Debevoise & Plimpton

FCPA Update
August 2020
Volume 12
Number 1

FCPA Update

A Global Anti-Corruption Newsletter

Also in this issue:

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

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

As we previously reported, the life sciences industry has been in the FCPA crosshairs for more than a decade. In 2018, the SEC sent a strong signal that the enforcement focus was not done yet, noting that "[w]hile bribery can impact any industry … more work needs to be done to address the particular risks posed in the pharmaceutical industry."[1]

In the first eight months of 2020, that focus has been clear. Of the seven FCPA settlements reached thus far in 2020, three have involved pharmaceutical companies – Cardinal Health, Novartis/Alcon, and Alexion. There have now been nearly 30 FCPA

Continued on page 2

1. U.S. Sec. & Exch. Comm'n, "Sanofi Charged With FCPA Violations," Press Rel. 2018-174 (Sept. 4, 2018), https://www.sec.gov/news/press-release/2018-174. *See* Kara Brockmeyer, Andrew M. Levine, Paul D. Rubin, Philip Rohlik & Andreas A. Glimenakis, "Sanofi Settlement Highlights Risk in the Life Sciences Industries," FCPA Update, Vol. 10, No. 2 (Sept. 2018), https://www.debevoise.com/insights/publications/2018/09/fcpa-update-september-2018.

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 1

enforcement actions in the pharmaceutical and medical device industries since 2011,[2] more than any other industry during that time period. And four of these recent cases involve recidivists – more than any other industry in the past decade.

As we previously discussed, operating in highly-regulated environments with many government touchpoints and often in higher-risk jurisdictions creates significant risk for life sciences companies, and that risk can be hard to manage. 2020's life sciences resolutions provide a timely reminder of the perils associated with clinical trials and efforts to secure regulatory approvals; the need to keep an eye on honoraria and medical congresses; and the critical importance of pre- and post-acquisition due diligence and remediation, especially with regard to retention of third-party distributors and other agents.

Cardinal Health

In February 2020, Cardinal Health Inc., an Ohio-based pharmaceuticals company, agreed to pay approximately $8.8 million to settle SEC charges relating to a former Chinese subsidiary's alleged use of marketing accounts for improper payments, gifts, and expenses.[3] The SEC charged Cardinal with violating the books and records and internal controls provisions of the FCPA; DOJ declined to take any enforcement action in this matter, likely based upon the company's voluntary disclosure, cooperation and significant remedial measures.[4]

According to the allegations in the SEC's Order, which Cardinal Health neither admitted nor denied, in 2010, Cardinal Health acquired a Chinese pharmaceuticals distribution company and rebranded it as Cardinal China. Cardinal China had pre-existing distribution contracts with many global manufacturers of medications, medical devices, and other consumer health products. In some cases, Cardinal China maintained (on its own books) financial accounts – comprised largely of excess distribution margin – from which it authorized payments at the direction of its customers to fund their operations and marketing efforts in China. Cardinal Health directed Cardinal China to wind down these accounts shortly after the acquisition, believing they posed too much of a compliance risk.

Cardinal China shut down marketing accounts for Italian and U.K. pharmaceutical manufacturers after receiving internal reports about improper benefits and payments, but the subsidiary continued to maintain accounts for some large suppliers, including

Continued on page 3

2. *See* Appendix A for a complete list of industry-specific FCPA settlements.
3. U.S. Sec. & Exch. Comm'n, "SEC Charges Cardinal Health With FCPA Violations," Press Rel. 2020-48 (Feb. 28, 2020), https://www.sec.gov/news/press-release/2020-48; *see also In re Cardinal Health*, Securities Exchange Act Rel. No. 88303 (Feb. 28, 2020), https://www.sec.gov/litigation/admin/2020/34-88303.pdf.
4. *See* Sarah Jarvis, "Cardinal Health Pays Nearly $9M To Resolve FCPA Claims," Law360 (Feb. 28, 2020), https://www.law360.com/articles/1248778/cardinal-health-pays-nearly-9m-to-resolve-fcpa-claims (a spokesperson for Cardinal Health added "that the DOJ declined to take action.").

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 2

a European dermocosmetic company that it viewed as low risk – and not subject to its full set of internal accounting controls. Cardinal China also hired and administratively managed 2,400 employees on the dermocosmetic company's behalf, some of whom worked in sales and marketing and regularly used the marketing expense accounts to pay third parties by submitting requests to Cardinal China.

In 2016, Cardinal China learned that payments in the form of cash, luxury goods, travel expenses, and gift cards – disguised as various "production fees" or supported by falsified or incomplete documentation – had been made to government healthcare providers ("HCPs") and employees of Chinese state-owned retailers from the marketing accounts in order to boost the dermocosmetic company's sales since at least 2013. Cardinal Health reported the misconduct to both the SEC and DOJ, and undertook significant remedial measures, including adding anti-bribery provisions to relevant contracts, terminating marketing accounts and marketing employee contracts, and adding strict limitations around remaining account balances with robust compliance controls and monitoring by legal and compliance personnel. The company sold Cardinal China to a Chinese pharmaceutical company in 2018.

"There have now been nearly 30 FCPA enforcement actions in the pharmaceutical and medical device industries since 2011, more than any other industry during that time period."

The SEC charged Cardinal Health in connection with failures to implement sufficient controls over marketing accounts it administered, improper evaluation of red flags, and failures to resolve known internal controls deficiencies. In particular, the SEC faulted the company for:

- Failing to assess whether its subsidiary followed though with winding down marketing account operation for several large suppliers despite the company's 2010 determination regarding the risks of administering such accounts; and
- Failing to investigate whether Cardinal China wound down such accounts even after it: (1) discovered and closed such accounts in Italy and the United Kingdom; (2) received warnings from employees concerning the potential illegality of the dermocosmetic company's marketing accounts; and (3) Cardinal China was fined by local Shanghai regulators in 2014 for providing a "secret commission" in products to employees of a Chinese retailer at the dermocosmetic company's request.

Continued on page 4

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry
Continued from page 3

Novartis/Alcon

In June 2020, Swiss pharmaceutical company Novartis AG became the first pharmaceutical and fourth life sciences company to resolve multiple FCPA cases. Novartis and two subsidiaries – current subsidiary Novartis Greece and former subsidiary (and current Alcon Inc. subsidiary) Alcon Singapore – entered into separate three-year DPAs with DOJ[5] and settled a cease-and-desist order with the SEC.[6] The entities agreed to pay more than $346 million to settle the DOJ and SEC charges: Novartis Greece agreed to pay a criminal penalty of $225 million to settle DOJ's charges of conspiracy to violate both the anti-bribery and books and records provisions; Alcon Singapore agreed to pay a criminal penalty of $8.9 million to settle DOJ's charges of conspiracy to violate the FCPA's books and records provision; and Novartis AG agreed to pay more than $112 million in disgorgement and prejudgment interest to the SEC and to adhere to a three-year reporting plan to settle charges of accounting violations related to conduct by Novartis Greece, Novartis Korea, and Alcon Singapore.

- *Conduct in Greece*. Between 2012 and 2015, Novartis Greece engaged in various "pay-to-prescribe" schemes to provide HCPs, who were employees of state-owned or controlled healthcare institutions, with improper benefits in order to increase the sales of its drug Lucentis. Payments and expenses were recorded as legitimate advertising, marketing, and sales expenses. HCPs deemed "Key Opinion Leaders" were paid to attend international medical events in exchange for increasing prescription rates, and these HCPs were internally ranked by prescription rates and "return on investment." Additionally, from 2009 through 2012, Novartis Greece sponsored clinical trials to assess a drug's safety and efficacy, but in certain instances, sales personnel (rather than Medical Affairs) selected HCPs in order to promote products and boost sales through improper payments to HCPs, including via "dummy vendors" without proper due diligence. The SEC's order recounts that company personnel were aware that HCPs believed they were being paid in return for their prescription-writing rather than for their roles in the study. Novartis Internal Audit discovered these deficiencies during reviews in 2012 and 2013.

Continued on page 5

5. U.S. Dep't of Justice, "Novartis Hellas S.A.C.I. and Alcon Pte Ltd Agree to Pay Over $233 Million Combined to Resolve Criminal FCPA Cases," Press Rel. 20-589 (June 25, 2020), https://www.justice.gov/opa/pr/novartis-hellas-saci-and-alcon-pte-ltd-agree-pay-over-233-million-combined-resolve-criminal; *see also U.S. v. Novartis Hellas S.A.C.I.*, Deferred Prosecution Agreement, No. 20-cr-538 (D.N.J. June 25, 2020), https://www.justice.gov/opa/press-release/file/1289746/download [hereinafter "Novartis DPA"]; *U.S. v. Alcon Pte Ltd.*, Deferred Prosecution Agreement, No. 20-cr-539 (D.N.J. June 25, 2020), https://www.justice.gov/opa/press-release/file/1289736/download [hereinafter "Alcon DPA"].

6. *In re Novartis AG*, Securities Exchange Act Rel. No. 89149 at 2, 13 (June 25, 2020), https://www.sec.gov/litigation/admin/2020/34-89149.pdf.

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 4

- *Conduct in Vietnam*. Novartis AG and Alcon, Inc. merged in 2011, and Alcon became Novartis' indirect wholly-owned subsidiary until it was spun off in 2019. Alcon Singapore oversaw the management of Alcon Vietnam's business operations during the relevant time period (2007 to 2014), when Alcon Vietnam engaged a distributor to conduct all of its sales and marketing activities of surgical equipment and consumables at a guaranteed margin of almost 25%. The distributor made improper payments to HCPs both privately and publically employed at state-owned or controlled facilities in order to increase sales of Alcon's intraocular lenses, engaging the providers in a sham consultancy program. While the distributor arrangement was in place well before the 2011 Novartis-Alcon merger, Novartis failed to halt the improper payments and instead the program was revised and referred to as "patient education" or other names that allowed the payments to continue.
- *Conduct in South Korea*. In a similar set of schemes, between 2011 and August 2016, Novartis Korea made corrupt payments to HCPs in order to increase prescriptions and sales of Novartis products. As local law prohibited such payments to providers, Novartis Korea disguised the payments as medical journal expenses paid through third-party journals, honoraria for round-table meetings, sponsorships to attend international medical conferences (including in the United States), and payments related to a clinical study. In 2017, the Korea Fair Trade Commission charged and fined Novartis Korea $446,000 for this conduct.
- *Conduct in China and throughout Asia*. From 2013 to 2015, Alcon Asia engaged in "equipment financing arrangements" whereby it provided surgical equipment to hospitals and clinics in China and other countries in Asia for a minimal down payment in exchange for contractual assurances to repay the cost through purchases of Alcon products. Novartis had insufficient internal controls to properly oversee these contracts, and as they became increasingly complex, bad debt levels grew such that Novartis and Alcon ultimately wrote off more than $50 million in bad debt from Chinese contracts alone. Beginning in 2015, an internal audit of Alcon China revealed the problems, and the financing arrangements ceased in 2016.

Alexion Pharmaceuticals

In July 2020, Boston-based Alexion Pharmaceuticals, Inc. agreed to pay approximately $21.5 million in disgorgement, prejudgment interest, and civil penalties to settle SEC claims that it violated the FCPA's accounting provisions in connection with alleged "pay to prescribe" schemes carried out by its subsidiaries in Turkey and Russia, and for its Brazil and Colombia subsidiaries' alleged failures to maintain accurate books

Continued on page 6

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 5

and records.[7] DOJ closed its investigation in May 2020 and declined to take any enforcement action.[8]

According to allegations in the SEC's order, which Alexion neither admitted nor denied, from 2010 to 2015, Alexion Turkey allegedly made improper payments to foreign officials in order to influence favorable regulatory treatment for Soliris and increase the number of government-approved prescriptions under Turkey's named patient sales program.[9] After initially failing to obtain the necessary approvals, Alexion Turkey hired a third-party consultant who the SEC claimed made payments in the form of cash, gifts, and meals to Turkish government officials in order to expedite the process and obtain confidential regulatory information in advance. Additionally, the SEC alleged that Alexion Turkey managers directly paid more than $100,000 in bribes to HCPs serving on the Ministry of Health commissions who were in charge of patient and regulatory approvals.

Similarly, the SEC claimed that, from 2011 to 2015, Alexion Russia made improper payments to HCPs employed by state-owned healthcare institutions through sham arrangements for research, educational, and consulting services, in order to influence the regulatory treatment of Soliris. Alexion Russia also sought to increase regional budget allocations that would in turn cover the reimbursement of Soliris prescriptions.

Additionally, from 2013 to 2015, the SEC alleged that employees at Alexion's Brazil and Colombia-based subsidiaries created or had patient advocacy organizations create inaccurate financial records that circumvented or misled Alexion's global grant review committee concerning payments to those same patient advocacy organizations and other third parties. In some cases, the employees misdirected funds for personal use, and in others, the funds improperly went to the patient advocacy group.

A Word on Trends, Declinations, and Recidivists

The SEC has remained active in enforcement across the board for life sciences companies, settling 16 actions since 2015, typically under the FCPA's accounting provisions – charging anti-bribery violations in only four of those cases. It has also pursued a number of recidivists, including most recently Novartis (2020 and 2016), but also Stryker (2013 and 2018), Biomet (2012 and 2017), and Orthofix (2012 and 2017).

Continued on page 7

7. U.S. Sec. & Exch. Comm'n, "SEC Charges Alexion Pharmaceuticals With FCPA Violations," Press Rel. 2020-149 (July 2, 2020), https://www.sec.gov/news/press-release/2020-149.
8. Alexion Pharmaceuticals, Inc., Press Release, "Alexion Finalizes Settlement with the U.S. Securities and Exchange Commission" (July 2, 2020), https://ir.alexion.com/news-releases/news-release-details/alexion-finalizes-settlement-us-securities-and-exchange.Second Edition, supra note 1, at 51-54.
9. *In re Alexion Pharmaceuticals, Inc.*, Securities Exchange Act Rel. No. 89214 (July 2, 2020), https://www.sec.gov/litigation/admin/2020/34-89214.pdf.

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 6

DOJ declined to pursue an enforcement action against both Alexion and Cardinal Health – both U.S.-based companies – while it did pursue enforcement against foreign Novartis and Alcon subsidiaries. DOJ has settled six cases in the life sciences industry since 2015 – three charging anti-bribery violations; one charging only internal controls violations; and two as NPAs. DOJ last settled an FCPA investigation against a U.S.-based pharmaceutical company in January 2017 (Zimmer Biomet).[10]

With the exception of non-issuer Olympus in 2016, the Novartis settlement appears to be the first DOJ DPA with a life sciences company in which the SEC did not also bring anti-bribery charges since the Pfizer/Wyeth settlements in 2012 – perhaps evincing DOJ's efforts to penalize FCPA recidivists. Novartis settled an FCPA investigation with the SEC in 2016 over improper payments made to increase sales in China,[11] and its recidivist status affected the penalty reduction its Greek subsidiary received for cooperation and remediation efforts under DOJ's FCPA Corporate Enforcement Policy ("CEP").[12] Despite Novartis Greece's full cooperation and remediation, its 25% penalty reduction was based on a deduction from a point near the midpoint of the applicable Sentencing Guidelines fine range. Had its parent company not been a recidivist, Novartis Greece could have been eligible for a 25% deduction from the low end of the Sentencing Guidelines range, which is how Alcon Singapore's penalty was calculated. Neither company was eligible for the CEP's alternative 50% penalty reduction credit due to a "failure to timely disclose" the underlying conduct to DOJ.[13]

"The Cardinal Health, Novartis/Alcon, and Alexion cases highlight the risks that pharmaceutical companies face while operating in a variety of markets across Asia, Europe, and South America that span CPI scores of 59 (South Korea) to 28 (Russia)."

Continued on page 8

10. *See* Appendix A.
11. *In re Novartis AG*, Securities Exchange Act Rel. No. 77431 (Mar. 23, 2016), https://www.sec.gov/litigation/admin/2016/34-77431.pdf.
12. U.S. Dep't of Justice, Justice Manual 9-47.120 "FCPA Corporate Enforcement Policy," last updated Nov. 2019, https://www.justice.gov/jm/jm-9-47000-foreign-corrupt-practices-act-1977#9-47.120.
13. Interestingly, while Novartis Greece "did not voluntarily self-disclose" the conduct to DOJ, it appears Alcon Singapore attempted to self-disclose, but did not receive credit because it did so only when "there was an imminent threat of disclosure" to DOJ and Novartis AG was already subject to reporting obligations under its prior SEC resolution. This suggests that had Novartis Greece voluntarily disclosed, Novartis AG's obligations may have prevented voluntary disclosure credit in that instance, too. *See* Novartis DPA, *supra* note 5 at 3-4; Alcon DPA, *supra* note 5 at 3-4.

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 7

Domestic Anti-Kickback Settlements for FCPA Offenders

Risks related to bribery and kickback schemes in the pharmaceutical industry are not unique to foreign jurisdictions, but such conduct in the U.S. market is prosecuted under different laws and often involves funds related to federal health programs. Alexion and Novartis both recently settled with DOJ for alleged violations of the Anti-Kickback Statute of the False Claims Act, which criminalizes payments made to induce referrals or patient purchases of items and services covered by federally-funded health care programs such as Medicare and Medicaid.

In April 2019, Alexion settled with DOJ for $13 million over an alleged improper payment scheme it conducted through a foundation in order to increase Medicare reimbursements between 2010 and 2016.[14] Alexion made donations to the foundation's "Complement-Mediated Disease" fund, and was its sole donor, in exchange for the fund paying the Medicare copay obligations of Soliris patients. Alexion referred patients prescribed Soliris to this foundation in order to increase drug sales, and therefore Medicare reimbursements.

Just last month, Novartis' U.S. subsidiary agreed to pay more than $642 million to settle two separate alleged violations of the Anti-Kickback Statute.[15] The first settlement alleged improper payments to three charitable foundations that covered the Medicare copays of patients using Novartis drugs Gilenya and Afinitor. The second settlement involved a "pay-to-prescribe" scheme where Novartis hosted tens of thousands of speaker programs and related events over more than a decade, for which it paid speakers honoraria designed to induce speakers to prescribe Novartis drugs. The speaking programs either lacked educational content and involved primarily social events, or in some cases, never occurred at all. Novartis sales representatives chose high-volume prescribers to serve as the speakers.

While these schemes did not involve bribes paid to public officials, unlike those of Alexion's and Novartis' foreign subsidiaries, the underlying goals remained similar around the world: increase the quantity of prescriptions issued in order to enhance profits. And FCPA and domestic anti-kickback crossover cases are of course not unique to Novartis and Alexion. Earlier this month,[16] DOJ filed a complaint against the U.S. subsidiary of Israeli generics manufacturer Teva Pharmaceuticals –

Continued on page 9

14. U.S. Dep't of Justice, "Three Pharmaceutical Companies Agree to Pay a Total of Over $122 Million to Resolve Allegations That They Paid Kickbacks Through Co-Pay Assistance Foundations," Press Rel. 19-318 (Apr. 4, 2019), https://www.justice.gov/opa/pr/three-pharmaceutical-companies-agree-pay-total-over-122-million-resolve-allegations-they-paid.
15. U.S. Dep't of Justice, "Novartis Pays Over $642 Million to Settle Allegations of Improper Payments to Patients and Physicians," Press Rel. 20-618 (July 1, 2020), https://www.justice.gov/opa/pr/novartis-pays-over-642-million-settle-allegations-improper-payments-patients-and-physicians.
16. U.S. Dep't of Justice, "United States Files False Claims Act Complaint Against Drug Maker Teva Pharmaceuticals Alleging Illegal Kickbacks," Press Rel. 20-789 (Aug. 18, 2020), https://www.justice.gov/opa/pr/united-states-files-false-claims-act-complaint-against-drug-maker-teva-pharmaceuticals.

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry
Continued from page 8

which entered into a three-year DPA and agreed to pay more than $519 million in December 2016 to resolve the still-largest FCPA settlement with a pharmaceutical company – in connection with channeling payments through two charitable foundations to boost sales of the same drug that got it wrapped into FCPA trouble.

So, while from an FCPA risk perspective, companies should pay particular attention to their pharmaceutical sales abroad, internal controls systems and compliance policies must also adequately address risks of domestic bribery and kickback schemes in the United States, in particular any touchpoints with government healthcare programs, lest these cracks in company-wide compliance culture yield improper conduct elsewhere.

Lessons Learned and Re-Learned from the Life Sciences Industries

The Cardinal Health, Novartis/Alcon, and Alexion cases highlight the risks that pharmaceutical companies face while operating in a variety of markets across Asia, Europe, and South America that span CPI scores of 59 (South Korea) to 28 (Russia).

Operating in highly-regulated industries around the world, life sciences companies rely on various business licenses and product approvals from government officials in order to sell and distribute products. Companies may find themselves in FCPA trouble for improperly attempting to influence these government decisions, either directly or through third parties. And these risks are multiplied in the life sciences space, where healthcare systems are often state-controlled and regulators' broad interpretation of "foreign official" under the FCPA vastly increases the number of public officials a company interacts with in order to do business.

Accordingly, we continue to see life sciences companies charged in connection with the same types of schemes: (1) attempts to influence decision-makers in national healthcare systems relating to access (*e.g.*, regulatory approvals) and large-scale purchasing; and (2) "pay to prescribe" campaigns designed to boost sales by inducing HCPs in national health or insurance systems to increase prescriptions in exchange for financial incentives through false travel, entertainment, and conference reimbursements.

Cardinal Health, Novartis Greece, and Alcon Singapore all participated in such "pay to prescribe" schemes; and the Alexion settlement illustrates the risks in attempts to influence regulatory treatment. Moreover, companies selling pharmaceuticals or medical devices use distributors as a matter of course – posing yet another common FCPA risk that becomes amplified in a highly-regulated industry.

Continued on page 10

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 9

The takeaways for life sciences companies we provided following Sanofi's 2018 resolution hold true today,[17] but we reiterate here – in light of updated guidance – a few lessons learned and re-learned:

- *Gifts, Travel, Entertainment: Honoraria & Medical Congresses*. Gifts, travel, and entertainment expenses – including company-sponsored travel for events like medical congresses – should be reasonable, related to legitimate business purposes, and supported by documentation evincing that the training or scheduled visits occurred as planned. The Cardinal, Novartis/Alcon, and Alexion cases feature a variety of "things of value" including cash, gift cards, luxury goods, meals, international congress sponsorships and paid travel expenses, and the leasing of surgical equipment through equipment financing arrangements – all to increase prescription-writing and sales or to secure approvals for patient prescriptions and to obtain confidential information and advance feedback on regulatory submissions.

"Cardinal Health's and Novartis/Alcon's recent settlements highlight the critical importance of rigorous and thorough pre-acquisition due diligence and post-acquisition follow-through when considering stepping into the shoes of companies operating in higher-risk industries and jurisdictions with multiple government touchpoints where there is frequent reliance on third parties."

- *Successor Liability Arising from M&A Activity – and Third Party Mismanagement*. While all companies should conduct rigorous due diligence before, during, and after mergers and acquisitions (and when establishing joint ventures), Cardinal Health's and Novartis/Alcon's recent settlements highlight the critical importance of rigorous and thorough pre-acquisition due diligence and post-acquisition follow-through when considering stepping into the shoes of companies operating in higher-risk industries and jurisdictions with multiple government touchpoints where there is frequent reliance on third parties.

Continued on page 11

17. *See* Brockmeyer, et al, *supra* note 1.

18. Debevoise & Plimpton LLP, DOJ Updates Guidance on Corporate Compliance Programs (June 8, 2020), https://www.debevoise.com/insights/publications/2020/06/doj-updates-guidance-on-corporate-compliance; U.S. Dep't of Justice, Criminal Division, "Evaluation of Corporate Compliance Programs" (2020), https://www.justice.gov/criminal-fraud/page/file/937501/download.

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 10

DOJ's June 2020 updated guidance on evaluating corporate compliance programs now expressly asks whether an acquiring company was able to complete pre-acquisition due diligence (and, if not, why not) and specifically instructs prosecutors to consider whether there is "a process for timely and orderly integration . . . into existing compliance program structures and internal controls" and for conducting post-acquisition audits.[18]

While FCPA-related M&A risk is of course not new to pharmaceutical companies,[19] the Cardinal Health and Novartis/Alcon settlements illustrate anew the risks associated with insufficient tracking and remediation of third-party relationships post acquisition. Businesses should carefully scrutinize distribution and marketing contracts with third parties, which, while inherent to the industry, appear to pose one of the greatest risks to a company operating in a newly acquired market.

Cardinal Health may have learned from Zimmer Biomet's settlement when it conducted an initial risk level review and cancelled some of the suspicious marketing contracts inherited in its Cardinal China acquisition, but its alleged failure to appropriately identify the risks posed by other contracts and terminate them accordingly shows that life sciences companies may benefit from performing even more aggressive due diligence before and after acquisitions.

Kara Brockmeyer

Bruce E. Yannett

Andreas A. Glimenakis

Stephanie D. Thomas

Kara Brockmeyer is a partner in the Washington, D.C. office. Bruce E. Yannett is a partner in the New York office. Andreas A. Glimenakis is an associate in the Washington, D.C. office and Stephanie D. Thomas is an associate in the New York office. Full contact details for each author are available at www.debevoise.com.

Continued on page 12

19. *See* Kara Brockmeyer, Andrew M. Levine, Sarah Wolf, & Javier Alvarez-Oviedo, "Mitigating Anti-Corruption Risk in M&A Transactions: Successor Liability and Beyond," FCPA Update, Vol. 10, No. 5 (Dec. 2018), https://www.debevoise.com/insights/publications/2018/12/fcpa-update-december-2018. For example, Pfizer's 2009 merger with Wyeth led to FCPA enforcement after it was discovered that Wyeth's subsidiaries had made improper payments and offered travel incentives to government doctors in China, Indonesia, and Pakistan in exchange for recommending Wyeth's products, and had made an improper payment to a customs official in Saudi Arabia. Pfizer and Wyeth settled with the SEC and DOJ in 2012, agreeing to disgorge more than $45 million to the SEC, and a Pfizer subsidiary paid an additional $15 million to DOJ.

    Then, in 2017, Zimmer Biomet agreed to pay more than $30 million to resolve DOJ and SEC investigations stemming from inherited violations committed by Biomet, which Zimmer acquired in 2015. Biomet was subject to and violated a 2012 DPA with DOJ, and Zimmer inherited the DPA obligations as a result of its acquisition. After 2015, Zimmer Biomet continued to work with both a Brazilian distributor and a third-party customs broker known to have paid bribes on behalf of Biomet in Brazil and Mexico.

Appendix A

Entity Charged	Violations
Alexion Pharmaceuticals, Inc. (July 2020)	SEC books and records and internal controls charges in connection with improper payments made to increase sales and influence regulatory decisions in Turkey and Russia, and improper payments in Brazil and Colombia
Novartis AG (June 2020)	DOJ and SEC anti-bribery, books and records, and internal controls charges in connection with improper payments made to increase sales in Greece, Vietnam, and throughout Asia operations
Cardinal Health, Inc. (Feb. 2020)	SEC books and records and internal controls charges in connection with improper payments made to increase sales in China
Fresenius (Mar. 2019)	DOJ and SEC anti-bribery, books and records, and internal controls charges in connection with improper payments made to increase sales and facilitate the opening of new medical centers in 17 countries across Africa and the Middle East
Stryker (Sept. 2018)	SEC books and records and internal controls charges in connection with improper payments made in India, China, and Kuwait
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

Continued on page 13

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 12

Entity Charged	Violations
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
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

Continued on page 14

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 13

Entity Charged	Violations
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 increase sales 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
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

Continued on page 15

Recent FCPA Settlements Signal Ongoing Risks in the Life Sciences Industry

Continued from page 14

Entity Charged	Violations
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

Continued on page 16

The European Public Prosecutor's Office Prepares to Go Live

Faced with widespread concern over impunity for fraudulent activities harming not only its finances but also its image, the European Union (the "EU") has set up the independent European Public Prosecutor's Office (the "EPPO").[1] This is a significant institutional development for the EU, and for all companies and individuals involved in the many projects and activities benefiting from EU funding, or engaged in EU cross-border trade. The EPPO will be exclusively or primarily responsible for investigating and prosecuting criminal offenses affecting the EU's financial interests in 22 of the EU's 27 Member States.[2] The EPPO thus has the potential to become a, if not the, primary white-collar enforcement body in Europe, including in relation to the bribery of public officials. The EPPO is due to start active investigations in November 2020, but there are lingering concerns that its budget is insufficient for it to live up to its full potential.

Context

Every year the EU provides billions of Euros in financial support to the European economy. Almost inevitably, large-scale public funding programs are susceptible to a certain amount of fraud. By way of example, the EU's Common Agricultural Policy ("CAP") is one of the EU's principal outlays. CAP funds are disbursed at the Member State level and have long been preyed upon by fraudsters.[3] Another example is corruption in public procurement for projects benefiting from EU funding, particularly through the Regional Development Fund which seeks to alleviate regional differences in economic development. Fraud and other criminal activities undermine both the effectiveness and the credibility of EU funding programs.

In a recent report,[4], the European Court of Auditors noted that due to underreporting by Member States, the European Commission's stated amount of EUR 390.7 million lost through detected fraud in 2017 (representing 0.29% of

Continued on page 17

1. Council Regulation (EU) 2017/1939 of October 12, 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office (the "EPPO Regulation"). For in-depth commentary on the EPPO, and links to all relevant background documents, please see Debevoise & Plimpton LLP's EPPO portal at https://www.debevoise.com/topics/eppo.
2. Denmark, Hungary, Ireland, Poland, Sweden, and the United Kingdom opted not to participate. In April 2019, the Swedish Prime Minister indicated that Sweden intends to join. Since February 1, 2020 the UK is no longer a member of the EU.
3. *See, e.g.*, Selam Gebrekidan, Matt Apuzzo, & Benjamin Novak, "The Money Farmers: How Oligarchs and Populists Milk the E.U. for Millions," *New York Times* (Nov. 3, 2019), available at https://www.nytimes.com/2019/11/03/world/europe/eu-farm-subsidy-hungary.html.
4. Special Report No 1/2019, "Fighting fraud in EU spending: action needed", available at https://www.eca.europa.eu/Lists/ECADocuments/SR19_01/SR_FRAUD_RISKS_EN.pdf.

The European Public Prosecutor's Office Prepares to Go Live

Continued from page 16

EU disbursements) "[does] do not provide a complete picture of [even] the detected fraud level in EU spending." The Court of Auditors concluded that due to a deficient fraud monitoring process, the Commission is simply unaware of the full scale of the problem.

The Commission's data on detected fraud relies on reports from Member States to the EU's Anti-Fraud Office ("OLAF"). In its annual report for 2018,[5] OLAF recounts that it opened 219 and concluded 167 investigations, resulting in 256 recommendations to competent authorities at the EU and national levels. Investigated cases ranged from cross-border collusion between contractors and beneficiaries, via schemes involving the fraudulent undervaluation of goods imported into the EU, to corruption in high-value EU tenders. Following the investigations concluded during 2018, OLAF recommended the recovery of EUR 371 million to the EU budget.

In addition to frauds on the EU budget, cross-border value added tax ("VAT") fraud causes losses estimated at EUR 50 billion per year to the budgets of the Member States and the EU.

Due to a combination of a lack of resources in law enforcement and Member States not prioritizing it, fraudulent and corrupt activities involving EU finances are often insufficiently investigated and prosecuted. In addition, resource-intensive investigations into cross-border cases are often hampered by a lack of cooperation. The EPPO intends to fill this lacuna in enforcement.

An independent EU prosecuting corps, working within the national systems

The EPPO, based in Luxembourg, will be the first supranational public prosecutor's office charged with the investigation and prosecution of white collar offences. It will be led by a European Chief Prosecutor ("ECP"), who will chair a College of 22 European Prosecutors ("EP"; one per participating Member State). The College, through Chambers of EPs, will supervise, coordinate, and direct investigations and prosecutions carried out at a decentralized level by European Delegated Prosecutors ("EDPs"). EDPs will bring cases before Member State courts, using local personnel and applying national procedures and legislation. They will have a common minimum set of investigative powers set out in the EPPO Regulation, as well as all powers available to equivalent national prosecutors.[6]

Continued on page 18

5. *See* European Anti-Fraud Office, "The OLAF report 2018," available at https://ec.europa.eu/anti-fraud/sites/antifraud/files/olaf_report_2018_en.pdf.

6. For further detail, *see* https://www.debevoise.com/insights/publications/2019/11/the-eppos-structure-and-powers.

The European Public Prosecutor's Office Prepares to Go Live

Continued from page 17

The institutional and operational independence of the EPPO as a whole is assured by strong EU law protections against administrative or political influence at both the EU and Member State levels. At the same time, the EPPO is ultimately accountable to the Court of Justice of the EU, which will have jurisdiction to issue preliminary rulings on the legality of procedural acts of the EPPO challenged before any national court. The EPPO is bound by the principles of legality, proportionality, impartiality, and fairness and must investigate objectively, pursuing both inculpatory and exculpatory lines of inquiry. It must also respect the Charter of Fundamental Rights of the European Union, which enshrines the right to a fair trial, the right to an effective defense, and the presumption of innocence, as well as the principle against double jeopardy.

"The [European Public Prosecutor's Office] thus has the potential to become a, if not the, primary white-collar enforcement body in Europe, including in relation to the bribery of public officials."

The operating costs of the central level and the salaries of EDPs will come out of the EU's budget, whereas the operational costs of investigations and proceedings at the decentralized level will be the responsibility of the participating Member States, with the possibility of assistance from the central budget.

Significant but strictly delineated jurisdiction[7]

The material jurisdiction of the EPPO is set out in the so-called "PIF Directive",[8] which provides a non-exhaustive list of what shall be regarded as fraud affecting the EU's financial interests:

- fraud relating to expenditures and revenues affecting funds or assets from the EU budget or budgets managed by the EU, or on its behalf;
- fraud relating to VAT if (i) connected with the territory of two or more Member States and (ii) worth at least EUR 10 million;
- active and passive corruption or misappropriation that affect the EU's financial interests;

Continued on page 19

7. For further detail, *see* https://www.debevoise.com/insights/publications/2019/11/the-eppos-field-of-operations.
8. Directive (EU) 2017/1371 of the European Parliament and of the Council of July 5, 2017 on the fight against fraud to the EU's financial interests by means of criminal law.

The European Public Prosecutor's Office Prepares to Go Live

Continued from page 18

- taking part in a criminal organization focused on committing crimes against the EU budget;
- the laundering of assets derived from such activities; and
- incidental offenses closely related to the aforementioned activities such as tax offenses, submission of false statements to public authorities, books-and-records violations, or breaches of trust.

Member States were obliged to introduce the corresponding offenses in their national criminal legislation. The EPPO, through the EDPs, will investigate and pursue such offenses before the courts of the Member States.

The first European Chief Prosecutor and the College of European Prosecutors

Laura Codruța Kövesi was formally appointed the first European Chief Prosecutor on October 17, 2019 for a non-renewable term of seven years. Kövesi is the former head of the Anti-Corruption Directorate of the Romanian Public Prosecutor's Office (the "DNA"). In a difficult political context, the DNA achieved significant successes, including the conviction and imprisonment of a former prime minister. Under Kövesi's stewardship, the DNA was seen as a rare bright spot in the context of general deterioration of Romania's commitment to the rule of law and, in particular, the fight against corruption. Having sought to neuter the DNA by passing amnesties and decriminalizing some forms of corruption, the Romanian government dismissed Kövesi from her post in 2018, an act subsequently ruled a violation of Kövesi's human rights by the European Court of Human Rights.[9]

Romania actively opposed Kövesi's appointment as ECP and made accusations of misrepresentation, abuse of office, and bribery against her, widely seen as an attempt to derail her nomination.[10] Kövesi's appointment was secured largely due to strong support from the European Parliament.

Earlier this summer, following a rigorous selection process, the 22 members of the College of European Prosecutors were appointed. Overall, the College consists of senior prosecutors and judicial officers with considerable experience in white collar criminal enforcement in their national jurisdictions, and many are experienced in international work.[11]

Continued on page 20

9. The judgment is available at https://hudoc.echr.coe.int/fre#{"itemid":["001-202415"]}. The European Court of Human Rights ("ECtHR") is *not* an EU institution; it is a creature of the Council of Europe. However, all EU Member States are members of the Council of Europe and EU law requires adherence to the European Convention of Human Rights enforced by the ECtHR.
10. *See* European Commission, On Progress in Romania under the Cooperation and Verification Mechanism, October 22, 2019, COM(2019) 499 final.
11. For more details, *see* https://www.debevoise.com/insights/publications/2020/07/eppo-meet-the-college-of-european-prosecutors.

The European Public Prosecutor's Office Prepares to Go Live
Continued from page 19

Impact on corporates[12]

Many corporations participate in projects and activities involving EU funding and the EU's cross-border VAT regime. Corporates can therefore expect to be an important source of reports, complaints, and evidence for the EPPO. Where possible in national law, corporate victims of fraud affecting the EU's financial interests will be able to become formal parties to proceedings. Significantly, the PIF Directive requires Member States to provide for corporate liability for fraud affecting the EU's financial interests.

For a corporate target of an EPPO investigation, deferred prosecution agreements and other non-conviction disposals will be available if they are provided for in the national law of the handling EDP. Convicted corporates will be sentenced according to national sentencing laws. However, it will be for the EPPO to establish policies and procedures on matters such as its approach to corporate suspects, victims, and witnesses and criteria that should determine jurisdiction among potentially competent national EDPs. All of these questions, and how the EPPO will interact with national corporate enforcement regimes, could be important for corporates operating within the EU.

Interaction with national, EU, and international authorities and bodies[13]

The EPPO will cooperate with the national law enforcement authorities of the participating Member States, particularly in relation to the sourcing of allegations and resolution of potential jurisdictional conflicts. The EPPO will also cooperate closely with a number of EU agencies, in particular Eurojust, OLAF, and Europol.

The EPPO will seek to establish working arrangements with law enforcement authorities in non-participating Member States, and it will be able to benefit from EU and national cooperation and MLAT arrangements with third countries and international organizations.

Outlook – EU budgetary expansion and concerns over funding

The EU Council made up of Member State heads of state or government recently reached agreement on its Multiannual Financial Framework ("MFF") for 2021-2027 as well as the exceptional recovery fund to deal with the economic fallout from the current pandemic, named "Next Generation EU" ("NGEU"). Assuming the MFF and the NGEU are finally approved by the European Parliament, the EU will be able to spend in excess of EUR 1.8 trillion over the next seven years, with a focus on supporting "investment in the green and digital transitions." The EUR 750 billion NGEU alone

Continued on page 21

12. For additional detail, *see* https://www.debevoise.com/insights/publications/2019/12/the-eppo-and-corporate-enforcement.
13. For additional detail, *see* https://www.debevoise.com/insights/publications/2019/12/the-eppo-and-international-co-operation.

The European Public Prosecutor's Office Prepares to Go Live
Continued from page 20

will represent over 5% of the EU's annual GDP, a massive expansion of the EU's fiscal firepower and a corresponding growth in the scope of the EPPO's jurisdiction.

Not taking into account the NGEU, the EPPO projected an initial caseload of 3,000 matters, with around 2,000 cases added every year. In order for it to be able effectively to sift through the cases brought to its attention and add value to the fight against complex frauds affecting the EU's budget, the EPPO needs to be adequately funded. From a relatively tiny initial allocation of EUR 11.7 million, there are now reports of a proposal to increase the EPPO's 2020 budget to EUR 37.7 million and the number of EDPs from 32 ¼ to 140.

ECP Kövesi has been outspoken about her view that the funding is still inadequate[14] and relevant comparisons lend credibility to this claim. OLAF, which has been allocated approximately EUR 61 million for 2020 and has some 335 staff, has a caseload roughly half of that expected at the EPPO and does not have the responsibility of preparing cases for and bringing them to trial. The UK's Serious Fraud Office is widely seen to be underperforming considerably with an annual budget of approximately GBP 60 million (EUR 66 million) and a selective caseload of 65.[15]

The EPPO has the potential to become a significant enforcer against sophisticated white collar criminality affecting the EU's financial interests. However, there is a clear risk that that the scale of the budget currently envisioned for the EPPO will be inadequate for it to be effective in protecting the EU's financial interests from often sophisticated frauds perpetrated by criminal organizations, corrupt public officials, and increasingly sophisticated money laundering schemes. Nevertheless, given the background and experience of its newly appointed leadership, it is reasonable to expect the nascent EU prosecutor to approach its mandate with ambition and vigor.

Karolos Seeger

Jane Shvets

Alexandre Bisch

Robin Lööf

Friedrich Popp

Karolos Seeger is a partner in the London office. Jane Shvets is a partner in the New York office. Alexandre Bisch is an international counsel in the Paris office. Robin Lööf is an international counsel in the London and Paris offices. Dr. Friedrich Popp is an associate in the Frankfurt office. Full contact details for each author are available at www.debevoise.com.

14. *See, e.g.*, Jennifer Rankin, "'The law is equal for everyone': Laura Codruţa Kövesi, Europe's first public prosecutor," *The Guardian* (Aug. 3, 2020), available at https://www.theguardian.com/world/2020/aug/03/laura-codrua-kovesi-europe-first-public-prosecutor-romania.

15. *See* Serious Fraud Office, "Annual Report and Accounts, 2019-2020," available at https://www.sfo.gov.uk/publications/corporate-information/annual-reports-accounts/.

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

Andreas A. Glimenakis
Associate Editor
+1 202 383 8138
aaglimen@debevoise.com

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

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