empowerment Act of 2003, that sought to promote participation in the South African economy by companies that were at least 25% owned by black South Africans.[21] It turned out, however, that its local partner was allegedly a front for South Africa's ruling political party.[22]

In the Halliburton case, an Angolan state oil company allegedly informed Halliburton that it would consider vetoing further subcontract work due to Halliburton's failure to comply with Angola's local content requirements.[23] According to the 2017 Halliburton Order, Halliburton allegedly responded by making payments to a local Angolan company owned by a former Halliburton employee who was also "a friend and neighbor of the government official who would . . . approve the award of . . . contracts to Halliburton."[24]

Even where particular projects may not involve local partners, project sponsors and developers often attempt to mitigate business risk by entering into joint ventures or consortiums. Such arrangements again often increase risks by exposing a company to liability for the actions of international venture partners. One of the largest FCPA settlements involved the TSKJ joint venture for the Bonny Island Project in Nigeria. The partners in this joint venture (JGC Corp., Halliburton/KBR, Technip, and ENI/Snamprogetti) allegedly devised a scheme to bribe Nigerian government officials to assist in obtaining multiple contracts worth over $6 billion to build liquefied natural gas production facilities on Bonny Island.[25] Although none of the TSKJ joint venture participants had a majority stake in the joint venture, the DOJ and SEC nevertheless imputed culpable knowledge to each company because

Continued on page 9

20. *See* Kara Brockmeyer *et al.*, "Summer Enforcement Actions (and Non-Actions): Halliburton, Guilty Verdicts, and Declinations," FCPA Update, Vol. 9, No. 1 at 4 (Aug. 2017), https://www.debevoise.com/~/media/files/insights/publications/2017/08/fcpa_update_august_2017.pdf (discussing FCPA risks from local content requirements).

21. *Id.*

22. Hitachi Order at ¶¶ 21, 58-61.

23. 2017 Halliburton Order at ¶ 7.

24. *Id.* at ¶¶ 9-11, 19.

25. SEC Press Release, *SEC Charges Technip With FCPA Violations* (June 28, 2010), https://www.sec.gov/news/press/2010/2010-110.htm. Additionally, Marubeni Corporation, which acted as a third-party agent for the TKSJ joint venture, agreed to pay a $54.6 million criminal penalty to resolve FCPA claims. *United States v. Marubeni Corporation*, Deferred Prosecution Agreement, No. 12 CR 022, ¶ 12 (S.D. Tex. Jan. 17, 2012), https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/01/24/2012-01-17-marubeni-dpa.pdf.

Focus on the Construction Industry: Identifying and Mitigating Construction-Related Corruption Risks
Continued from page 8

senior officials from each company allegedly participated in meetings where bribery of Nigerian government officials was discussed and where improper payments were authorized to secure construction contracts.[26] The legal approach taken by DOJ and the SEC in these joint-venture cases have been brought into doubt by the Second Circuit's recent ruling in *Hoskins*, because each of these cases was brought based upon a conspiracy or aiding and abetting theory that appears no longer viable against overseas joint venture partners.[27]

Additionally, despite large fines that were imposed on both Halliburton and another company involved Bonny Island Project, Marubeni, both companies went on to become repeat FCPA offenders, suggesting the difficulties construction companies face in high-risk jurisdictions. Halliburton went on to pay $29.2 million in connection with the 2017 Halliburton Order.[28] Marubeni subsequently agreed to plead guilty to foreign bribery charges, pay $88 million in fines, and implement an enhanced global anti-corruption compliance program in connection with an alleged scheme to bribe high-ranking foreign officials in Indonesia to secure a contract to provide power-related services.[29]

Construction-related anti-corruption efforts also are not limited to U.S. enforcement agencies. Many foreign regulators have pursued construction-related investigations, either in parallel with U.S. regulators or in follow-on investigations.[30] In at least one case, which involved highway construction projects in India, CDM Smith was subject to a "declination with disgorgement" resolution with the DOJ under the FCPA Pilot Program after the company used local subcontractors to funnel money to highway authority officials in order to win $4 million in contracts. Despite the declination by the DOJ, Indian authorities thereafter began an investigation.[31]

Continued on page 10

26. *United States v. Kellogg Brown & Root LLC*, Information, No. H-09-071, ¶¶ 9, 19 (S.D. Tex. Feb. 6, 2009).

27. As noted in our discussion of the impact of *Hoskins*, the surviving "agency" theory of liability for foreign entities may not work in the context of a joint venture. Depending on the legal structure of the joint venture, the joint venture partners would likely be found to be agents of the joint venture, not agents of the individual entities that participate in the joint venture. FCPA Update Aug. 2018 at 6-7.

28. 2017 Halliburton Order at 9.

29. U.S. Dep't of Justice Press Release, *Marubeni Corporation Agrees to Plead Guilty to Foreign Bribery Charges and to Pay an $88 Million Fine* (Mar. 19, 2014), https://www.justice.gov/opa/pr/marubeni-corporation-agrees-plead-guilty-foreign-bribery-charges-and-pay-88-million-fine.

30. U.S. Dep't of Justice Press Release *Odebrecht and Braskem Plead Guilty and Agree to Pay at Least $3.5 Billion in Global Penalties to Resolve Largest Foreign Bribery Case in History* (Dec. 21, 2016), https://www.justice.gov/usao-edny/pr/odebrecht-and-braskem-plead-guilty-and-agree-pay-least-35-billion-global-criminal.

31. Philip Rohlik *et al.*, "The Collateral Consequences of Declinations with Disgorgement: Revisiting the CDM Smith Declination," FCPA Update, Vol. 9, No. 7, at 2-3 (Feb. 2018) https://www.debevoise.com/insights/publications/2018/02/fcpa-update-feb-2018-vol-9-no-7.

Focus on the Construction Industry: Identifying and Mitigating Construction-Related Corruption Risks

Continued from page 9

As in other areas of FCPA enforcement, cases brought at the tendering stage have not been limited to companies. Many individuals have been charged in connection with the construction cases highlighted above.[32]

The Procurement and Construction Phase

Few reported FCPA cases have arisen during the procurement and construction phase, when the project is actually executed. Despite the scarcity of reported cases in this stage, execution of construction projects presents significant FCPA risks. Such projects require a cascade of permits, including those related to insurance, excavation, health and safety, fire, electrical, and, at the end of construction, occupation certificates.

"Construction-related anti-corruption efforts also are not limited to U.S. enforcement agencies. Many foreign regulators have pursued construction-related investigations, either in parallel with U.S. regulators or in follow-on investigations."

Many such permits require associated inspections. In connection with obtaining each permit and passing each inspection, there are significant risks of requests for corrupt payments. And while such demands often can be small, where a permit or inspection affects the critical path of the project, the risks of delay and disruption (and attendant additional costs) can make the temptation to make a small payment hard to resist.

Another common obstacle faced by construction firms includes potential demands for payment in order to receive police protection or labor peace. Occupational health and safety incidents also can give rise to payment demands, where local officials may exercise considerable discretion in choosing penalties that range from extremely minor fines to project suspension or even criminal culpability for project managers.

In the Layne Christensen case, the SEC alleged that the company made improper payments to customs officials to avoid paying customs duties and to obtain clearance to import and export its equipment.[33] The SEC also alleged that the company bribed

Continued on page 11

32. *See, e.g.*, U.S. Dep't of Justice Press Release, *Alstom Pleads Guilty and Agrees to Pay $772 Million Criminal Penalty to Resolve Foreign Bribery Charges* (Dec. 22, 2014), https://www.justice.gov/opa/pr/alstom-pleads-guilty-and-agrees-pay-772-million-criminal-penalty-resolve-foreign-bribery (mentioning charges against five individuals); U.S. Dep't of Justice Press Release, *Louis Berger International Resolves Foreign Bribery Charges* (July 17, 2015), https://www.justice.gov/opa/pr/louis-berger-international-resolves-foreign-bribery-charges (stating two former company executives pleaded guilty to participating in bribery scheme).

33. SEC Press Release No. 2014-240, *SEC Charges Texas-Based Layne Christensen Company with FCPA Violations* (Oct. 27, 2014), https://www.sec.gov/news/press-release/2014-240.

Focus on the Construction Industry: Identifying and Mitigating Construction-Related Corruption Risks
Continued from page 10

police, border officials, immigration officials, and labor inspectors to secure work permits for its expatriate employees.[34]

In the Odebrecht matter, a high-level Brazilian official reportedly requested payment in order for the company to continue on a project.[35] Odebrecht also allegedly agreed to make improper payments to an Ecuadorian government official with control over public contracts to obtain that official's help with solving unspecified problems related to its construction contract.[36]

Change orders and extra claims in government sponsored projects also are a significant potential source of corruption risk. In the United Industrial Corporation ("UIC") case, UIC's wholly-owned subsidiary was awarded a contract to build an aircraft depot for the Egyptian Air Force and to train Egyptian labor to use the associated testing equipment for the depot.[37] The SEC alleged that, following this award, the subsidiary made improper payments to obtain a related contract to provide personnel for technical assistance at the depot construction site, so that EAF personnel could receive training on testing and repairing their aircraft.[38] The SEC's cease-and-desist order against UIC alleged that the subsidiary's president, who authorized the improper payments, acted as an agent of UIC and that some UIC employees participated in the scheme.[39]

The Completion and Occupancy Phase

Finally, construction projects face occupancy and exit risks. Arguably, many of the Panalpina-related enforcement actions involved servicing already existing oil and gas projects, concessions that often last decades. Similarly, Cadbury-Mondelez's 2017 SEC enforcement action,[40] relating to obtaining permits associated with the expansion of a chocolate factory in India, can be seen as either an execution phase enforcement action (viewing the expanded facility as a new construction) or an occupancy phase enforcement action (viewing the expanded facility as a upgrade).

Continued on page 12

34. *Id.*

35. *United States v. Odebrecht S.A.*, Information, No. 16-643, ¶¶ 41-43 (E.D.N.Y. Dec. 21, 2016).

36. *Id.* at ¶¶ 56-57.

37. *In the Matter of United Industrial Corporation*, Corrected Order Instituting Cease-and-Desist Proceedings Pursuant to Section 21C of the Securities Exchange Act of 1934, Making Findings, and Imposing a Cease-and Desist Order, Securities Exchange Act of 1934 Rel. No. 60005, Accounting and Auditing Enforcement Rel. No. 2981, Admin. Proc. File No. 3-13495, ¶ 5 (May 29, 2009), https://www.sec.gov/litigation/admin/2009/34-60005.pdf.

38. *Id.* at ¶ 11.

39. *Id.* at ¶ 27.

40. *In the Matter of Cabury Limited and Mondelez International, Inc., Securities Exchange Act of 1934* Rel. No. 79753; Accounting and Auditing Enforcement Rel. No. 3841; Admin. Proc. File. No. 3-17759 (Jan. 6, 2017), https://www.sec.gov/spotlight/fcpa/fcpa-cases.shtml.

Focus on the Construction Industry: Identifying and Mitigating Construction-Related Corruption Risks

Continued from page 11

Many infrastructure projects, especially in the transportation and power sectors, involve build-own-operate-transfer ("BOOT") contracts. Under such arrangements, the developer builds infrastructure and then recoups its investment by operating (and collecting fees for) the toll road or power plant for a period of time (often decades) before transferring the facility to a local body. Although there have been no enforcement actions related to such contracts, the developer is subject to ongoing inspections and licensing requirements (much like in the execution phase), and often subject to difficult periodic negotiations with local authorities in connection with the user fees required for the developer to recoup its investment.

Approaches to Managing and Minimizing Corruption Risks

Firms engaged in construction projects may minimize risks by focusing on prevention and detection of anti-corruption violations. Prudent compliance steps include the following:

- **Ensure compliance policies and programs are robust, and designed to meet the specific challenges of the construction industry**. A robust compliance program reduces the likelihood that employees will succumb to demands for illicit payments. Such programs should include thorough policies and procedures that are easy to understand and easily accessible, empowered compliance personnel with authority to implement and enforce those policies and procedures, appropriate employee training and sufficient follow-up, expense controls, hotlines and other confidential avenues for raising concerns, mechanisms for timely escalation of red flags, and internal audits or other periodic testing to assess compliance. To increase the effectiveness of the compliance policies, the compliance department should partner with other compliance-related functions, such as internal audit and accounting, to help assure that no red flags will be missed and that misconduct will be detected. Where red flags are identified, they must be thoroughly reviewed and their resolution documented.
- **Require employees to receive practical compliance training**. Given the broad range of risks affecting the construction industry, employees at almost every level may face demands for payment from government officials. Those in supervisory positions and those who regularly interact with government authorities obviously need sophisticated compliance training. Consideration also should be given to training other employees who may need practical training about what to do when a demand for payment is made. This includes how to say "no" and how to report such demands up the chain and to relevant compliance personnel. Given the dispersion of both authority and responsibility in large construction projects, such training and empowerment is essential for managing corruption risk.

Continued on page 13

Continued from page 12

- **Conduct risk-based due diligence on third parties**. Construction projects naturally involve the employment a numerous third parties, because many construction processes require significant specialization. From architects to engineers, environmental specialists to logistics, and excavation to drywall, specialist subcontractors are a necessary part of every project. Some of these specialists will present limited corruption risks, and others will present potentially significant risks. A drywall subcontractor obviously presents a significantly different risk profile than an environmental engineer who will be expected to deal directly with government authorities in obtaining environmental approvals. The vetting process for each of the scores of third parties hired for such a project should take account of the risk and receive the level of scrutiny appropriate to the risk. For all such subcontractors, the minimum requirements for due diligence should include understanding the specific tasks they will undertake, their qualifications for executing those tasks, and the specific milestones that will prompt payment for their services. For other subcontractors who present more significant risks, reputational due diligence may be appropriate, as well as gaining a deeper understanding of the subcontractor's own internal compliance standards, programs, and training. Given the number and variety of potential subcontractors in construction projects, a one-size-fits-all approach to due diligence is unlikely to be efficient, effective, or necessary. An adaptable due diligence program, based on risks presented, is almost certainly going to be a more appropriate solution.
- **Plan ahead to avoid unwanted surprises**. From tendering through exit, a company may mitigate anti-corruption risks by obtaining necessary permits and licenses in advance and building in extra time to handle unexpected demands for payments, bureaucratic red tape, and other potential delays. Additionally, companies should ensure that joint venture partners and subcontractors are both contractually obligated and have systems in place to protect against corruption and bribery risks. The expectations of partners and subcontractors should be clear from the beginning, and their obligations should encompass each phase of the project, from tendering through operation and exit. Although ongoing oversight and audits of partners can mitigate the risks of improper payments during the tender and execution phase, partners may make promises associated with operation or exit (*e.g.,* service contracts, sale, or leasing arrangements connected with all or part of a finished project) that only become due (and only become known to the foreign investor) after the project is complete.

Continued on page 14

Focus on the Construction Industry: Identifying and Mitigating Construction-Related Corruption Risks
Continued from page 13

- **Develop a reputation for not participating in bribes**. If government officials, such as those who award tenders, permits, or other clearances to contractors, understand that asking a company for bribes will be futile, they may become frustrated and react by responding slowly to a company's request, but usually they eventually will grant the request. In contrast, companies that develop reputations for making illicit payments will find that such demands multiply and eat into profitability and the ability to bid competitively for projects. Large construction projects, especially those involving significant infrastructure, create jobs and are highly visible within communities. These facts can be used to pressure politicians and others to clear the way for such projects to proceed, even without succumbing to demands for payment. The Siemens experience is instructive. Since its FCPA corruption scandal was resolved in 2008, Siemens has continued to thrive as a company, almost doubling its share price and proving that "[c]lean business and success are not a contradiction.[41]

"As these prophylactic measures suggest, even though the construction industry may be rife with corruption risks, a company may reduce its exposure by taking prudent and appropriate steps to build a robust compliance program that is designed to prevent and detect potential violations."

- **Recognize that some projects may not be worth pursuing**. Corruption risk is not merely limited to the reputational risk and significant penalties that can flow from being caught in the kinds of scandals that have befallen some companies in the construction industry. There also is significant business risk associated with such projects. For example, where the ability to participate in a large infrastructure project is obtained through corrupt payments rather than through competitive bidding and a legitimate tendering process, a company that obtains the right to participate in a significant part of a large project may find that the incompetence of others who won their contracts through corruption rather than skill significantly affects everyone's ability to profitably complete their part of the contract. Delays may result and, in some instances, equipment and supplies may be produced or put in place a considerable expense that end up never being used and for which payment is never received.

Continued on page 15

41. Peter Y. Solmssen, *40 Years of FCPA: The Siemens Lesson—Tillerson is Right*, Law360 (Dec. 6, 2017), https://www.law360.com/articles/990391/40-years-of-fcpa-the-siemens-lesson-tillerson-is-right.

Continued from page 14

As these prophylactic measures suggest, even though the construction industry may be rife with corruption risks, a company may reduce its exposure by taking prudent and appropriate steps to build a robust compliance program that is designed to prevent and detect potential violations. These efforts are increasingly important in light of the continued focus by U.S. and other authorities on anti-corruption enforcement and the expected growth in global construction spending, particularly infrastructure spending in emerging markets and other high-risk jurisdictions.

Colby A. Smith

Andrew M. Levine

Philip Rohlik

Sok Tea Jiang

Rebecca M. Urquiola

Colby A. Smith is a partner in the Washington, D.C. office. Andrew M. Levine is a partner in the New York office. Philip Rohlik is a counsel in the Shanghai office. Sok Tea Jiang and Rebecca M. Urquiola are associates in the New York office. The authors may be reached at casmith@debevoise.com, amlevine@debevoise.com, prohlik@debevoise.com, stjiang@debevoise.com, and rmurquiola@debevoise.com. Full contact details for each author are available at www.debevoise.com.

Continued on page 16

Sanofi Settlement Highlights Risk in the Life Sciences Industries

On September 4, 2018, the U.S. Securities and Exchange Commission ("SEC") announced that Paris-based pharmaceutical company Sanofi agreed to a cease-and-desist order that requires the company to pay more than $25 million to settle charges that it violated the FCPA's books and records and internal controls provisions.[1] The alleged violations involve improper payments made to foreign officials by Sanofi's overseas subsidiaries in Kazakhstan and the Middle East to win tenders and increase prescription sales from 2011 to 2015.

This settlement marks the twenty-fifth time the U.S. government has announced an FCPA action against a pharmaceutical or medical device company since the beginning of 2011, and there is no indication that government scrutiny will ease. Indeed, in the press release announcing the case, the chief of the SEC's FCPA Unit warned that the government does not think the industry has gotten it right yet, stating that "[w]hile bribery can impact any industry, [the Sanofi case] illustrates that more work needs to be done to address the particular risks posed in the pharmaceutical industry."[2]

The pharmaceutical and medical device sectors present unique risks, because they operate in highly-regulated environments with many government touchpoints. Life sciences companies often must obtain licenses and approvals from governmental officials, and frequently rely on third parties who — among other things — may help obtain approvals and distribute products. The fact that many companies use distributors or other third parties to sell their products increases possible channels for making improper payments, and may subject the life sciences company to FCPA liability. In addition, because the definition of a "foreign official" under the FCPA is broad, and the U.S. government views individual doctors and health care providers employed at state-owned hospitals or medical centers as foreign officials, there are numerous opportunities for companies to run into trouble.

These circumstances make the life sciences industry particularly susceptible to "pay-to-prescribe" schemes aimed at increasing sales by inducing healthcare providers ("HCPs"), as well as larger bribe schemes to obtain regulatory approvals and win tenders.

Continued on page 17

1. *In re Sanofi*, Securities Exchange Act Rel. No. 84017 (Sept. 4, 2018), https://www.sec.gov/litigation/admin/2018/34-84017.pdf [hereinafter "Sanofi Order"].

2. SEC Press Release No. 2018-174, *Sanofi Charged With FCPA Violations* (Sept. 4, 2018), https://www.sec.gov/news/press-release/2018-174 [hereinafter "SEC Sanofi Press Release"].

Continued from page 16

The Sanofi Order

The Sanofi case is instructive because it provides textbook examples of these types of issues. According to the SEC's Order, Sanofi's violations occurred in connection with activities of three Sanofi subsidiaries: one in Kazakhstan engaged in a scheme to influence the awarding of public tenders for pharmaceuticals and two in the Middle East engaged in pay-to-prescribe schemes to increase prescription sales. In particular:

- *Kazakhstan:* From 2007 to 2011, senior managers of Sanofi's Kazakhstan-based subsidiary ("Sanofi KZ") engaged in a scheme to bribe Kazakh officials to win public tenders for pharmaceuticals using funds kicked back from discounts to collusive distributors.[3] Sanofi sold tender-fulfilling products to its distributors with a pre-determined discount from the sale price between the distributor and the public institution; a portion of these discounts were kicked back to Sanofi employees who delivered them to Kazakh officials.[4] The kickbacks were tracked on an internal spreadsheet as "marzipans." (The reference to bribes as "sweets" is a recurring theme: in 2011, Orthofix was charged with paying bribes in Mexico that employees referred to as "chocolates."[5]) According to the SEC's order, Sanofi's tender sales increased by over 200%, and the company — which did not review discounts provided by local management — profited by nearly $11.6 million.[6]
- *Levant:* From 2011 to 2013, employees and agents of Sanofi's Lebanon-based subsidiary ("Sanofi Levant") — which covers Jordan, Lebanon, Syria, and the "region of Palestine" — engaged in pay-to-prescribe schemes to increase prescription sales.[7] The "pay" included a variety of things of value ranging from sponsorships and donations to large quantities of product "samples," consulting agreements, and grants. According to the Order, Sanofi derived $4.2 million in profits in connection with Sanofi Levant's engagement of influential HCPs as consultants (with little to no evidence of receipt of services) to boost prescription sales.[8]

Continued on page 18

3. Sanofi Order Section III ¶¶ J–K.
4. *Id.* ¶ K.
5. *See* Complaint ¶ 1, *SEC v. Orthofix Int'l N.V.*, No. 12-cv-419 (E.D. Tex. July 10, 2012), https://www.sec.gov/litigation/complaints/2012/comp-pr2012-133.pdf.
6. Sanofi Order Section III ¶ L.
7. *Id.* ¶¶ B, G, M.
8. *Id.* ¶ M–P.

Sanofi Settlement Highlights Risk in the Life Sciences Industries

Continued from page 17

- *Gulf:* From 2012 to 2015, sales managers and medical representatives of Sanofi's UAE-based subsidiary ("Sanofi Gulf") — which operates in Bahrain, Kuwait, Qatar, Yemen, Oman, and the UAE) — pooled the funds of doctored travel and entertainment reimbursement receipts to bribe HCPs in the private sector to boost prescription sales.[9] A 2015 internal audit found that "[s]election of HCPs, attendance list and detailed hospitality costs were neither documented nor reviewed by Sanofi."[10] Sanofi profited more than $1.7 million as a result of the scheme.[11]

"The pharmaceutical and medical device sectors present unique risks, because they operate in highly-regulated environments with many government touchpoints."

The SEC found that Sanofi violated the FCPA's books and records provisions by falsely recording improper payments generated through fake expenses made by its subsidiaries' employees and agents, and violated the internal controls provisions by failing to devise and maintain sufficient accounting controls to detect and prevent the improper payments to public institutions and HCPs.[12] To resolve the SEC's charges, Sanofi agreed to pay more than $25 million, consisting of $17.5 million of disgorgement, $2.7 prejudgment interest, and a $5 million civil penalty.[13] In addition, Sanofi agreed to self-report to the SEC on the status of its remediation for at least two years.[14]

Sanofi did receive both cooperation and remediation credit from the SEC.[15] As set forth in the SEC Order, Sanofi cooperated with the SEC by providing regular briefings as it conducted its internal investigation and by highlighting relevant documents, among other things. The company remediated by independently

Continued on page 19

9. *Id.* ¶ R.
10. *Id.* ¶ U.
11. *Id.* ¶ V.
12. *Id.* ¶¶ C, W.
13. *Id.* Section IV ¶ B. According to Sanofi's 2017 Form 20-F, DOJ declined to prosecute. Sanofi, 2017 Form 20-F at 198 (Mar. 7, 2018), https://www.sanofi.com/media/Project/One-Sanofi-Web/sanofi-com/en/investors/docs/Sanofi-20-F-2017-EN-PDF-e-accessible_01.pdf.
14. *See* Sanofi Order Section III ¶¶ Y–FF.
15. *Id.* ¶ X.

Sanofi Settlement Highlights Risk in the Life Sciences Industries
Continued from page 18

enhancing its compliance program; revamping its internal controls over HCP expenditures; increasing compliance personnel; and enhancing anti-corruption training and due diligence procedures for third-party agents, among other things. Sanofi also took what appears to be quite aggressive disciplinary action, terminating or accepting the resignations of 135 employees and disciplining 49 others.

Life Sciences Industry Remains A Focus of U.S. (and International) Enforcement

Since 2011, the SEC and DOJ have settled twenty-five enforcement actions against companies in the pharmaceutical and medical devices space, ordering more than $1 billion in disgorgement, prejudgment interest, and penalties.[16] These actions were brought primarily against U.S. and U.K.-based companies in connection with their subsidiaries' activities in more than 35 different countries. The violations can generally be divided into two types: (i) instances where foreign subsidiaries of life sciences companies attempt to influence decision-makers in a national healthcare system relating to access and large-scale purchasing and (ii) jurisdictions (often developing or transitional economies) where national health or insurance systems result in underpayment of HCPs relative to other professionals, resulting in a pay-to-prescribe model through which HCPs supplement their income by seeking money or other benefits (which life sciences companies can provide through false travel, entertainment, and conference reimbursements) for prescribing company products. While the Sanofi case provides us with examples of each, a few others have served as the prototypical cases in the space, highlighting additional features — attention-grabbing penalties, M&A risk, and the importance of monitoring joint ventures.

The largest FCPA settlement thus far was resolved in December 2016 with the world's largest manufacturer of generics, Israeli Teva Pharmaceuticals. Teva agreed to enter into a three-year DPA with DOJ, to retain and independent compliance monitor, and to pay more than $519 million to settle DOJ and SEC charges that it violated the FCPA by paying bribes to high-ranking foreign officials in Russia and Ukraine and to doctors in Mexico to increase market share, influence drug purchase decisions, and to obtain regulatory and formulary approvals between 2001 and 2012.[17]

In January 2017, Texas-based medical device company Orthofix International agreed to pay more than $6 million and to retain an independent compliance monitor for one year to settle SEC charges that it violated the FCPA's books

Continued on page 20

16. *See* Appendix A.

17. *See* Deferred Prosecution Agreement at A-6, *U.S. v. Teva LLC*, No. 16-CR-20968 (S.D. FL. Dec. 22, 2016), https://www.justice.gov/criminal-fraud/file/920436/download; Complaint, *SEC v. Teva Pharm. Indus. Ltd.*, No. 16-cv-25298 (S.D. FL. Dec. 22, 2016), https://www.sec.gov/litigation/complaints/2016/comp-pr2016-277.pdf. Teva's Russian subsidiary pleaded guilty to a one-count information charging it with conspiring to violate the FCPA's anti-bribery provisions.

Sanofi Settlement Highlights Risk in the Life Sciences Industries

Continued from page 19

and records and internal controls provisions. According to the SEC's Order, Orthofix's Brazilian subsidiary offered high discounts and made improper payments through third-party representatives and distributors (using fake invoices) to doctors at state-owned hospitals to increase sales from 2011 to 2013.[18] This was the company's second FCPA settlement. In 2012, Orthofix entered into a three-year DPA with DOJ and agreed to pay more than $7.2 million to settle DOJ and SEC charges that one of its subsidiaries paid bribes to officials at Mexico's government-owned health care and social services institution to obtain sales contracts with government hospitals from 2003 to 2010.[19]

A few cases have highlighted the importance of addressing the risks associated with M&A activity in the life sciences space. For example, in January 2017, Indiana-based medical device manufacturer Zimmer Biomet entered into a DPA with DOJ and agreed to pay more than $30 million and to retain an independent monitor for a three-year period to settle charges that it continued to use a distributor in Brazil known to have paid bribes on behalf of Biomet, which Zimmer Holdings acquired in 2015 from a group of private equity firms that had taken Biomet private in 2007.[20] According to the DPA, the company's failure to implement due diligence procedures allowed subsidiaries to make unlawful payments to customs officials to permit Biomet to export mislabeled dental products to Mexico. This was Biomet's second FCPA settlement;[21] in March 2012, Biomet entered into a three-year DPA that required retention of an independent compliance monitor for an 18-month period[22] and agreed to pay more than $22 million to DOJ and the SEC to settle charges that its subsidiaries violated the FCPA in connection with improper payments made to publicly-employed HCPs in Argentina, Brazil, and China to secure business with hospitals from 2000 to 2008.[23] Zimmer Biomet's 2017 settlement stems from DOJ's 2016 determination that Biomet had breached its 2012 DPA — the obligations

Continued on page 21

18. *See In re Orthofix Int'l N.V.*, Securities Exchange Act Rel. No. 79828 (Jan. 18, 2017), https://www.sec.gov/litigation/admin/2017/34-79828.pdf.

19. Deferred Prosecution Agreement, *U.S. v. Orthofix Int'l, N.V.*, No. 12-cr-150 (E.D. Tex. July10, 2012), https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/08/15/2012-07-10-orthofix-dpa.pdf; Consent of Defendant Orthofix Int'l N.V., *SEC v. Orthofix Int'l N.V.*, No. 12-cv-419 (E.D. Tex. July 10, 2012); *see also* Bruce E. Yannett, Andrew M. Levine, Philip Rohlik & Maxwell K. Weiss, *Corporate Recidivism in the FCPA Context*, FCPA Update, Vol. 8, No.9 (Apr. 2017), https://www.debevoise.com/~/media/files/insights/publications/2017/04/fcpa_update_april_2017.pdf.

20. *See* Deferred Prosecution Agreement at A-5, *U.S. v. Zimmer Biomet Holdings, Inc.*, No. 12-CR-00080 RBW (D.D.C. Jan. 13, 2017), https://www.justice.gov/criminal-fraud/case/file/925831/download; *In re Biomet, Inc.*, Securities Exchange Act Rel. No. 79780 (Jan. 12, 2017), https://www.sec.gov/litigation/admin/2017/34-79780.pdf. A subsidiary agreed to plead guilty to a one-count information charging it with causing Biomet's books and records violations.

21. *See* Yannett et al., *Corporate Recidivism in the FCPA Context*, *supra* note 19.

22. This was subsequently extended, first to a three-year period and then for an additional year. *See* Zimmer Biomet DPA ¶ 4(b).

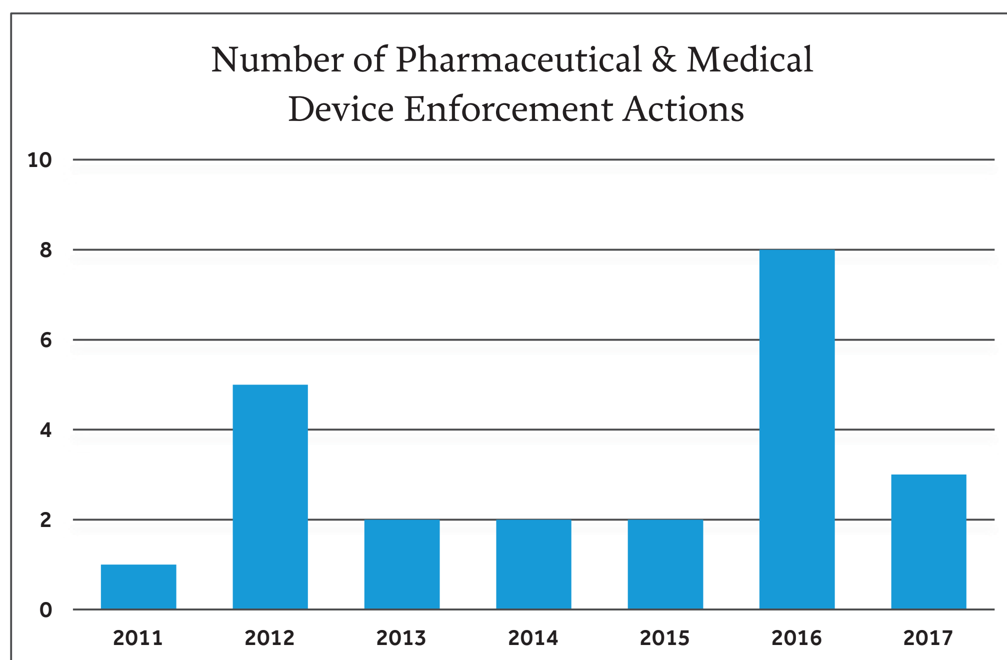
23. Deferred Prosecution Agreement ¶ 16(a), *U.S. v. Biomet, Inc.*, No. 12-cr-00080-RBW (D.D.C. Mar. 26, 2012), https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/03/30/2012-03-26-biomet-dpa.pdf; Compliant, *SEC v. Biomet, Inc.*, No. 12-cv-454 (D.D.C. Mar. 26, 2012), https://www.sec.gov/litigation/complaints/2012/comp22306.pdf.

Sanofi Settlement Highlights Risk in the Life Sciences Industries

Continued from page 20

of which Zimmer, as Biomet's acquirer, had inherited — based on the conduct in Mexico and Brazil, and based on its failure to implement and maintain a satisfactory compliance program.[24]

In 2012, Pfizer, too, was held accountable for the FCPA violations of a subsidiary, here Wyeth, that predated its acquisition of Wyeth. Both agreed to pay a combined $25 million to settle SEC charges, and a Pfizer subsidiary entered into a DPA with DOJ, paying an additional $15 million.[25] According to the SEC's Order, Wyeth subsidiaries, primarily before their acquisition by Pfizer, bribed government doctors in China, Indonesia, and Pakistan with cash, cell phones and travel incentives to recommend their products and made an improper payment to a customs official in Saudi Arabia to release a shipment of promotional items. Following a post-acquisition risk-based due diligence review, Pfizer self-reported its findings to the SEC.[26]



Continued on page 22

24. Status Report ¶ 3, *U.S. v. Biomet, Inc.,* No. 12-cr-00080-RBW (D.D.C. June 6, 2016).

25. *See* Complaint, *SEC v. Pfizer Inc.,* No. 12-cv-01303 (D.D.C. Aug. 7, 2012), https://www.sec.gov/litigation/complaints/2012/comp-pr2012-152-pfizer.pdf; *SEC. v. Wyeth LLC,* Complaint, No. 12-cv-01304 (Aug. 7, 2012), https://www.sec.gov/litigation/complaints/2012/comp-pr2012-152-wyeth.pdf; Deferred Prosecution Agreement, *U.S. v. Pfizer H.C.P. Corp.,* No. 12-cr-169 (D.D.C. Aug. 7, 2012), https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2012/08/15/2012-08-07-pfizer-dpa.pdf.

26. *See also In re Jun Ping Zhang*, Securities Exchange Act Rel. No.78825 (Sept. 13, 2016), https://www.sec.gov/litigation/admin/2016/34-78825.pdf (SEC opted not to bring charges against Harris Corporation, in part because of its self-reporting, cooperation and remediation related to its acquisition of a Chinese subsidiary whose CEO facilitated the giving of gifts to officials at Chinese state-owned hospitals to induce the purchase of electronic medical records software). *See also* Bruce E. Yannett, Andrew M. Levine & Philip Rohlik, *The Difficulty of Defining a Declination: An Update on the DOJ Pilot Program,* FCPA Update, Vol. 8, No. 3 (Oct. 2016), https://www.debevoise.com/~/media/files/insights/publications/2016/10/fcpa_update_october_2016.pdf.

Continued from page 21

Finally, it's important to keep tabs on company joint ventures. In October 2015, New York based pharmaceutical company Bristol-Myers Squibb agreed to pay $14 million to settle SEC charges that its majority-owned China-based joint venture made cash payments to HCPs at Chinese state health institutions to increase prescription sales from 2009 to 2014.[27] Bristol-Myers Squibb was charged with violating the FCPA's books and records and internal controls provisions for failing to investigate claims by the joint venture's terminated employees whose doctored invoices, receipts, and purchase orders were used to funnel funds to HCPs. According to the SEC's Order, the company was too slow to remediate gaps in internal controls over the joint venture's interactions with HCPs and to address potential inappropriate payments that were identified repeatedly in annual internal audits.

"Given the Sanofi settlement, [recent] disclosures, and the heavy emphasis on pharmaceutical and medical device companies outlined herein, it seems likely that the U.S. authorities will continue their close scrutiny of the activities of life sciences companies (and their agents) outside the United States."

Takeaways from Sanofi and Prior Life Sciences Cases

The world's leading provider of dialysis products and services, Fresenius, disclosed earlier this year that it was setting aside a $245 million settlement reserve.[28] Given the Sanofi settlement, this and other disclosures, and the heavy emphasis on pharmaceutical and medical device companies outlined herein, it seems likely that the U.S. authorities will continue their close scrutiny of the activities of life sciences companies (and their agents) outside the United States.

This scrutiny has not been confined to U.S. government agencies. For example, Brazil's Federal Prosecution Service ("MPF") is conducting an investigation arising out of Lavo Jato into a potential medical devices cartel of some 35 local and international companies (including reportedly Phillips, Johnson & Johnson, Zimmer Biomet, and Orthofix, among others) that it alleges made improper

Continued on page 23

27. *See In re Bristol-Myers Squibb Company,* Securities Exchange Act Rel. No. 76073 ¶ 11 (Oct. 5, 2015), https://www.sec.gov/litigation/admin/2015/34-76073.pdf.

28. Fresenius Medical Care AG & Co. KGaA, Second Quarter 2018 Form 6-K at 55 (noting that Fresnius "recorded a charge of €200,000 in the fourth quarter of 2017 . . . based on ongoing settlement negotiations").

Sanofi Settlement Highlights Risk in the Life Sciences Industries
Continued from page 22

payments to public officials to influence tenders for medical equipment contracts.[29] The MPF announced 13 preventative detentions and search warrants for 44 companies in July 2018.

A number of other countries, including China, also have active investigations focused on life sciences companies.[30]

The lessons from this expansive enforcement activity are multifold:

- K**eep compliance policies robust and up to date.** A robust anti-corruption compliance program reduces the likelihood that red flags will be ignored and misconduct undetected. If an issue surfaces, a company with a strong compliance program is in a better position to identify the issue early and ultimately negotiate a positive resolution with a government regulator.
- **Interpret "anything of value" broadly.** Non-cash benefits, such as gifts, travel, and entertainment expenses must be reasonable and related to a legitimate business purpose. Points or bonus programs[31] that reward prescription-writing and unlawful payments veiled as charitable contributions[32] are of particular risk in the pharmaceutical industry. All of these things of value must be carefully scrutinized.
- **Keep an eye on conferences, dining, entertainment, and travel.** Where company-sponsored travel is provided, make sure that there is a reasonable business purpose for the travel, and document that the training or scheduled visits actually occurred.

Continued on page 24

29. Emily Casswell, *Brazilian Healthcare Corruption Investigations Show No Sign of Abating,* Global Investigations Review (Sept. 14, 2018), https://globalinvestigationsreview.com/article/1174152/brazilian-healthcare-corruption-investigations-show-no-sign-of-abating.
30. *See, e.g.,* Te-Ping Chen, Fanfan Wang & Preetika Rana, *China Opens Corruption Probe at Vaccine Maker, Detains Executives*, WSJ (July 24, 2018), https://www.wsj.com/articles/china-opens-corruption-probe-at-vaccine-maker-detains-executives-1532443879; Novartis AG, Second Quarter 2018 Form 6-K at 227 (noting that Novartis is providing information to Greek authorities related to "potentially inappropriate economic benefits to healthcare professionals, governments officials and others in Greece").
31. *See, e.g.,* Pfizer Complaint ¶¶ 25, 33.
32. To date charitable contribution cases have generally been confined to life sciences and consumer product companies. *See, e.g., In re Stryker Corp.*, Securities Exchange Act Rel. No. 70751 ¶ 29 (Oct. 24, 2013), https://www.sec.gov/litigation/admin/2013/34-70751.pdf (Michigan-based medical technology company Stryker Corporation agreed to pay $13.2 million to settle FCPA charges that alleged in part that Stryker's Greek subsidiary made a nearly $200,000 donation to a public university to fund a doctor's pet project in exchange for the doctor's agreement to provide Stryker business); Complaint, *SEC v. Schering-Plough Corp.,* 04-cv-945 (D.D.C. June 9, 2004), https://www.sec.gov/litigation/complaints/comp18740.pdf (New Jersey-based pharmaceutical company paid a $500,000 penalty to settle FCPA charges that a subsidiary made improper payments to a charitable organization in Poland headed by the director of a Polish governmental health fund to influence the health fund's purchase of pharmaceutical products). More recently, Utah-based consumer product manufacturer Nu Skin agreed to pay nearly $766,000 to resolve the SEC's charges that it violated the books and records and internal controls provisions as a result of its subsidiary's payment of a "donation" to a charity in exchange for a high-ranking Chinese Communist party official's influence over an ongoing government investigation into Nu Skin. *See In re Nu Skin Enters, Inc.,* Securities Exchange Act Rel No. 78884 (Sept. 20, 2016), https://www.sec.gov/litigation/admin/2016/34-78884.pdf; *see also* Colby A. Smith, Andrew M. Levine & Philip Rohlik, *Charitable Donations as FCPA Violations: SEC Settles with Nu Skin Over Donation by Chinese Subsidiary,* FCPA Update, Vol. 8, No. 2 (Sept. 2016), https://www.debevoise.com/~/media/files/insights/publications/2016/09/fcpa_update_september_2016.pdf.

Sanofi Settlement Highlights Risk in the Life Sciences Industries
Continued from page 23

Especially in connection with conferences and customer travel, sales employees should be encouraged to work with compliance professionals to manage customer expectations in a compliant manner.

- **Perform pre- and post-retention risk-based due diligence on third parties.** Thoroughly vet third-party agents and distributors to fully understand the business rationale for working with them and to ensure that any payments made are for legitimate business expenses. Many life sciences companies use distributors in addition to third-party agents, creating an extra layer of cash flow that carries the risk of distributors using their spread to create slush funds for foreign officials.[33] Life sciences companies may also face officials with licensing and inspections authority or customs officials with the ability to ensure quick customs clearance for perishable medicines or mislabeled goods. Have a mechanism in place to track third-party usage in writing and ensure that third parties receive the appropriate due diligence, and be willing to terminate distributors that do not live up to your expectations.
- **Be proactive and conduct regular risk assessments.** Perform periodic risk assessments that acknowledge the life sciences industry's worldwide presence, paying particular attention to high-risk jurisdictions. If you see that a competitor is under investigation, look to see whether you use the same agent or distributor, or operate in the same jurisdictions to head off a problem early.
- **Work with industry groups, medical associations, and local governments to devise local codes of conduct/best-practices for healthcare professionals** (to the extent possible under local competition law). Underfunding, unequal funding, or poor administration of national healthcare systems can result in demands from healthcare professionals seeking to supplement meagre salaries. Working to encourage reform and improvement in local healthcare systems and practices can do more to reduce corruption risks than improvements to the policies and procedures of a single company.
- **In addition to the lessons from recent FCPA actions, don't neglect other risks.** Although most pharmaceutical and medical device cases have involved pay-to-prescribe schemes with HCPs or global purchasing arrangements with national health systems or government regulators, pharmaceutical companies can also face other risks including: customs clearance; dealings with both national regulators and multilateral institutions in developing jurisdictions

Continued on page 25

33. *See, e.g.,* Teva DPA at A-10 (Teva's Russian subsidiary retained a repackaging and distribution company owned by a Russian official with influence over Ministry of Health decisions to increase Teva drug sales to the Russian government).

Continued from page 24

relating the purchase and distribution of vaccines, test kits, and similar products; health & safety and other regulatory approvals and inspections; and dealings with national intellectual property issues, all of which pose corruption risk distinct from the more common tender process or pay-to-prescribe scenarios.

- **Get help in difficult situations.** Experienced counsel can help you determine the right approach to managing anti-corruption risk. For FCPA issues involving life sciences companies, it is often advisable to combine FCPA expertise with FDA (and foreign equivalent) expertise, in order to make sure that applicable issues are appropriately identified and resolved.

Kara Brockmeyer

Andrew M. Levine

Paul D. Rubin

Philip Rohlik

Andreas A. Glimenakis

Kara Brockmeyer and Paul D. Rubin are partners in the Washington, D.C. office. Andrew M. Levine is a partner in the New York office. Philip Rohlik is a counsel in the Shanghai office. Andreas A. Glimenakis is an associate in the Washington, D.C. office. The authors may be reached at kbrockmeyer@debevoise.com, amlevine@debevoise.com, pdrubin@debevoise.com, prohlik@debevoise.com, and aaglimen@debevoise.com. Full contact details for each author are available at www.debevoise.com.

Continued on page 26

Sanofi Settlement Highlights Risk in the Life Sciences Industries

Continued from page 25

Appendix A

Entity Charged	Violations
Sanofi (Sept. 2018)	SEC books and records and internal controls charges in connection with improper payments made to increase sales and improperly influence foreign officials in Kazakhstan and several countries in the Middle East
Alere, Inc. (Sept. 2017)	SEC books and records and internal controls charges in connection with improper payments made to increase sales in Colombia and India
Orthofix Int'l N.V. (Jan. 2017)	SEC books and records and internal controls charges in connection with improper payments made to increase sales in Brazil
Zimmer Biomet Holdings, Inc./Biomet, Inc. (Jan. 2017)	DOJ and SEC anti-bribery, books and records, and internal controls charges in connection with unlawful payments made to increase sales in Brazil and to facilitate importation of mislabeled products into Mexico
Teva LLC (Dec. 2016)	DOJ and SEC anti-bribery, books and records, and internal controls charges in connection with unlawful payments made to obtain regulatory and formulary approvals and increase sales in Russia, Ukraine, and Mexico
GlaxoSmithKline plc (Sept. 2016)	SEC books and records and internal controls charges in connection with improper payments made to increase prescription sales in China
AstraZeneca plc (Aug. 2016)	SEC books and records and internal controls charges in connection with improper payments made to boost drug sales in China and Russia
Analogic Corp./BK Medical ApS (June 2016)	DOJ and SEC books and records and internal controls charges in connection with sham transactions with distributors
Novartis AG (Mar. 2016)	SEC books and records and internal controls charges in connection with improper payments made to increase sales in China
Olympus Latin America, Inc. (Mar. 2016)	DOJ anti-bribery charges in connection with improper payments made to increase sales in Argentina, Bolivia, Brazil, Colombia, Costa Rica, and Mexico

Continued on page 27

Sanofi Settlement Highlights Risk in the Life Sciences Industries
Continued from page 26

Entity Charged	Violations
Nordion (Canada) Inc. (Mar. 2016)	SEC internal controls charges in connection with improper payments, parts of which were used to bribe Russian officials to approve distribution of a cancer treatment
SciClone Pharmaceuticals, Inc. (Feb. 2016)	SEC anti-bribery, books and records, and internal controls charges in connection with improper payments made to increase sales in China
Bristol-Myers Squibb Co. (Oct. 2015)	SEC books and records and internal controls charges in connection with improper payments made by joint venture to increase sales in China
Mead Johnson Nutrition Co. (July 2015)	SEC books and records and internal controls charges in connection with improper payments made to win business in China
Bruker Corp. (Dec. 2014)	SEC books and records and internal controls charges in connection with improper payments made to obtain business in China
Bio-Rad Labs, Inc. (Nov. 2014)	DOJ and SEC anti-bribery, books and records, and internal controls charges in connection with improper payments made to win business in Russia, Thailand, and Vietnam
Stryker Corp. (Oct. 2013)	SEC books and records and internal controls charges in connection with improper payments made in Argentina, Greece, Mexico, Poland, and Romania
Koninklijke Philips Electronics N.V. (Apr. 2013)	SEC books and records and internal controls charges in connection with improper payments made to influence public tenders in Poland
Eli Lilly & Co. (Dec. 2012)	SEC anti-bribery, books and records, and internal controls charges in connection with improper payments made to win business in Brazil, China, Poland and Russia
Pfizer Inc. (Aug. 2012)	DOJ and SEC anti-bribery, books and records, and internal controls charges in connection with improper payments made to increase sales and obtain regulatory and formulary approvals in several countries

Continued on page 28

Continued from page 27

Entity Charged	Violations
Wyeth LLC (Aug. 2012)	SEC books and records and internal controls charges in connection with improper payments made to increase sales in China, Indonesia, and Pakistan and to facilitate shipping clearance in Saudi Arabia
Orthofix Int'l N.V. (July 2012)	DOJ and SEC books and records and internal controls charges in connection with improper payments made to obtain sales contracts in Mexico
Biomet, Inc. (Mar. 2012)	DOJ and SEC anti-bribery, books and records, and internal controls charges in connection with improper payments made to win business in Argentina, Brazil and China
Smith & Nephew plc (Feb. 2012)	DOJ and SEC anti-bribery, books and records, and internal controls charges in connection with improper payments made to win business in Greece
Johnson & Johnson (Apr. 2011)	DOJ and SEC anti-bribery, books and records, and internal controls charges in connection with improper payments made to win business and increase sales in Greece, Poland and Romania and to win Oil-for-Food Program contracts in Iraq

FCPA Update

FCPA Update is a publication of
Debevoise & Plimpton LLP

919 Third Avenue
New York, New York 10022
+1 212 909 6000
www.debevoise.com

Washington, D.C.
+1 202 383 8000

London
+44 20 7786 9000

Paris
+33 1 40 73 12 12

Frankfurt
+49 69 2097 5000

Moscow
+7 495 956 3858

Hong Kong
+852 2160 9800

Shanghai
+86 21 5047 1800

Tokyo
+81 3 4570 6680

Bruce E. Yannett
Co-Editor-in-Chief
+1 212 909 6495
beyannett@debevoise.com

Andrew J. Ceresney
Co-Editor-in-Chief
+1 212 909 6947
aceresney@debevoise.com

David A. O'Neil
Co-Editor-in-Chief
+1 202 383 8040
daoneil@debevoise.com

Jane Shvets
Co-Editor-in-Chief
+44 20 7786 9163
jshvets@debevoise.com

Philip Rohlik
Co-Executive Editor
+852 2160 9856
prohlik@debevoise.com

Kara Brockmeyer
Co-Editor-in-Chief
+1 202 383 8120
kbrockmeyer@debevoise.com

Andrew M. Levine
Co-Editor-in-Chief
+1 212 909 6069
amlevine@debevoise.com

Karolos Seeger
Co-Editor-in-Chief
+44 20 7786 9042
kseeger@debevoise.com

Erich O. Grosz
Co-Executive Editor
+1 212 909 6808
eogrosz@debevoise.com

Jil Simon
Associate Editor
+1 202 383 8227
jsimon@debevoise.com

Please address inquiries regarding topics covered in this publication to the editors.

All content © 2018 Debevoise & Plimpton LLP. All rights reserved. The articles appearing in this publication provide summary information only and are not intended as legal advice. Readers should seek specific legal advice before taking any action with respect to the matters discussed herein. Any discussion of U.S. Federal tax law contained in these articles was not intended or written to be used, and it cannot be used by any taxpayer, for the purpose of avoiding penalties that may be imposed on the taxpayer under U.S. Federal tax law.

Please note:
The URLs in *FCPA Update* are provided with hyperlinks so as to enable readers to gain easy access to cited materials.