

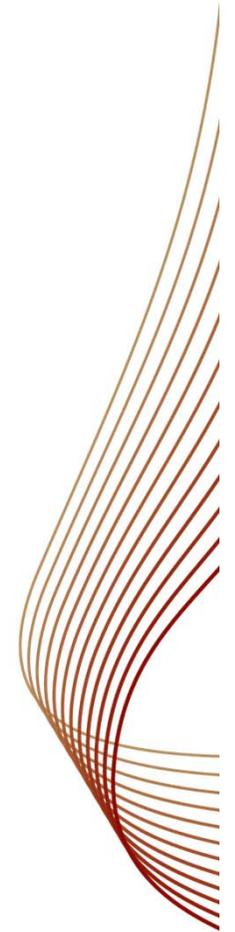
2016 Best Approaches to IP Disputes and *Compliance/Enforcement Risks in Life Sciences, Healthcare* and Technology Industries

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November 10, 2016

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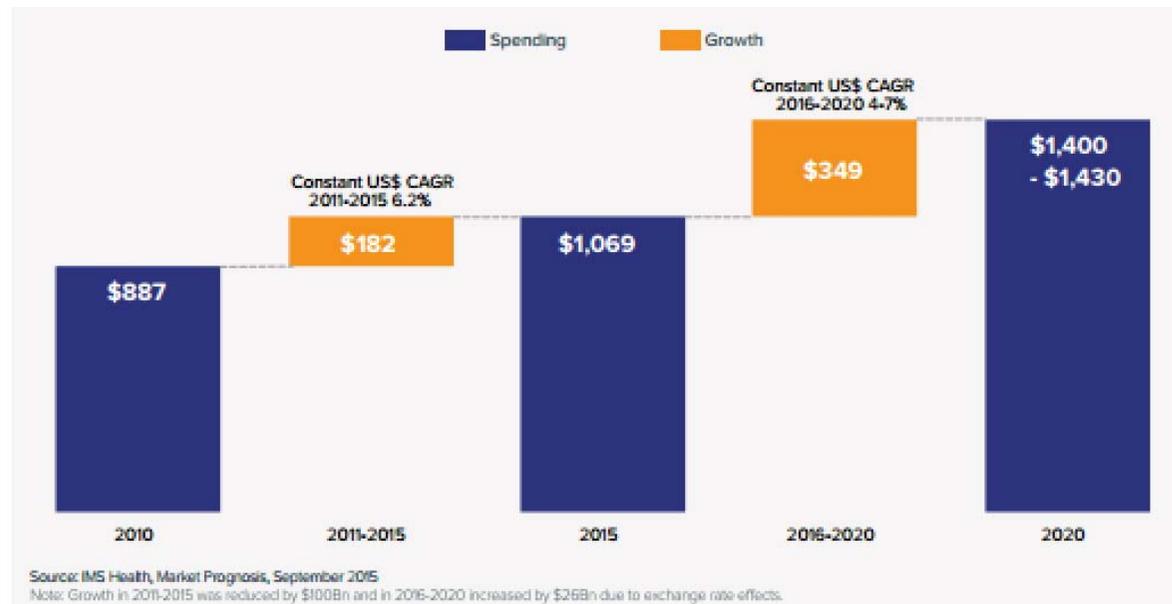
- General Business Backdrop
(Life Sciences Sector Example)
- Specific Markets And Compliance Risks
 - United States
 - China
 - ASEAN Nations
- Mitigating Compliance Risks



THE GLOBAL PHARMACEUTICAL MARKET

- The worldwide market for pharmaceuticals is projected to grow from \$1 trillion in 2015 to **\$1.3 trillion** by 2020 - International Trade Administration Life Sciences Top Markets Report (2016)
- Global drug spending is projected to increase 30% by 2020, to **\$1.4 trillion** - IMS Health, Global Spending on Medicines in 2020 Report (2015).

Global Spending and Growth, 2010-2020



THE GLOBAL PHARMACEUTICAL MARKET (CONT'D)

Global Growth, 2014-2018



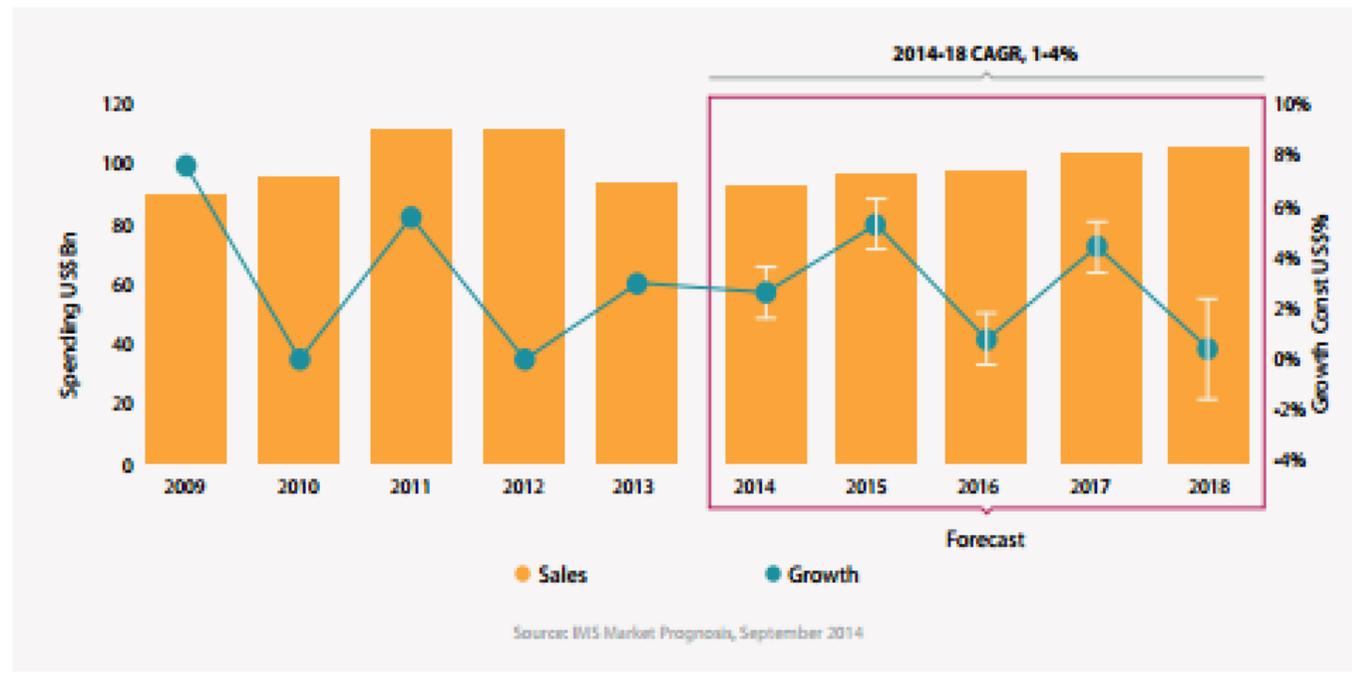
- Growth in developed markets is expected to be moderate in 2017 and 2018, and to be lower than growth in pharmerging markets
- Growth in pharmerging markets will largely be driven by China, which represents 46% of the pharmerging market
- Pharmerging: China, Brazil, Russia, India, Algeria, Argentina, Colombia, Egypt, Indonesia, Mexico, Nigeria, Pakistan, Poland, Romania, Saudi Arabia, South Africa, Thailand, Turkey, Ukraine, Venezuela, Vietnam.



JAPAN'S PHARMACEUTICAL MARKET

- At \$94 billion, Japan's pharmaceutical market is the second largest in the world, just behind the United States
- Growth in the market is expected to grow at a CAGR of 1-4% between 2014 and 2018.

Japan spending and growth, 2009-2018



OUTWARD BOUND INVESTMENTS IN JAPAN'S LIFE SCIENCES SECTOR ARE ON THE RISE

- A number of domestic factors have caused Japan's pharmaceutical companies to look outward for growth opportunities over the past decade, including:
 - **Mandated, biennial drug price cuts**
 - **Pro-generic drug government policies**
 - Aimed at doubling generic usage by 2018
 - **Modest domestic economic growth**



JAPAN REAL TIME

To Raise or Not to Raise: Japan's Drug Prices

THE WALL STREET JOURNAL

NATIONAL / SCIENCE & HEALTH

Generic drugs to be priced at 10% less from April

The Japan Times

KYODO

INTERNATIONAL JAPAN

Japan's Economy Stalls in Second Quarter, Casting Doubts on Abenomics

by Reuters AUGUST 15, 2016, 12:24 AM EST

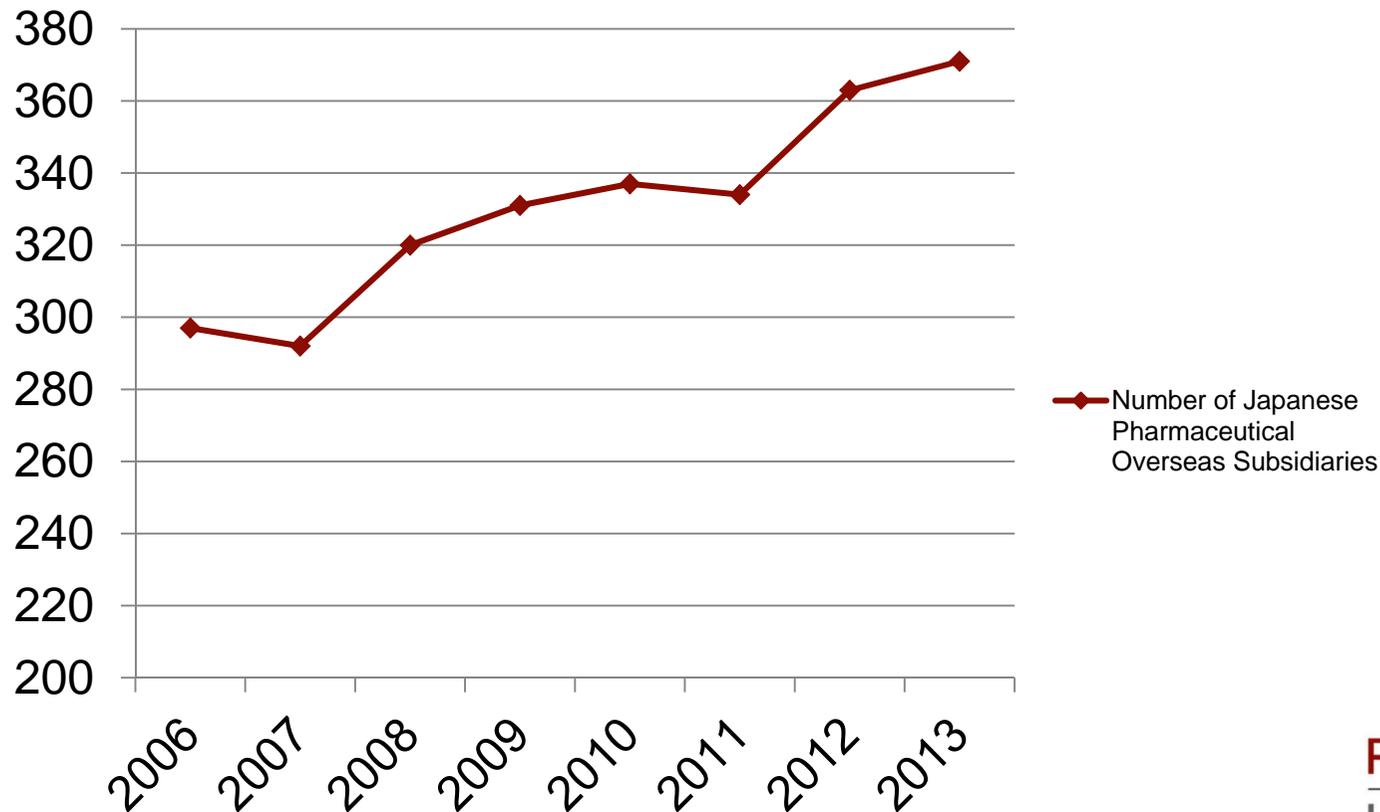
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OUTWARD BOUND INVESTMENTS IN JAPAN'S LIFE SCIENCES SECTOR ARE ON THE RISE

- From 2006 to 2013, the number of overseas subsidiaries owned by Japanese healthcare companies increased from 297 to 371.
- In 2013, Japan's top pharmaceutical companies derived approximately half their revenue from foreign markets.

Overseas Subsidiaries of Japanese Pharmaceutical Companies



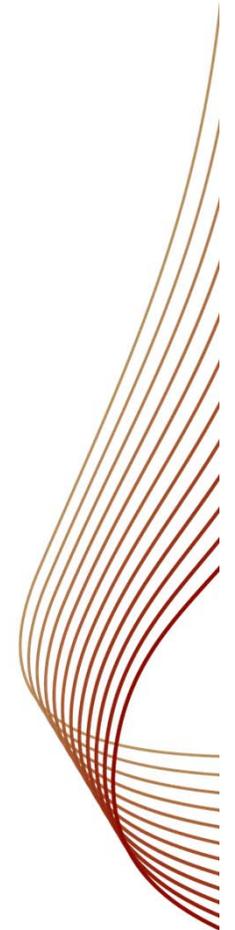
OUTWARD BOUND INVESTMENTS IN JAPAN'S LIFE SCIENCES SECTOR EXPECTED TO CONTINUE

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- In 2015, Japan's pharmaceutical and chemical industry invested **\$8.3 billion** in foreign markets, up from \$5.9 billion the previous year.
 - Example: Otsuka Pharmaceuticals acquired Vanir Pharmaceuticals for \$3.5 billion in 2015
- In 2016, some of Japan's largest pharmaceutical companies publicly announced earmarking billions of dollars for overseas acquisitions.
 - One company earmarked up to **\$15 billion** for acquisitions in the U.S.
 - Another company published a five year business plan in April that includes spending **\$4.4 billion** on M&A, either at home or abroad.



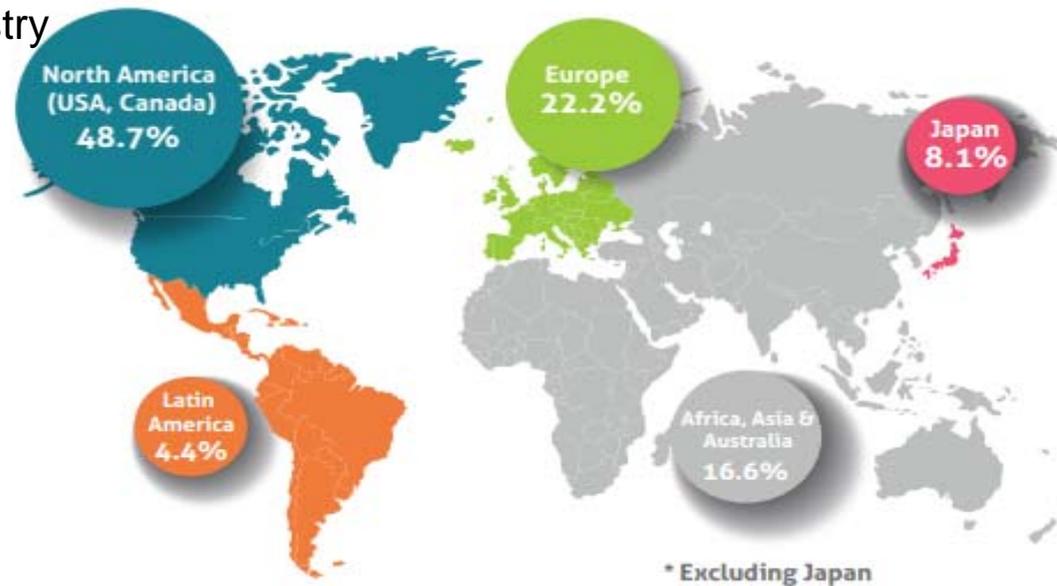
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BUSINESS BACKDROP: THE UNITED STATES

- In 2015, Japanese companies invested **\$44.8 billion** in the U.S., more than any other country by an astounding \$30 billion.
- With North America having a 48.7% share of sales in the global pharmaceutical market in 2015, it should be unsurprising that **\$7.1 billion** of Japan's FDI into North America last year occurred in the pharmaceuticals and chemicals industry, up from \$1.4 billion the previous year.

2015 Sales in Pharmaceutical Industry



Source: European Federation of Pharmaceutical Industries and Associations

U.S. ENFORCEMENT: SIGNIFICANT INVESTMENT IN RESOURCES

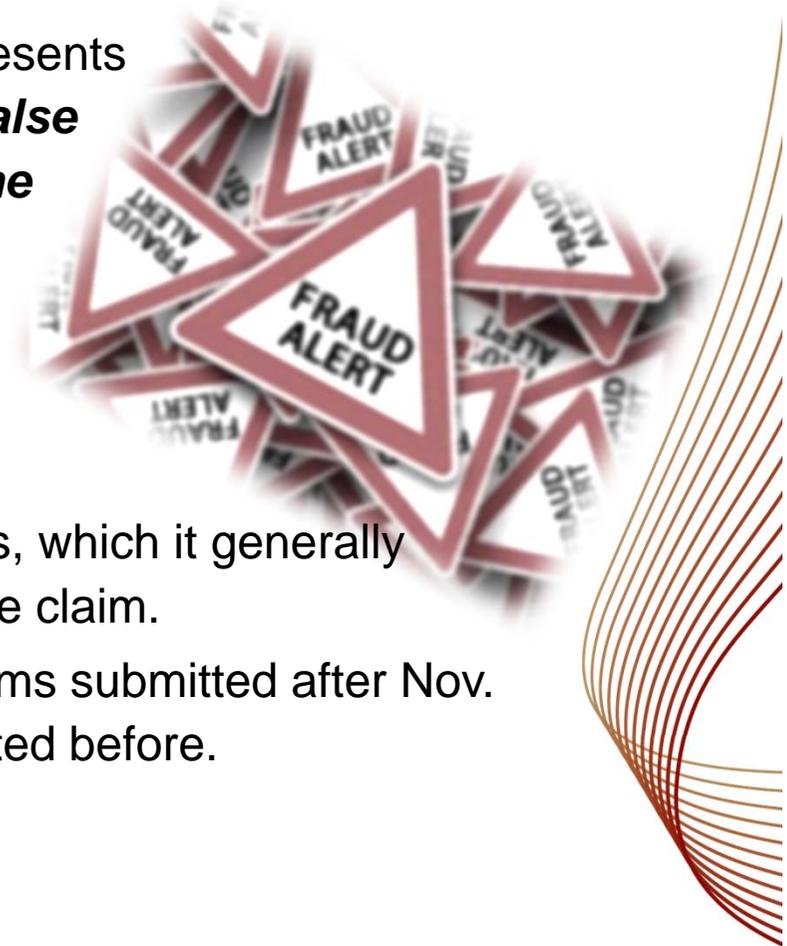
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- Combatting Fraud in the U.S.:
 - Created the Health Care Fraud Prevention and Enforcement Team (HEAT) in May 2009.
 - From 2009 to 2015, the DOJ recovered **\$26.4 billion** in False Claims Act settlements, and approximately **62.5%** of that figure derives from the healthcare industry alone.
- Combatting Fraud Abroad:
 - In January 2015, the FBI announced plans to more than **triple the number of agents** dedicated to dealing with “overseas bribery.”
 - On April 16, 2016, the DOJ announced that it was adding **10 more prosecutors** to the Fraud Section’s FCPA Unit.

FALSE CLAIMS ACT (“FCA”)

- **FCA Provisions**
 - Prohibits any person who knowingly presents or causes someone else to present ***a false or fraudulent claim for payment to the government.***
- **Scope of Liability**
 - Civil statute
- **Penalties**
 - Three times the government’s damages, which it generally contends is the full amount of each false claim.
 - A penalty of up to \$21,563 for false claims submitted after Nov. 2, 2015, and \$11,000 for claims submitted before.

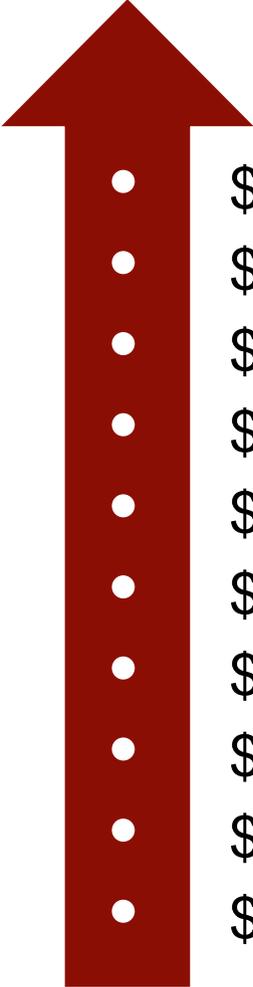


FCA: OTHER PROVISIONS

- **Qui Tam Provisions:** FCA allows private persons to bring actions on behalf of the government (relators in *qui tam* action)
 - Relators are most often former or current employees and can prosecute action if government declines
 - Incentives:
 - Government intervention: 15 – 25%
 - No government intervention: 25 – 30%
 - Plus attorney's fees
- **Anti-Retaliation Provisions:** FCA bars adverse employment actions against employee because of lawful acts “to stop” an FCA violation
 - Not limited to retaliation for filing an FCA *qui tam*
 - Can extend to retaliation for trying to remedy fraud through other means, such as internal reporting and refusal to participate in unlawful conduct
 - Relief includes reinstatement; two-times back-pay; interest; special damages; and attorney's fees



TOP 10 LARGEST U.S. HEALTHCARE WHISTLEBLOWER AWARDS

- 
- \$168M Johnson & Johnson (2013)
 - \$102M Pfizer (2009)
 - \$96M GlaxoSmithKline (2010)
 - \$95M TAP Pharmaceuticals (2001)
 - \$79M Eli Lilly (2009)
 - \$84M Abbott Labs (2012)
 - \$68M Merck (2008)
 - \$65M DaVita (2009)
 - \$52M Serrano (2005)
 - \$51M Olympus (2016)



OLYMPUS – \$646M (MARCH 2016)

- Manufactures and distributes specialized medical imaging and surgical equipment
- ***Olympus Latin America (“OLA”) provided “cash, money transfers, personal or non-Olympus medical education travel, free or heavily discounted equipment and other things of value” to HCPs working at government hospitals and clinics***
 - OLA provided such benefits to targeted HCPs through various “training centers” set up around the region
- Unlawful payments / benefits totaled around \$3M from 2006 – 2011; offenses occurred in Argentina, Brazil, Bolivia, Chile, Colombia, Costa Rica, and Mexico
- No voluntary disclosure; but DOJ noted cooperation and awarded cooperation credit
- DPA with the DOJ: \$22.8M; penalty; three-year monitorship

Settlement ***also resolved alleged violations of the AKS and FCA. . .***

OLYMPUS – \$646M (MARCH 2016) (CONTINUED)

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- **Olympus** Corporation of the Americas (“Olympus”) settled claims that it **violated** the **AKS** and **FCA** by:
 - **Paying Illegal bribes to doctors and hospitals** across U.S. **to induce purchases of products**
 - Obtaining new business and rewarding sales by **giving doctors and hospitals** kickbacks, including **consulting payments, foreign travel, lavish meals, millions of dollars in grants and free endoscopes**
- Olympus agreed to pay \$623.2M to settle AKS and FCA violations
- These resolutions combine to set two notable records:
 - **Largest total amount paid** in U.S. history **for AKS violations**
 - **Largest amount ever paid by a medical device company**
- **FCA settlement resolves** civil allegations filed in 2010 **qui tam action** by the Company’s **former Chief Compliance Officer**, as well as criminal allegations subsequently brought by the government

FOREIGN CORRUPT PRACTICES ACT (“FCPA”)

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- **Anti-Bribery Provisions:** Prohibit *directly or indirectly making, promising, or authorizing* the making of a “corrupt payment” to a “public official” to *“obtain or retain business”*
 - **Third Parties:** Payments to third parties (e.g., agents) made with knowledge that funds would be used to make a corrupt payment violate the FCPA
 - Watch payments to distributors / wholesalers, rented field force, etc.
 - Knowledge includes “willful blindness”
 - Per the Organization for Economic Cooperation and Development’s 2014 Foreign Bribery Report, **75% of FCPA cases resolved** since 1999 **involved improper payments made through third-party intermediaries**
 - **Non-cash benefits** (e.g., travel and expense, consultant contracts, grants) can be improper payments if intended to influence registration and reimbursement, placement on hospital formularies, or the writing of prescriptions that fall within “obtain or retain business”

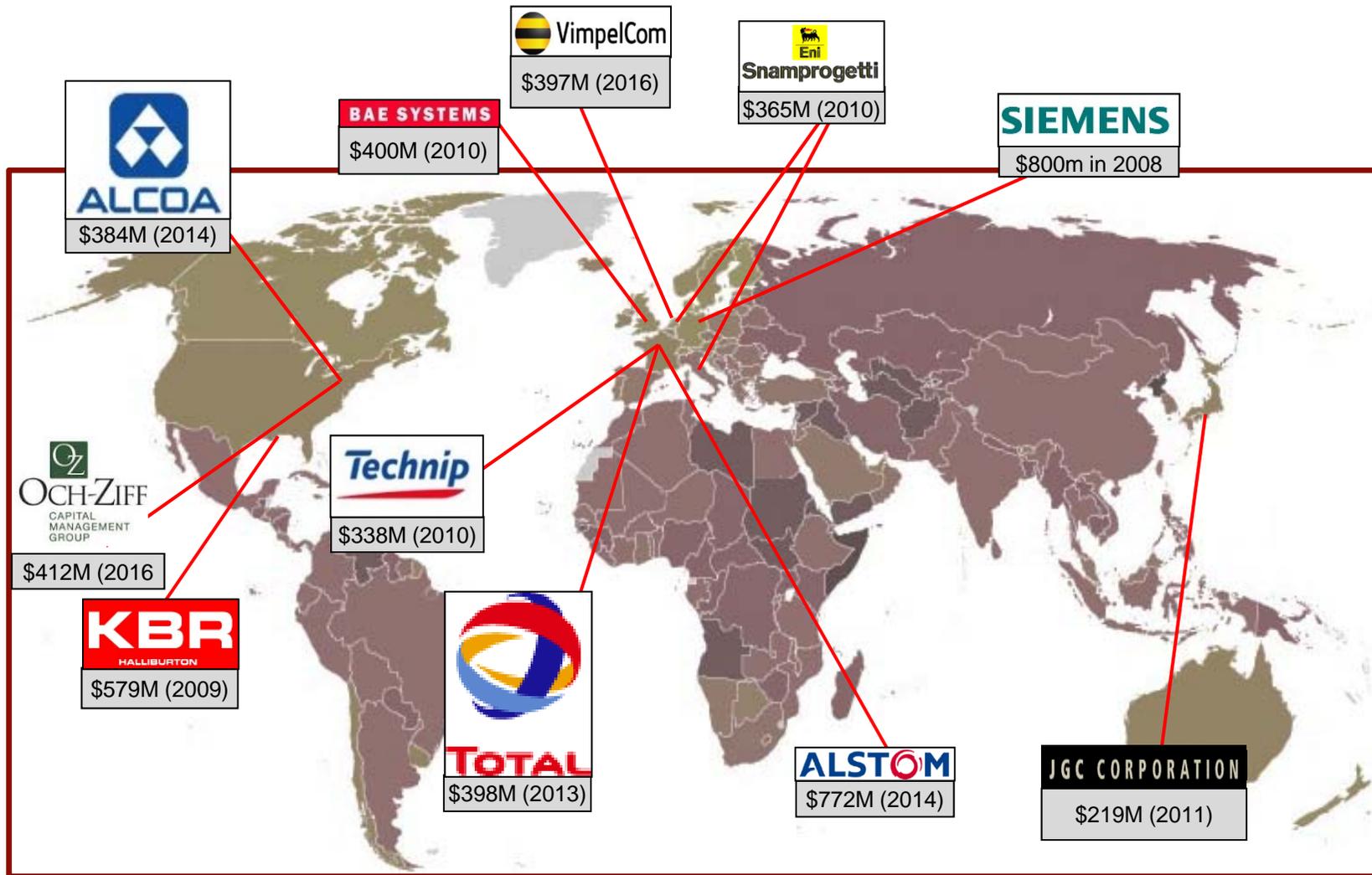
FOREIGN CORRUPT PRACTICES ACT (“FCPA”)

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- **Books & Records Provisions:** Require public companies (“issuers”) to maintain accurate books and records, and to implement accounting and financial controls
 - **Books and records** must be accurate and in “reasonable detail”
 - **Internal controls** must provide reasonable assurances that transactions are (i) executed in accordance with management authorization and (ii) recorded as necessary for preparation of financial statements in conformity with GAAP
 - **NO materiality requirement**—essentially strict liability for violations
- **Parent / Subsidiary:** Parent company may face liability for inaccurate books / records of subsidiary either based on (i) ownership; (ii) roll up of inaccurate records; or (iii) both
- **Foreign subsidiaries** generally not subject to accounting provisions
- **Ownership:**
 - If parent owns >50%, parent liability for subsidiary is likely
 - If less, parent must “proceed in good faith to use its influence”

TOP 11 FCPA RECOVERIES (8 OF 11 OUTSIDE U.S.) 19



All companies are headquartered in countries with disclosure laws and / or industry codes requiring HCP payments disclosures

BMS: \$14M SEC RESOLUTION (OCT. 2015)

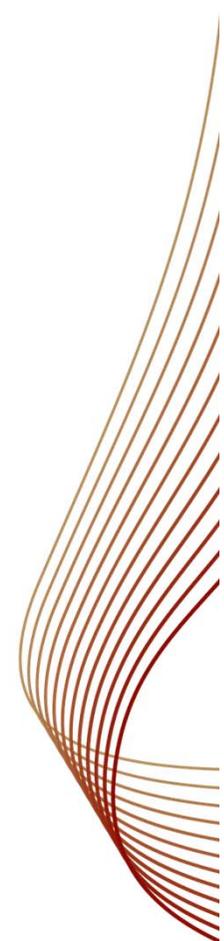
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- BMS operates *in China* primarily w/ majority-owned joint venture
 - Formed in 1982; “operational control” since 2009 (right to name President and majority of directors)
 - By 2014, 2,400 employees and \$500M in net sales in China
- SEC alleged BMS ***failed to “respond effectively to red flags”*** of “widespread practice” of improper payments at the JV
 - ***Internal and external audit reports*** provided to BMS management showing T&E concerns and “substantial” control gaps; documents “replete” with indications of non-compliant payments; admissions by BMS China employees
 - Three core failures of BMS noted: (1) ***failure to investigate allegations*** raised by employees; (2) failure to remediate control deficiencies; and (3) insufficient compliance resources
- \$11.9M disgorgement / interest, \$2.75M penalty; 2 year self-monitorship, and reasonably “quick” resolution (~3 years)
- ***DOJ declination*** (despite absence of voluntary disclosure)

NOVARTIS AG: \$25M SEC RESOLUTION (MAR. 2016)

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- **Switzerland-based** Novartis AG; **traded on NYSE**
- **Two Novartis subsidiaries in China** provided cash payments, gifts, and entertainment to Chinese HCPs and family members to boost sales
 - Subsidiary sponsored 20 Chinese HCPs to attend conference in Chicago and paid for spouses to attend, provided sightseeing / recreational activities (including excursion to Niagara Falls) and \$150 in “pocket” or “walking around” money, and paid cover charges at strip clubs
 - ~\$1K in falsified expenses to provide holiday gifts to 25 HCPs
- Cash generated via **falsified expense reports** improperly recorded as T&E, conferences, lecture fees, marketing events, educational seminars, and medical studies
- \$23M disgorgement / prejudgment interest; \$2M penalty; self-reporting obligations for two years
- To this point, all but four of the agency’s 25-plus enforcement actions since the beginning of 2014 had been resolved as administrative proceedings (not requiring court approval)



ASTRA ZENECA (AUG 2016)

- **U.K.-based** Astra Zeneca; **traded on NYSE**
- **Chinese and Russian subs** concealed improper payment to HCPs at state-owned / controlled entities and/or local GOs to incentivize purchase of and prescriptions (2005-2010)
 - **China:** Provision of maintenance fees, gifts, entertainment, cash etc. via fraudulent reimbursements, bank accounts in names of doctors, collusion with travel vendors, and fraudulent speaker programs
 - **Russia:** Employee tracking of HCPs influence, and managers involved with provision of improper incentives to government-employed HCPs
 - In 2006, SEC requested documents regarding payments to doctors and controls in **Croatia, Italy, Russia, and Slovakia**, back to 2003
- SEC Cease and Desist Order (\$4.325M disgorgement, \$822K interest, \$375K civil penalty)
- No voluntary disclosure
- Minimal penalty based on prompt “cooperative posture,” **and** remedial efforts, **including “significant increase” in compliance resources**; overhaul of internal controls, training, and audits
- DOJ inquiry initially disclosed; no indicator of formal resolution

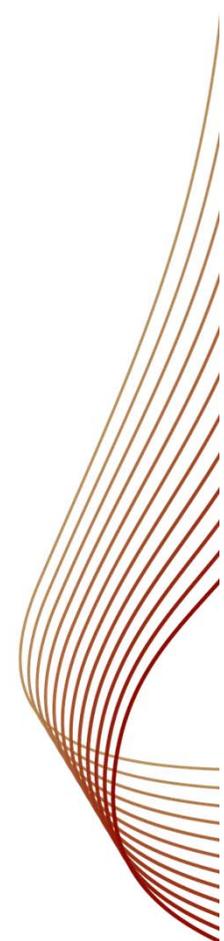
GLAXOSMITHKLINE (SEPT 2016)

23

- **U.K.-based** GlaxoSmithKline (“GAS”); **traded on NYSE**
- From at least 2010 to June 2013, **GlaxoSmithKline (China)** Investment Co Ltd and Sino-American Tianjin Smith Kline & French Laboratories Ltd, **a public-private joint venture** (GAS' indirectly owns 55 percent) made improper payments
 - Improper payments took varied forms, including gifts, improper travel and entertainment with no or little educational purpose, shopping excursions, family and home visits, **and cash**
 - **Similar improper conduct occurred in other countries**
 - Local internal audit and compliance reviews **identified controls deficiencies and improper payment mechanisms**, but were treated as isolated instances rather than signs of larger problems
- SEC Cease and Desist Order and \$20M civil penalty
- Remediation included global changes to its business (ex. elimination of most HCP payments, such as speaker program fees, **and sales force compensation structure changes**)

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INTERNATIONAL CRITICISM OF JAPANESE PROSECUTION OF FOREIGN BRIBERY

- Since 2002, the OECD's Working Group on Bribery ("WEB") has been monitoring Japan's implementation of the Anti-Bribery Convention.
- In the latest 2014 report, the WEB continued its criticism:
 - *"The WEB 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 2014 WEB report noted the following deficiencies:
 - ***Laundering the proceeds of foreign bribery is not a crime*** in Japan;
 - Japanese government has ***no authority to confiscate the proceeds of foreign bribery***;
 - There is ***a lack of targeted resources*** for detecting, investigating, and prosecuting foreign bribery cases;
 - There is ***a lack of guidelines to refer foreign bribery tips to law enforcement authorities***.
- In 2015, Transparency International echoed the Webb's concerns, noting that Japan had "little or no enforcement."



- General Business Backdrop
(Life Sciences Sector Example)
- Specific Markets And Compliance Risks
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BUSINESS BACKDROP: CHINA

- 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
- While growth of the Chinese pharmaceutical market is expected to be slower than earlier in the decade, it is expected to be at or above GDP growth through 2020.



CHINA AND FCPA ENFORCEMENT ACTIONS IN 2016

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- Since January 1, 2016, Chinese officials have been involved in 11 of the 22 FCPA corporate enforcement actions
- Below, each enforcement action involving alleged misconduct in China has been **emboldened**
 - SAP SE (2/1/16)
 - **Cyclone Pharmaceuticals** (2/4/16)
 - **PTC** (2/16/16)
 - VimpelCom (2/18/16)
 - **Qualcomm** (3/1/16)
 - Olympus (3/3/16)
 - **Nordion Inc.** (3/3/16)
 - **Novartis AG** (3/23/16)
 - **Las Vegas Sands** (4/7/16)
 - Nortek (6/7/16)
 - **Akamai Technologies** (6/7/16)
 - Analogic Corp. (6/21/16)
 - **Johnson Controls** (7/11/16)
 - LAN Airlines (7/25/16)
 - Key Energy Services (8/11/16)
 - **AstraZeneca** (8/30/16)
 - **Nu Skin Enterprises** (9/20/16)
 - Anheuser-Busch InBev (9/28/16)
 - OZ Africa (9/29/16)
 - Och-Ziff Capital Management (9/29/16)
 - **GlaxoSmithKline** (9/30/16)
 - Embraer (10/24/16)



CHINA: DEVELOPMENTS IN THE LAW

- Commercial and official bribery have been outlawed in China since 1979, during the post-Mao era.
- In 2011, China outlawed foreign bribery and bribery of officials of international public organizations.
- In August 2015, China further strengthened the country's anti-corruption laws with amendments that:
 - *make it more difficult for bribe-givers to escape punishment,*
 - *decrease mitigating factors for bribery offenses, and*
 - *increase the severity of punishments for such offenses.*



Increasing focus on corruption?

“Xi, who became president last year, is trying to unwind a culture of bribery and graft that has hurt the government’s legitimacy and jeopardized economic growth.... The crackdown comes as Xi moves to consolidate his power. He heads a newly created national security commission, a new group to craft national strategies on Internet security and an economic reform group that met for the first time this year.” – Bloomberg News, Mar. 4, 2014

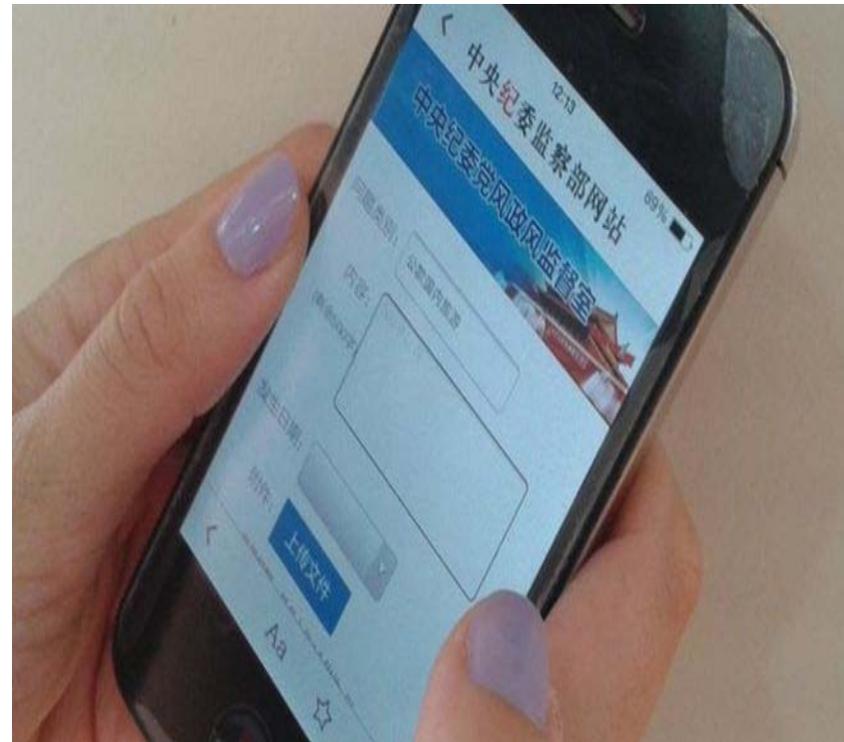


CHINA: DEVELOPMENTS IN ENFORCEMENT

- In January 2015, China launched ***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.
- According to the Central Committee, the initial launch of the app lead to a substantial surge in the number of tip-offs, going from an average of approximately ***300 a day to 1,000 a day***.

BBC
NEWS

China: 'Petty graft' app feature sees tip-offs soar



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CHINA: DEVELOPMENTS IN ENFORCEMENT

- On September 19, 2014, **a Chinese court found a major pharmaceutical company's local subsidiary guilty of bribery and fined the company nearly \$500 million**, capping an enforcement action that has shaken China's pharmaceutical industry, and companies generally in China.
- In connection with the case, **Chinese authorities also prosecuted** five of the company's managers, including **a foreign-born executive**.
- The executive in question received a suspended **three year prison sentence** for allegedly orchestrating a "massive bribery network" that involved bribing officials in Beijing and Shanghai.



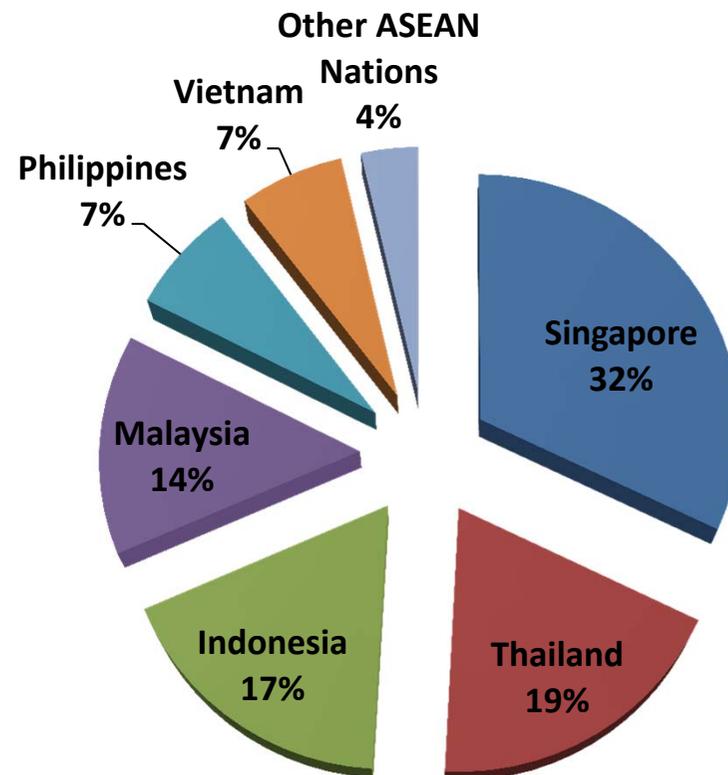
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BUSINESS BACKDROP: ASEAN

- In 2015, **\$20.2 billion** of Japanese FDI outflows went to ASEAN, with the most FDI going to Singapore and Thailand.

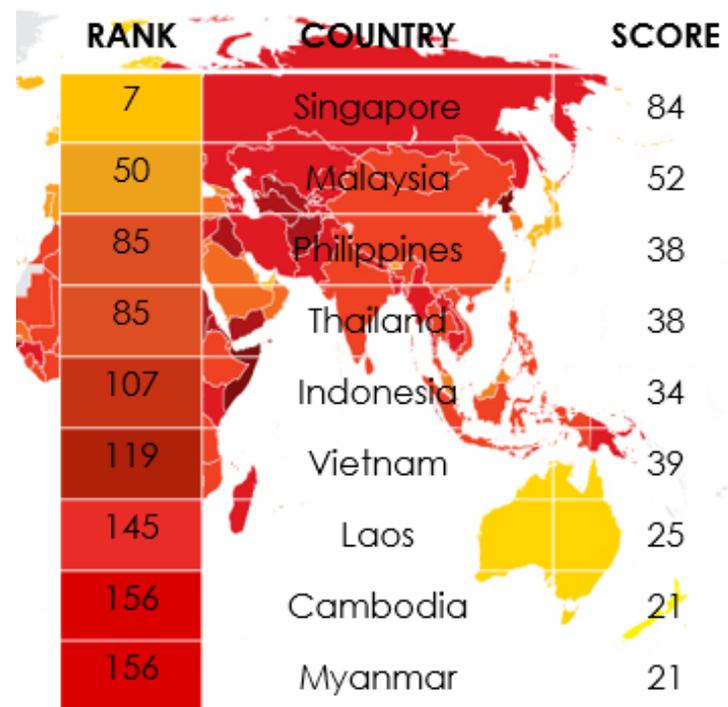
2015 Japanese FDI Outflows to ASEAN



Source: Japan External Trade Organization (JETRO)

RISK OF CORRUPTION IN ASEAN NATIONS IS HIGH 33

- Many ASEAN nations have a relatively high risk of corruption according to Transparency International's Corruption Perceptions Index score (where 100 is very clean and 0 is highly corrupt).



#cpi2014

www.transparency.org/cpi

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FCPA ENFORCEMENT ACTIONS IN ASEAN

- In each year since 2013, there has been at least one FCPA enforcement action involving one or more ASEAN nations.
- ***A notable 2014 FCPA enforcement action*** in Indonesia involved ***a Japanese trading company's*** scheme to pay bribes to ***Indonesian officials*** to secure an energy services deal.
 - The company paid bribes to a member of the Indonesian Parliament and high-ranking employees of a state-owned electricity company in Indonesia.
 - To conceal these bribes, the Japanese multinational enlisted two consultant firms that acted as intermediaries in seeking out and providing the bribes to government officials.
 - The company ultimately settled with authorities and paid a ***\$88 million fine***, one of the largest in history.



ASEAN ENFORCEMENT UPDATE: INDONESIA

- ***Indonesia will institute new procedures that will enable Indonesian authorities to prosecute corporations for bribery for the first time.***
 - The Corruption Eradication Commission (“KPK”) has struggled to indict corporations. The KPK has stated that this is due to a lack of procedures.
- To help the KPK prosecute corporations, Indonesia’s Supreme Court has drafted—and will soon sign—a regulation providing procedures for the prosecution of corporations for bribery. Under the draft regulation:
 - ***Officials from companies*** accused of bribery ***will stand trial on the company’s behalf***, and the sentence will be in the form of fines, not prison sentences.
 - ***The KPK will be provided a guide to seizing assets*** from corporations convicted of corruption.
 - ***Judges will also be provided a guide on how to consider cases of corporate corruption.***

The headquarters of KPK



ASEAN ENFORCEMENT UPDATE: THAILAND

- Key changes to Thailand's anti-corruption laws and enforcement in 2016
 - Introduced **a new anti-corruption court** to expand corruption prosecution into the private sector / lower levels of government.
 - Amended the law to include **strict liability for companies** that benefit from a bribe by a "related person," which includes an employee, agent, affiliate, or any person acting for or on behalf of the company, **irrespective of whether or not the related person has the authority to act.**
 - "appropriate" internal controls will be a defense.
 - Amended the law to **prohibit bribery of international organizations** such as NGOs.



NEWS | THAILAND 2 OCTOBER 2016

Thailand introduces new anti-corruption court

Ruling generals seen as trying to prove their sincerity by fundamentally reforming country's legal process.

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JAPANESE PROSECUTION OF FOREIGN BRIBERY IN ASEAN: O.D.A. BRIBERY (2014)

37

- In Oct. 2014, a different Japanese consulting company and three of its current and former executives pled guilty to paying bribes to officials in **Vietnam**, **Indonesia**, and Uzbekistan.
- The Bribes:
 - The defendants provided ¥70 million (approx. \$665,937) to three senior officials in **Vietnam's** state-run railway company between 2009 and 2014 to win favor for an urban railway project in Hanoi funded with Japanese O.D.A.
 - The defendants also gave some ¥20 million (approx. \$190,197) worth of rebates to five officials in **Indonesia's** transportation ministry between 2010 and 2013, and some ¥54 million (approx. \$513,530) to three officials in Uzbekistan's state-run railway firm between 2012 and 2013.
- The Penalties:
 - The executives were sentenced to terms of imprisonment ranging between two to three years, following a two-year/three-year suspension.
 - The company was fined ¥90 million (approx. \$856,026)

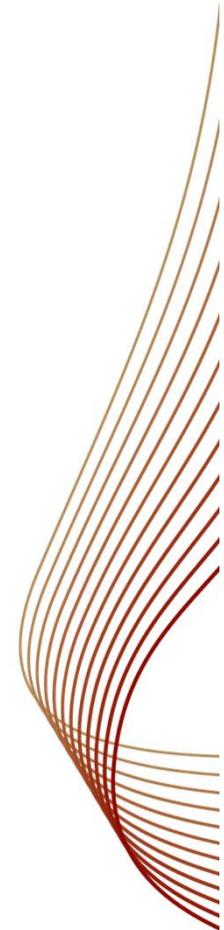


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DOJ and SEC, A Resource Guide to the U.S. Foreign Corrupt Practices Act, released on Nov. 14, 2012

- As with most of the coverage, the FCPA Guide doesn't create new rules, but rather summarizes available prior guidance
- Successor company generally assumes the predecessor company's liabilities
- No liability for successor company if DOJ/SEC had no jurisdiction over the target's pre-acquisition misconduct
- Post-acquisition conduct would be the responsibility of the acquiring company
- Bottom line is that companies must conduct pre- and post-acquisition due diligence to mitigate FCPA risks



LOCKHEED MARTIN / TITAN GROUP (2003-05)

40

- In September 2003, Lockheed Martin and Titan announced an agreement to pursue a merger
 - Value set at \$1.83B (\$22 per share of Titan stock)
- During pre-acquisition diligence, Lockheed identified that Titan had paid over \$2M in “social fees” to a presidential election campaign in return for receiving a higher management fee for its contract in Benin
- On June 26, 2004, with the Titan FCPA issues still ongoing, Lockheed announced the termination of the merger deal
- In March 2005, Titan pleaded guilty to violating the anti-bribery and books and records provisions of the FCPA
- Titan agreed to a \$13M criminal fine, and a civil \$15.4M disgorgement penalty to the SEC (then largest outcome)
- SEC announcement to investigate disclosure issues



PFIZER / WYETH (2009-12)

- In October 2009, Pfizer announced the Wyeth acquisition
- Over the next 18 months, Pfizer cooperated with DOJ and SEC in the context of its ongoing voluntary disclosure:
 - It conducted a due diligence and investigative review of the Wyeth business operations; and
 - It integrated the former Wyeth entities into Pfizer's internal controls system
- The DOJ “considered these extensive efforts . . . in its determination not to pursue a criminal resolution for the pre-acquisition improper conduct of Wyeth subsidiaries”
- Pfizer's diligence efforts were cited in the DOJ/SEC FCPA Resource Guide, and recognized as the “pre- and post-closing due diligence and compliance activities an acquiring company must undertake in order to avoid successor and direct liability for the pre-acquisition conduct of targets”



Wyeth



BMS/OTSUKA CO-PROMOTION (2007 – 2008)

- Otsuka developed **Abilify**, a blockbuster antipsychotic drug, in Japan but co-promoted the drug in the U.S. with BMS
- In September 2007, 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.
- Then, in March 2008, **Otsuka paid \$4 million and entered into a five year Corporate Integrity Agreement** to settle related government and whistleblower allegations regarding their own sales representatives who worked on sales teams led primarily by BMS sales managers.



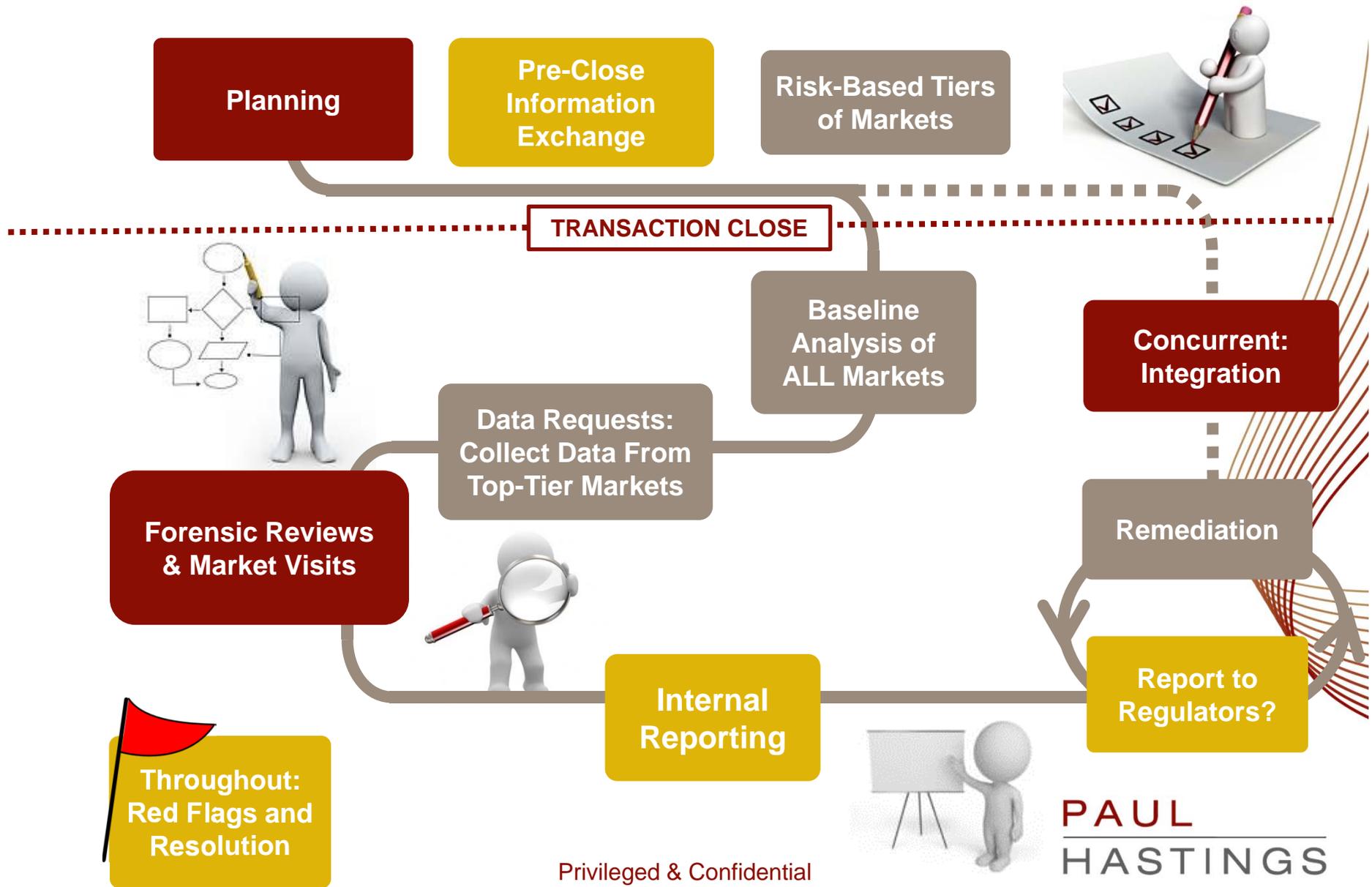
Otsuka



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DILIGENCE PLANNING: OVERVIEW



INTEGRATION

- Begin immediately upon Closing
- Joint Legal / Compliance effort leveraging in-house resources

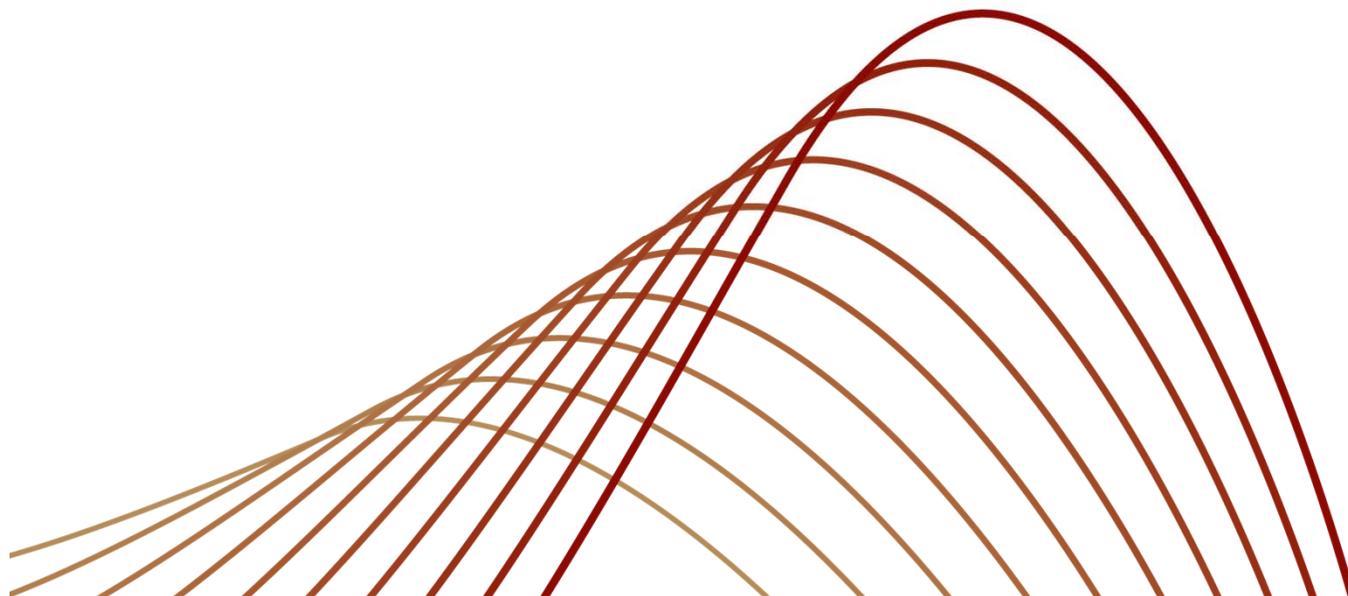


- Need to conduct pre- and post-close diligence
- Post-close diligence, including testing, may be different depending on the nature and structure of the deal
- Operational issues:
 - Composition of the JV board
 - Chief compliance officer
 - Structure and timing of compliance program
 - Compliance support provided by the JV partners
 - Oversight by the JV partners, including audit rights
 - Who determines much of this? And how?
- Liability considerations
 - Ownership percentages, location of business, etc.



THE END - QUESTIONS?

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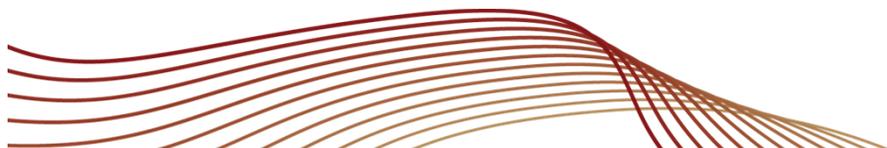
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- Advises biotechnology, pharmaceutical, medical device and other life sciences companies on day-to-day U.S. healthcare and FCPA compliance matters
- Represents corporations in federal and state investigations, including those involving federal and state False Claims Act (whistleblower / qui tam suits)
- Works with both large multinational pharmaceutical companies and smaller companies in the early stages of commercializing their products on a global basis
- Extensive experience with all facets of the U.S. healthcare and anti-corruption landscape, including more advanced compliance programs and measures
- Significant experience with global due diligence and integration associated with business transactions
- Previously served as Vice President, Assistant General Counsel and Head of Government Investigations at Pfizer Inc., and as Deputy Compliance Officer responsible for global compliance programs
- Brings critical practical and operational experience of someone who served on the front lines inside a global organization for more than a decade



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Litigation Department

- Mr. Hagiwara offers more than 20 years of experience in representing the world's leading technology, automobile and life sciences companies in cross-border disputes, litigations, investigations, and transactions. He is well-recognized as the leading IP litigation expert in the industry and also frequently advises clients in civil and criminal investigation matters relating to trade secret misappropriation, Foreign Corrupt Practices Act, and alleged regulatory rules violations. Leveraging the rare combination of deep US litigation training and long-standing experience in Japan, Mr. Hagiwara has represented the world's most admired corporations.
- Clients and other independent sources have singled him out as one of the very best in advising Japanese clients in navigating the complex cross-border dispute landscape. One source says Mr. Hagiwara "is admired for his robust approach and is deeply experienced in IP generally and U.S. patent litigation in particular." (*Chambers Global 2013*). Another source calls Mr. Hagiwara a "Local Dispute Star" (Benchmark Litigation Asia Pacific).

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