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Growth Opportunities Come With Danger: As Japanese Life Sciences Companies' Outward Bound Investments Continue to Grow, So Do the Significant Compliance and Enforcement Risks



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The global pharmaceutical and life sciences sector is growing at a record pace—thanks in no small part to the contributions of Japanese multinationals, which year after year continue not only to sustain Japan as the second largest pharmaceutical market in the world, but also to invest billions of dollars in acquisitions, mergers, and joint ventures in foreign markets. However, following the landmark \$646 million settlement between Olympus Corporation of the Americas—a subsidiary of Japanese medical device company Olympus Corp.—and the U.S. Department of Justice in March 2016, it has become increasingly clear that in order to take full advantage of growth in the life sciences sector, Japanese multinationals must move quickly to take a more proactive approach to assessing and managing anti-corruption and other compliance risks with

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respect to their overseas operations, or the news could well go from good to bad.

Growth Opportunities: Continued Outflow of Japanese Life Sciences Foreign Direct Investment

The good news for Japanese multinationals is that there continues to be a strong and growing outflow of foreign direct investment (“FDI”) from Japan’s life sciences sector and the country in general. Specifically, in 2015, Japanese FDI outflows increased by 13 percent to \$129 billion, making Japan the third largest source of FDI outflows that year,¹ behind only the U.S. and China, with much of these flows driven by outward mergers and acquisitions (“M&A”) activity, which exceeded \$82 billion for the first time.² Of those outflows, \$8.3 billion came from Japanese multinationals in the chemical and pharmaceutical manufacturing industry, up from \$5.9 billion the previous year.³ Such investments can bring tremendous benefits and growth to

¹ *FDI in Figures April 2016*, ORG. FOR ECON. CO-OPERATION & DEV., at 3, 5 (April 2016), available at <http://www.oecd.org/corporate/FDI-in-Figures-April-2016.pdf>.

² *Japanese Outbound M&A*, FINANCIER WORLDWIDE (April 2016), available at <http://www.financierworldwide.com/japanese-outbound-ma-apr16/#.WA0H35wri2w>.

³ *Balance of Payments, Direct Investment by Region and Industry, Direct Investment Flows, 2014 C.Y.*, BANK OF JAPAN (May 12, 2016), available at http://www.boj.or.jp/en/statistics/br/bop_06/index.htm/#p0103; *Balance of Payments, Direct Investment by Region and Industry, Direct Investment Flows,*

Japanese multinationals, as outward FDI can improve a company's productivity, revenues, market share, and technological capabilities, all of which can support domestic expansion in Japan.

The upward trend in Japanese FDI outflows in the life sciences sector has been the norm for some time. At \$94 billion, Japan's life sciences sector is the second largest in the world,⁴ but a number of domestic factors, including Japan's biennial, mandated pharmaceutical price cuts, have caused Japan's pharmaceutical companies to look outward for growth and acquisition opportunities over the last decade.⁵ Thus, from 2006 to 2013, the number of overseas subsidiaries owned by Japanese health-care companies increased from 297 to 371.⁶ Additionally, in 2013, Japan's top pharmaceutical companies derived approximately half their revenue from foreign markets.⁷ Significant outbound M&A activity only continued in 2015 with, for example, Otsuka Pharmaceuticals' \$3.5 billion acquisition of Avanir Pharmaceuticals, a California-based company,⁸ and such activity is likely to continue into the foreseeable future, as several of Japan's largest pharmaceutical companies have recently earmarked billions of dollars for overseas acquisitions.

The Danger: Compliance and Enforcement Risks Are Also Growing

However, with the positives associated with Japan's life sciences sector standing at second in the world for the time being, and its continued outward bound investment, comes the increasing anti-corruption and other compliance and enforcement risks attendant with doing business in a few of Japan's top FDI destinations: The U.S., China, and the Association of Southeast Asian Nations ("ASEAN"). These compliance and enforcement risks are significant, and demand that Japanese multinational companies be suitably prepared to deal with them.

The U.S.—The Longtime Home for Compliance Risks and Government Enforcement

In 2015, Japanese companies invested \$44.8 billion in the U.S., more than any other country by an astounding \$30 billion.⁹ With North America having 48.7 percent

market share in the global pharmaceutical market,¹⁰ it should be unsurprising that \$7.1 billion of Japan's FDI into North America last year occurred in the chemicals and pharmaceuticals industry, up from \$1.4 billion the previous year.¹¹ Yet, for Japanese multinationals operating in this space, it is extremely important to be conscious of the significant resources that the U.S. government devotes to investigating and prosecuting fraud, waste, and abuse in connection with the health-care system. Additionally, although U.S. authorities have actively investigated and brought actions against Japanese multinationals in the electronics and auto sectors for more than a decade, *Olympus* now makes it more clear than ever that Japanese multinationals in the life sciences sector are also at risk of U.S. government enforcement and investigation.

Over the last decade, the U.S. government has invested significant resources in fighting federal health-care fraud, including by creating the Health Care Fraud Prevention and Enforcement Team (HEAT) in May 2009.¹² These efforts have been largely successful, as from 2009 to 2015, the DOJ recovered \$26.4 billion in False Claims Act ("FCA") settlements, and approximately 62.5 percent of that figure derives from the health-care industry alone.¹³ The U.S. government is not skimping when it comes to combatting fraud abroad either under the Foreign Corrupt Practices Act ("FCPA"). In January 2015, the FBI made plans to more than triple the number of agents dedicated to dealing with "overseas bribery,"¹⁴ and on April 16, 2016, the DOJ announced that it was adding 10 more prosecutors to the Fraud Section's FCPA Unit. Given these dedicated resources, more investigations and enforcement in the U.S. and abroad can be expected.

Olympus' record-setting settlement demonstrates that the cost of noncompliance can be extremely high for Japanese multinationals that face enforcement actions, both on the FCPA and U.S. health-care fronts. As outlined in our client alert dated March 21, 2016, available here, *Olympus* involved allegations that OCA engaged in a scheme to pay U.S. health-care providers with various items of value to induce or reward pur-

and Region, Historical Data, JAPAN EXTERNAL TRADE ORG. (2015) ("JETRO FDI Flows by Country"), available at <https://www.jetro.go.jp/en/reports/statistics/>.

¹⁰ *The Pharmaceutical Industry in Figures 2016*, at 14, EUROPEAN FED'N OF PHARM. INDUS. & ASS'N, available at <http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>.

¹¹ *Balance of Payments, Direct Investment by Region and Industry, Direct Investment Flows, 2014 C.Y.*, BANK OF JAPAN (May 12, 2016), available at http://www.boj.or.jp/en/statistics/br/bop_06/index.htm/#p0103; *Balance of Payments, Direct Investment by Region and Industry, Direct Investment Flows, 2015 C.Y.*, BANK OF JAPAN (Apr. 8, 2016), available at http://www.boj.or.jp/en/statistics/br/bop_06/index.htm/#p0103.

¹² *Health Care Fraud Unit Overview*, U.S. DEP'T OF JUSTICE, available at <https://www.justice.gov/criminal-fraud/health-care-fraud-unit>.

¹³ *Justice Department Recovers Over \$3.5 Billion From False Claims Act Cases in Fiscal Year 2015*, U.S. DEP'T OF JUSTICE (Dec. 3, 2015), available at <https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015>.

¹⁴ Joel Schectman, *FBI To Bulk Up Foreign Bribery Efforts*, WALL ST. J. (Jan. 14, 2015), available at <http://blogs.wsj.com/riskandcompliance/2015/01/14/fbi-to-bulk-up-foreign-bribery-efforts/>.

2015 C.Y., BANK OF JAPAN (April 8, 2016), available at http://www.boj.or.jp/en/statistics/br/bop_06/index.htm/#p0103.

⁴ *Pharmaceutical and Life Sciences Deals Insights Quarterly Q1 2015*, PwC, (May 2015), available at <https://www.pwc.com/us/en/health-industries/pharma-life-sciences/publications/assets/pwc-health-services-deals-insights-q1-2015.pdf>.

⁵ *Biennial Drug Price Cuts Show No Sign of Holding Back the Japanese Market*, EVALUATE (March 11, 2015); available at <https://www.evaluategroup.com/Universal/View.aspx?type=Story&id=562562§ionID=&isEPVantage=yes>.

⁶ *Data Book 2015*, JAPANESE PHARM. MFRS. ASSOC., at 22 (2015) ("JPMA Databook"), available at http://www.jpma.or.jp/about/issue/gratis/databook/pdf/databook2015_eng.pdf.

⁷ JPMA Data Book at 16.

⁸ *Otsuka Pharmaceutical Completes Acquisition of Avanir Pharmaceuticals*, EVALUATE (Jan. 30, 2015), available at <http://www.evaluategroup.com/Universal/View.aspx?type=Story&id=552431>.

⁹ *Japan's Outward and Inward Foreign Direct Investment, FDI Flows (Based on Balance of Payments, Net), By Country*

chases of its products, including by awarding hundreds of thousands of dollars in grants to hospitals that agreed to purchase OCA's products, in violation of the Anti-Kickback Statute ("AKS") and the FCA. In addition, OCA's subsidiary, Olympus Latin America ("OLA"), engaged in a similar scheme to induce or reward purchases of products by publicly-employed health-care providers in Latin America, including by providing lavish meals and elaborate parties for key decision makers. To settle these allegations, OCA agreed to pay \$623.2 million in criminal penalties and civil fines, the largest AKS and medical device company settlement in U.S. history, while OLA agreed to pay \$22.8 million.¹⁵ Both companies entered into separate deferred prosecution agreements that impose disclosure, compliance enhancement, monitoring, and testing requirements, and OCA entered into a corporate integrity agreement that imposes similar requirements for a period of five years.¹⁶

Notably, *Olympus* had an increasingly familiar start in the U.S.: a compliance corporate insider turned whistleblower filing a *qui tam* action and, in return, receiving a hefty award from the government—\$51 million to be exact.¹⁷ This genesis underscores three notable whistleblower trends of which Japanese multinationals operating in the U.S. should be aware. First, corporate insiders turned whistleblowers are increasingly receiving some of the largest awards, both under the FCA and other U.S. federal laws, when it would be extremely difficult for the government to uncover wrongdoing without insider assistance. For instance, in September 2014, the SEC awarded \$30 million under the Dodd-Frank Whistleblower Program to a corporate insider, who went to the SEC "with information about an on-going fraud that would have been very difficult to detect." Similarly, in April 2016, the SEC awarded \$22 million to another corporate insider whose tips helped uncover a "well-hidden fraud." Second, *Olympus* also highlights that U.S. authorities are increasingly providing whistleblower awards to corporate insiders who perform compliance functions. The first whistleblower award to go to a compliance corporate insider occurred in August 2014, when the SEC awarded more than \$300,000 to a corporate insider who served a compliance and auditing function.¹⁸ Then, in April 2015, the

¹⁵ *Medical Equipment Company Will Pay \$646 Million for Making Illegal Payments to Doctors and Hospitals in United States and Latin America*, U.S. DEP'T OF JUSTICE (Mar. 1, 2016), available at <https://www.justice.gov/opa/pr/medical-equipment-company-will-pay-646-million-making-illegal-payments-doctors-and-hospitals>.

¹⁶ *Id.*

¹⁷ By way of background, under the FCA's *qui tam* provisions, individuals who file suits for violations of the FCA on behalf of the government are eligible to receive up to 30 percent of the recovery. 31 U.S.C. § 3730(d)(1). These provisions have proven rather successful, as from 2009 to 2015 the U.S. government has awarded *qui tam* relators \$3 billion and most FCA actions today begin with a *qui tam* action. *Justice Department Recovers Over \$3.5 Billion From False Claims Act Cases in Fiscal Year 2015*, U.S. DEP'T OF JUSTICE (Dec. 3, 2015), available at <https://www.justice.gov/opa/pr/justice-department-recovers-over-35-billion-false-claims-act-cases-fiscal-year-2015>.

¹⁸ *SEC Announces \$300,000 Whistleblower Award to Audit and Compliance Professional Who Reported Company's Wrongdoing*, U.S. SEC. AND EXCH. COMM'N (Aug. 29, 2014), available at <https://www.sec.gov/News/PressRelease/Detail/PressRelease/1370542799812>.

SEC again awarded more than \$1 million to a prosecuted company's compliance officer turned whistleblower.¹⁹ *Olympus* itself involved OCA's chief compliance officer reporting OCA's wrongdoing to the government after OCA allegedly terminated him for attempting to cure OCA's and its subsidiaries' compliance deficiencies.²⁰ Lastly, in May 2015 the SEC awarded its first-ever FCPA-related whistleblower award—\$3.5 million—to an insider whistleblower for providing the SEC with detailed information about alleged bribery of Asian and African officials in connection with the 2008 Beijing Olympics.²¹

Making matters even more challenging, Japanese multinationals must also worry about their dealings with copromotion and other business partners in the U.S., and the array of potential whistleblowers ready to go to the government. In September 2007, for example, Bristol-Myers Squibb ("BMS") and its wholly owned subsidiary, Apothecon, Inc., agreed to pay over \$515 million to resolve a broad array of civil allegations involving their drug marketing and pricing practices around Abilify, a blockbuster atypical antipsychotic drug that Otsuka Pharmaceuticals ("Otsuka") had developed in Japan, but co-promoted with BMS in the U.S.²² Six months later, in March 2008, Otsuka itself paid \$4 million to settle related government and whistleblower allegations regarding its own sales representatives who worked on sales teams led primarily by BMS sales managers.²³ Beyond the relatively small settlement, though, Otsuka had to operate the ensuing five years under an unwelcome Corporate Integrity Agreement.

It is also worth noting that the U.S. government is increasingly focused on individual corporate wrongdoers in the context of corporate investigations, but this effort has proven to be challenging. On Oct. 29, 2015, the U.S. Attorney's Office for the District of Massachusetts announced the indictment of former Warner Chilcott President W. Carl Reichel, charging him with conspiracy to violate the AKS following Warner Chilcott's agreement to "pay \$125 million to resolve its criminal and civil liability arising from the company's illegal marketing of certain drugs."²⁴ The indictment detailed his alleged involvement in a scheme to pay kickbacks in

¹⁹ *SEC Announces Million-Dollar Award to Compliance Officer*, U.S. SEC. AND EXCH. COMM'N (April 22, 2015), available at <http://www.sec.gov/news/pressrelease/2015-73.html>.

²⁰ *United States ex rel v. Olympus America, Inc., Second Amended Complaint*, ¶¶ 178-193 (D.N.J. Feb. 4, 2016), available at <http://www.taf.org/SLOWIK-OLYMPUS-SAC.pdf>.

²¹ Andrews Kurth, *The SEC Remains Active with Whistleblowers*, NATIONAL LAW REVIEW (Sept. 16, 2016), available at <http://www.natlawreview.com/article/sec-remains-active-whistleblowers>.

²² *Bristol-Myers Squibb to Pay More Than \$515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing*, U.S. DEP'T OF JUSTICE (Sept. 27, 2008), available at https://www.justice.gov/archive/opa/pr/2007/September/07_civ_782.html.

²³ *Otsuka to Pay More than \$4 Million to Resolve off-label Marketing Allegations Involving Abilify*, U.S. DEP'T OF JUSTICE (March 27, 2008), available at https://www.justice.gov/archive/opa/pr/2008/March/08_civ_244.html.

²⁴ *Warner Chilcott Agrees to Plead Guilty to Health Care Fraud Scheme and Pay \$125 Million*, U.S. DEP'T OF JUSTICE (Oct. 29, 2015), available at <https://www.justice.gov/usao-ma/pr/warner-chilcott-agrees-plead-guilty-health-care-fraud-scheme-and-pay-125-million>.

the form of speaker fees, dinners, and other remuneration, to doctors in exchange for their prescription of Warner Chilcott drugs. Although acquitted of the charges, Reichel faced up to five years in prison and mandatory exclusion from federal health care benefit programs.²⁵ Additionally, U.S. authorities have also struggled to prosecute foreign nationals suspected of violating U.S. law due to territorial jurisdictional challenges. The primary example is the DOJ's 2010-2015 auto-parts cartel investigation. There, the DOJ successfully prosecuted a number of companies for price-fixing and bid-rigging in the auto-parts industry, but the DOJ's prosecution of 52 foreign nationals charged in connection with the wrongdoing has been less successful. Specifically, of the 52 foreign nationals charged, 22 cases remain unresolved because the individuals—all Japanese nationals—refuse to plead guilty or come to the U.S. to appear in court,²⁶ and historically the U.S. has had immense trouble securing extradition of Japanese individuals from Japan. Despite these challenges, however, the U.S. government has repeatedly stressed its commitment to prosecuting individuals for corporate wrongdoing, and thus increasingly successful enforcement actions against individuals can be expected.

China—Japan's Neighbor With Ever-Increasing Economic Opportunity and Compliance Risks

China has long been a major destination of Japanese FDI, and 2015 was no different, with Japanese entities investing \$8.8 billion in China last year.²⁷ Although FDI into China has decreased somewhat in recent years in favor of ASEAN,²⁸ many Japanese pharmaceutical and medical device companies, including Japan's largest pharmaceutical companies, already have significant operations and subsidiaries in China.²⁹ Additionally, the market continues to present some of the best growth opportunities to be found anywhere in the life sciences sector. Yet, for Japanese life sciences companies to take full advantage of China's growing pharmaceutical and medical device markets, it is important to be mindful of the increasing risk of enforcement in China from the U.S. government, the Chinese authorities themselves, and maybe the Japanese.

It is not uncommon for multinationals operating in China to be subject to FCPA enforcement actions and investigations based on operations there, but a review of the current year's FCPA enforcement actions shows that the risk of FCPA compliance liability in China is at an all-time high, including for life sciences companies. Since Jan. 1, 2016, Chinese officials have been involved in 11 of the 22 FCPA corporate enforcement actions brought to date, with four of these actions occurring in

²⁵ *Id.*

²⁶ *Division Update Spring 2015*, U.S. DEP'T OF JUSTICE (ANTI-TRUST DIV.), available at <https://www.justice.gov/atr/division-update/2015/criminal-program-update>.

²⁷ JETRO FDI Flows by Country.

²⁸ Keiko Ujikane, *Japan Shifts Investment from China to Southeast Asia*, BLOOMBERG (May 30, 2016), available at <http://www.bloomberg.com/news/articles/2016-05-30/southeast-asia-is-winning-more-japanese-investment-than-china>.

²⁹ JPMA Data book at 23 (noting that 47 Japanese pharmaceutical companies have subsidiaries in China, more than any other country save the U.S.)

China's life sciences sector.³⁰ In contrast, in both 2014 and 2015, there were only two FCPA enforcement actions involving China, although included were such notables as Bristol-Myers Squibb, Mead Johnson Nutrition, and Novartis. Additionally, one has to go back to 2012 to find the last time that the U.S. government brought four FCPA enforcement actions against life sciences companies in a single year, and China was involved in only three of these actions along with a diverse array of other countries.³¹

In addition to rising FCPA compliance risks, Japanese multinationals operating in China's life sciences sector also face an increasing risk of investigation and prosecution under China's anti-bribery laws. China's prohibitions against private sector bribery (i.e. bribes given to induce the selling or purchasing of merchandise)³² and public sector bribery (i.e. bribing incumbent or former state personnel to induce a benefit or assistance to obtain a benefit)³³ are nothing new, but enforcement by Chinese authorities has historically been sparse and focused, if at all, on the recipients of bribes.³⁴ However, ever since President Xi Jinping took office in 2013 and vowed to ramp up anti-corruption efforts, there have been a series of unprecedented investigations by Chinese authorities of pharmaceutical multinationals for possible bribe-giving and price-fixing.³⁵ Additionally, in 2015 China strengthened its anti-corruption laws and enforcement measures considerably, including by amending the law to make it more difficult for bribe-givers to evade punishment and launching an app-based whistleblower program that allows whistleblowers to instantly report graft to the Central Committee for Discipline and Inspection by uploading videos, photos, and/or written details of the corruption observed.³⁶

Increased enforcement risks related to business in China have not been limited to U.S. and Chinese authorities. In September 2013, Japanese authorities arrested an executive of a Japanese automobile parts supplier for bribing Chinese officials to overlook irregularities at the company's China subsidiary.³⁷ Specifically, the Japanese executive was arrested for providing a

³⁰ *SEC Enforcement Actions: FCPA Cases*, U.S. SEC. & EXCH. COMM'N, available at <https://www.sec.gov/spotlight/fcpa/fcpa-cases.shtml>.

³¹ *Id.*

³² Anti-Unfair Competition Law of the People's Republic of China, Ch. 1, Art. 8, available at <http://en.chinacourt.org/public/detail.php?id=3306>.

³³ Criminal Law of the People's Republic of China, Ch. 8, Art. 389, available at <http://www.asianlii.org/cn/legis/cen/laws/clotproc361/>.

³⁴ Daniel C.K. Chow, *Why China's Crackdown on Commercial Bribery Threatens U.S. Multinational Companies Doing Business in China*, ARIZ. J. OF INT'L & COMP. L., at 512 (2014), available at <http://arizonajournal.org/wp-content/uploads/2015/09/1-Chow1.pdf>.

³⁵ *China Cracks Down on Foreign Pharmaceutical Companies for Price Fixing*, THINK ADVISOR (Aug. 1, 2013), available at <http://www.thinkadvisor.com/2013/08/01/china-cracks-down-on-foreign-pharmaceutical-compan>.

³⁶ *China Upgrades Anti-Graft App so Whistleblower Can Send Images of Officials Caught Red-Handed*, SOUTH CHINA MORNING POST (Jun. 19, 2015), available at <http://www.scmp.com/tech/apps-gaming/article/1823789/china-upgrades-anti-graft-app-so-whistleblowers-can-send-images>.

³⁷ Manabu Ito & Rosemary Marandi, *Asian Governments Get Tough on Corruption*, NIKKEI (July 28, 2015), available at

Chinese official with \$4,500 and a \$1,500 handbag in exchange for a lenient fine rather than a work suspension order. A Japanese court found the executive guilty of violating Japan's Unfair Competition Law in October 2013 and fined him ¥500,000.³⁸ This is the first and only time that Japan has enforced its Unfair Competition Prevention Law for foreign bribery occurring in China, but given that Japan is under intense pressure from the OECD to dedicate more resources to the prosecution of foreign bribery,³⁹ we can expect to see similar actions in the future.

ASEAN—Will This Be the Next Hot Area of the Asian Neighborhood?

Last but not least, in 2015, \$20.24 billion of Japanese FDI outflows went to ASEAN, a figure that has been increasing for years, with the most FDI going to Thailand, Indonesia, and Singapore.⁴⁰ Admittedly, the balance of FDI outflows from Japan into ASEAN's pharmaceuticals and chemicals market dropped in 2015 to \$879 million from \$1.3 billion the previous year.⁴¹ However, considering that ASEAN pharmaceutical sales are expected to more than double by 2023 to reach \$50 billion a year,⁴² increased Japanese investments in ASEAN's health-care and pharmaceutical industries can be expected.

Yet, as Japanese multinationals in the life sciences sector take advantage of ASEAN's quickly growing economic community, it is important to remain mindful that many ASEAN nations carry a relatively high risk of corruption,⁴³ and multinationals operating in this region have not been immune to anti-corruption enforcement actions and investigations from the U.S. or Japan.

<http://asia.nikkei.com/Politics-Economy/Policy-Politics/Asian-governments-get-tough-on-corruption?page=2>.

³⁸ *Auto Exec Fined ¥500000 Over Bribes*, THE JAPAN TIMES (Oct. 4, 2013), available at <http://www.japantimes.co.jp/news/2013/10/04/national/crime-legal/auto-exec-fined-500000-over-bribes/>.

³⁹ In February 2014, the OECD, in analyzing Japan's prosecution of foreign bribery, wrote: "The Working Group on Bribery (WGB) continues to have significant concerns about the low level of foreign bribery enforcement in Japan, and notes that the media has reported numerous allegations involving Japanese companies. The WGB believes that implementation of the Anti-Bribery Convention is not given adequate priority by the Japanese authorities, including a lack of targeted resources for the purpose of detecting, investigating and prosecuting foreign bribery cases." *Japan: Follow-Up to the Phase 3 Report & Recommendations*, ORG. FOR ECON. CO-OPERATION & DEV., at 4 (Feb. 2014), available at <https://www.oecd.org/daf/anti-bribery/JapanP3WrittenFollowUpReportEN.pdf>.

⁴⁰ JETRO FDI Flows by Country.

⁴¹ *Balance of Payments, Direct Investment by Region and Industry, Direct Investment Flows, 2014 C.Y.*, BANK OF JAPAN (May 12, 2016), available at http://www.boj.or.jp/en/statistics/br/bop_06/index.htm/#p0103; *Balance of Payments, Direct Investment by Region and Industry, Direct Investment Flows, 2015 C.Y.*, BANK OF JAPAN (April 8, 2016), available at http://www.boj.or.jp/en/statistics/br/bop_06/index.htm/#p0103.

⁴² Anthony Fensom, *ASEAN: The Next Big Thing?*, ACCJ J. (August 2015), available at <https://journal.accj.or.jp/asean-the-next-big-thing/>.

⁴³ Indonesia, Thailand, Vietnam, Cambodia, Myanmar, and Laos all have a score of 38 or less on Transparency International's 2015 Corruption Perception Index. In contrast, the U.S. has a score of 76. See *Corruption Perceptions Index 2015*, TRANSPARENCY INTERNATIONAL, available at <https://www.transparency.org/cpi2015/#results-table>.

In each year since 2013, there has been at least one FCPA enforcement action involving one or more of the ASEAN nations, and 2014 alone had three FCPA enforcement actions involving improper payments to Indonesian officials.⁴⁴ For instance, a notable 2014 FCPA enforcement action involved a Japanese trading company's scheme to pay bribes to Indonesian officials to secure an energy services deal, which earned the company an \$88 million FCPA settlement, one of the largest in history.⁴⁵ Court filings related to the enforcement action revealed that the company paid bribes to not only high-ranking employees of a state-owned electricity company in Indonesia, but also a member of the Indonesian Parliament.⁴⁶ In order to conceal these bribes, the Japanese multinational enlisted the services of two consultant firms that acted as intermediaries in seeking out and providing the bribes to government officials.⁴⁷ As has been well-publicized, the vast majority of FCPA resolutions have involved improper payments by third-party intermediaries.

On the Japan front, ever since Japan began prosecuting foreign bribery under its Unfair Competition Prevention Law in 2007, three out of the four prosecutions thus far have involved bribery of officials in the Philippines or Vietnam.⁴⁸ Although the penalties in the cases were fairly modest, with one fine as low as \$1,700 in 2007 terms,⁴⁹ the fact that 75 percent of Japan's foreign bribery prosecutions involve ASEAN demonstrates that Japan, despite international criticism of its efforts to prosecute foreign bribery, is willing and able to enforce its laws with respect to corrupt payments in ASEAN.

Looking Forward: Mitigating Compliance Risks in Overseas Operations

In light of the foregoing, for Japanese multinationals in the life sciences sector to take full advantage of Japan's strong levels of outward bound investment in the U.S., ASEAN, China, and elsewhere, it is imperative that they proactively assess and manage the growing anti-corruption and other compliance risks that they face in their overseas operations. At a minimum, this requires effecting acquisition and third-party due diligence grounded in not only the FCPA but also Japan's anti-corruption laws and, if applicable, China's anti-

⁴⁴ *SEC Enforcement Actions: FCPA Cases*, U.S. SEC. & EXCH. COMM'N, available at <https://www.sec.gov/spotlight/fcpa/fcpa-cases.shtml>.

⁴⁵ See Zach Warren, *Japanese Trading Company Pays Second FCPA Penalty in Three Years*, INSIDE COUNSEL (March 20, 2014), available at <http://www.insidecounsel.com/2014/03/20/japanese-trading-company-pays-second-fcpa-penalty>.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ See *Kyudenko Exec. Under Probe for Philippine Bribes*, THE JAPAN TIMES (March 2, 2007), available at <http://www.japantimes.co.jp/news/2007/03/02/national/kyudenko-exec-under-probe-for-philippine-bribes/#.WAVfrPkrJdg>; *Tokyo District Court Convicts Former Officers of PCI in ODA Bribery*, KYODOTSUSHIN (Jan. 29, 2009) (involving bribes of Vietnamese officials); *Consultants Plead Guilty to Bribing Asian Officials*, THE JAPAN TIMES (Oct. 1, 2014) (involving bribes of officials in Vietnam, Indonesia, and Uzbekistan), available at <http://www.japantimes.co.jp/news/2014/10/01/national/crime-legal/consultants-plead-guilty-bribing-asian-officials-oda/#.WAVgAPkrJdg>.

⁴⁹ See, *Summary Prosecution of Two Kyudenko Employees—First Application of the Bribery of Foreign Public Officials*, KYODOTSUSHIN (March 16, 2007).

corruption laws as well. The DOJ and SEC have long been of the view that an acquiring entity inherits the FCPA liability of the acquired entity, and that companies can be liable for a third-party agent's FCPA violations if the company knew or should have known of the improper conduct. Whether China and Japan will pursue similar positions with their own legal regimes remains to be seen, but it is not something to be left to chance. Then, once an entity is established in the foreign market, it is imperative to quickly create and implement effective compliance programs and internal controls designed to detect and prevent violations of lo-

cal anti-corruption and other applicable laws. These efforts should be based on the risks faced by the specific entity in the specific market in which it operates, and a one-size-fits-all approach should be avoided. Lastly, periodic assessments of internal controls, monitoring efforts, and investigative strategies are essential. As demonstrated by the evolving anti-corruption laws and enforcement landscape in China, companies' risk profiles are not static across time and once fruitful tools and strategies can and do become outdated and ineffective for detecting corruption and mitigating enforcement risk.