

FOREIGN CORRUPT PRACTICES ACT & UK BRIBERY ACT

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AGENDA

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- FCPA Books and Records Provision
- FCPA Affirmative Defenses and Penalties
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- UK Bribery Act Affirmative Defenses and Penalties

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PART I: THE FOREIGN CORRUPT PRACTICES ACT & UK BRIBERY ACT

Foreign Corrupt Practices Act

Anti-Bribery Provision



Books & Records Provision



The Foreign Corrupt Practices Act (“FCPA”) is a United States (“U.S.”) anti-bribery and corruption law that:

- prohibits U.S. persons and businesses (“domestic concerns”) from offering or providing anything of value to a foreign official to influence the foreign official in his or her official capacity in an effort to obtain or retain business
- requires companies with securities listed on a U.S. exchange (“issuers”) to keep accurate financial records and to maintain adequate internal controls to prevent and detect potentially corrupt payments to foreign officials

ANTI-BRIBERY PROVISION

An **issuer** or **domestic concern** is guilty of violating the anti-bribery provision if the following five elements are present:

1. There is a payment, offer, authorization, or promise to pay money or **anything of value**;
2. To a **foreign official**, or to **any third party knowing** that the payment or promise will be passed on to a foreign official;
3. Willfully and with a corrupt motive;
4. For the **improper purpose** of (a) influencing any act or official decision of a foreign official, (b) inducing a foreign official to do or omit any action in violation of his or her lawful duty, (c) securing an improper advantage, or (d) inducing the foreign official to use his or her influence to affect an official act or decision;
5. In order to **obtain or retain business**



According to the World Bank, businesses and individuals pay an estimated \$1.5 trillion in bribes each year. This is about 2% of global GDP and 10x the value of overseas development assistance

ISSUERS AND DOMESTIC CONCERNS

Issuers

- Any company with a class of securities listed on a national securities exchange in the U.S., or any company with a class of securities quoted in the over-the-counter market in the U.S.
- The anti-bribery provision applies to issuers and officers, directors, employees, agents, or stockholders acting on behalf of issuers

Domestic Concerns

- Any citizen, national, or resident of the U.S., or any legal entity organized under the laws of the U.S. or with its principal place of business in the U.S.
- The anti-bribery provision applies to domestic concerns and officers, directors, employee, agents, or stockholders acting on behalf of domestic concerns

- The anti-bribery provisions can apply to **conduct both inside and outside of the U.S.**
- The anti-bribery provisions may also **apply to certain foreign nationals or entities** that are not issuers or domestic concerns if:
 - Either directly or indirectly through an agent,
 - They engage in any act in furtherance of a corrupt payment;
 - While in the U.S. or its territories

ANYTHING OF VALUE

Examples of anything of value include:

Cash or cash equivalents	gift cards, traveler's checks, red envelopes, per diems, shares, securities, tips, investment in foreign official family business, etc.
Gifts	token, nominal and ceremonial ones, spa treatments, electronics, educational classes, scholarships, training programs
Hospitality	meals, beverages, catering, drinks, coffee breaks
Entertainment	sporting events, golf outings, recreational events, theater tickets, festivals
Travel expenses	per diems, hotel accommodations, airline tickets, etc.
Charitable donations	including to a bona fide, charitable organization
Political contributions	campaign contributions
Favors or services	babysitting or tutoring for the children of a foreign official, car service
Payment of bills	phone bills, utility bills, repair bills, tuition
Business or investment opportunities	discounted or waived fees for investing in a fund, or even just the mere inclusion in the opportunity
Memberships	boards of directors, board committees, and country club memberships
Employment opportunities	jobs, internships, clerkships, etc., even where these opportunities might not involve compensation

FOREIGN OFFICIALS

- The statute prohibits payments to foreign officials, not foreign governments
- The statute has been **interpreted broadly** to include any:
 - employee of a department, agency, or instrumentality of a foreign government
 - foreign political party, political party official, or political candidate
 - employee of a public international organization
- For a **life sciences company**, a foreign official may include:
 - healthcare professionals and other individuals employed by state-owned or managed hospitals or clinics
 - individuals working for the Ministry of Health or other public advisory committees
 - employees at federal healthcare agencies
 - individuals conducting research in public hospitals, universities, or research facilities
 - pharmacists and employees at state-owned pharmacies

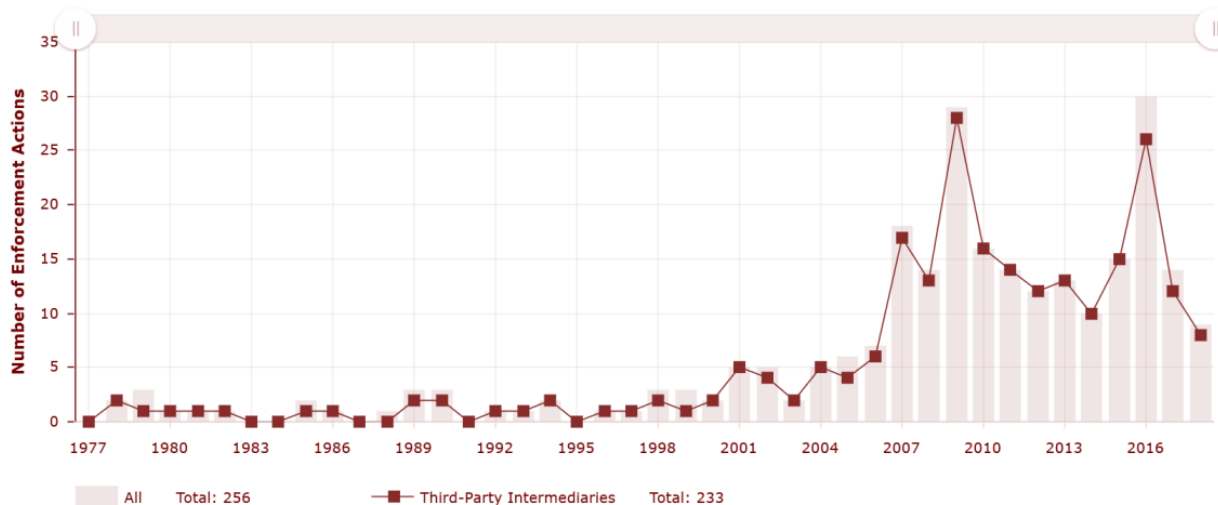


Of the 13 enforcement actions in 2017, 54% involved, in whole or in part, employees of alleged state-owned or state-controlled entities with 15% involving, in whole or in part, individuals associated with foreign health care systems

THIRD PARTIES

- The statute expressly prohibits corrupt payments made through third party intermediaries
- **Common third party intermediaries** include:
 - Sales agents or co-promoters
 - Consultants
 - Regulatory intermediaries
 - Distributors and wholesalers
 - Customs brokers, customs agents, and freight forwarders
 - Partners or members of teaming arrangements
 - Joint venturers

FCPA Enforcement – Third Party Intermediaries



Since its passage in 1977, **91% of all FCPA enforcement actions have involved a third party intermediary**

IMPROPER PURPOSE & OBTAIN OR RETAIN BUSINESS

- The statute only applies to payments or transfers of value that are provided for the improper purpose of **inducing some official act** by the foreign official or obtaining some **improper advantage**, whether through action, inaction, or influence from the foreign official
- One **does not have to actually influence or induce** the foreign official to violate the anti-bribery provision, the offer of something of value with the corrupt motive to influence or induce an official act is sufficient to violate the law
- Similarly, one **does not have to successfully obtain or retain business**, so long as the official act or improper advantage was for the purpose of obtaining or retaining business

Examples of Actions to Obtain or Retain Business

- Winning a contract
- Selling or leasing a product
- Influencing a procurement process
- Circumventing import regulations
- Gaining access to non-public information
- Evading taxes or penalties
- Obtaining licenses or permits
- Obtaining exceptions to regulations
- Avoiding contract termination
- Affecting prosecutorial decisions

BOOKS AND RECORDS PROVISION

An **issuer** is guilty of violating the books and records provision in the following two circumstances:

1. The issuer fails to make and keep books, records, and accounts that, in reasonable detail, **accurately and fairly** reflect the transactions and disposition of its assets;
2. The issuer fails to devise and maintain a system of **internal accounting controls** sufficient to provide reasonable assurances that unauthorized payments are not made and that the issuer can prepare accurate financial statements

“The FCPA’s books and records provisions operate in tandem with the anti-bribery provisions and prohibit off-the-books accounting. Company management and investors rely on a company’s financial statements and internal accounting controls to ensure transparency in the financial health of the business, the risks undertaken, and the transactions between the company and its customers and business partners. The accounting provisions are designed to strengthen the accuracy of the corporate books and records and the reliability of the audit process which constitute the foundations of our system of corporate disclosure.”

A Resource Guide to the U.S. Foreign Corrupt Practices Act



Exception	Affirmative Defenses
Facilitation Payments: Facilitating or expediting payment, the purpose of which is to expedite or secure the performance of a routine governmental action (e.g., obtaining permits, licenses or other documents to do business, providing phone, power and water services, police protection, etc.)	Lawful Under Local Law: The payment, gift, offer, or promise of anything of value is lawful under the written laws and regulations of the foreign official's country Bona Fide Expenditure Expense: The payment, gift, offer, or promise of anything of value is a reasonable and bona fide expenditure, such as travel and lodging expenses, directly related to the promotion, demonstration, or explanation of products or services, or the execution or performance of a contract with a foreign government or agency thereof

POSSIBLE PENALTIES UNDER THE FCPA

Corporate

- Fine up to \$2M per violation
- Disgorgement of profit
- Debarment from business with the U.S. Government
 - Temporary suspension possible where Company is indicted (not yet convicted) for a violation of the anti-bribery provisions
- Deferred Prosecution Agreement (“DPA”)
- Independent Monitor
- Follow-on litigation

Individuals

- Individuals may be fined up to \$10,000 (civil) / \$250,000 (criminal) per violation
- Imprisonment up to 5 years
- Disgorgement
- Follow-on litigation



U.K. BRIBERY ACT

There are four separate offenses under the Act:

1. offering, promising, or providing a financial or other advantage with the intention of inducing or rewarding **any person** to perform certain functions improperly, where there is an expectation that those functions are to be performed in good faith, impartially, or in a position of trust
2. **Agreeing to receive** or **accepting** a bribe
3. offering, promising, or providing a financial or other advantage with the intention of influencing the performance of a **foreign official** to obtain a business advantage
4. Failing as a commercial organization to implement **adequate procedures** to **prevent** bribery by associated persons



Bribery Act 2010

U.K. BRIBERY ACT & THE FCPA

Provision	UK Bribery Act	FCPA
Covered Individuals	U.K. companies, citizens and residents; non-U.K. citizens or residents that commit any act in the U.K.; failure to prevent bribery offense applies to any entity which undertakes business in the U.K., regardless of whether the bribery has a connection to the U.K.	Issuers, domestic concerns, and any other person who takes any act in furtherance of a corrupt payment while within the U.S.
Bribery of Foreign Official	Prohibits	Prohibits
Bribery of a Private Individual	Prohibits	Does not prohibit
Active and Passive Bribery	Applies to giving and receiving a bribe	Only applies to giving a bribe
Adequate Procedure	Affirmative defense	Not an affirmative defense
Facilitating Payments	No exception	Exception

POSSIBLE PENALTIES UNDER THE UK BRIBERY ACT

Corporate

- Unlimited fine
- Disgorgement of profit
- Debarment from public contracts
- Deferred Prosecution Agreement (“DPA”)
- Independent Monitor

Individuals

- Unlimited fine
- Imprisonment up to 10 years



PART II: OECD CONVENTION ON COMBATING BRIBERY OF FOREIGN PUBLIC OFFICIALS

- Requires signatories to criminalize bribery of foreign public officials and to establish legally binding standards to be implemented
- In 2009, made recommendations to enhance ability of signatory parties to prevent, detect and investigate allegations of foreign bribery
- Implementation and enforcement of Convention is monitored by OECD Working Group through a rigorous peer-review monitoring system
 - OECD Working Group made up of representatives from signatory parties
- Monitoring has occurred through three phases:
 - Phase 1 evaluates adequacy of a country's legislation
 - Phase 2 assesses whether a country is applying the legislation effectively
 - Phase 3 focuses on enforcement efforts and outstanding recommendations
 - Phase 4 endeavors to take a tailored approach, considering each country's unique situation and challenges, and reflecting positive achievements



- 41 countries and 5 Latin American markets are OECD signatories:
 - **Mexico** (1999)
 - In June 2014, Working Group concluded that 4 of the Phase 3 recommendations were satisfactorily implemented, 10 were partially implemented and 8 were not implemented
 - **Brazil** (2000)
 - In October 2014, Working Group made 16 Phase 3 recommendations. It also listed 14 areas where the Working Group planned to follow-up.
 - **Argentina** (2001)
 - In December 2014, Working Group made 14 Phase 3 recommendations and 12 areas for follow-up
 - **Chile** (2001)
 - In March 2014, Working Group made 12 Phase 3 recommendations and 6 areas for follow-up
 - **Colombia** (2013)
 - In October 2015, Working Group made 13 Phase 2 recommendations and 9 areas for follow-up

PART III: FCPA AND UK BRIBERY ACT ENFORCEMENT IN LATIN AMERICA

SOCIO-POLITICAL CLIMATE IN THE REGION

LatAm's Presidential Legal Woes



Political Instability

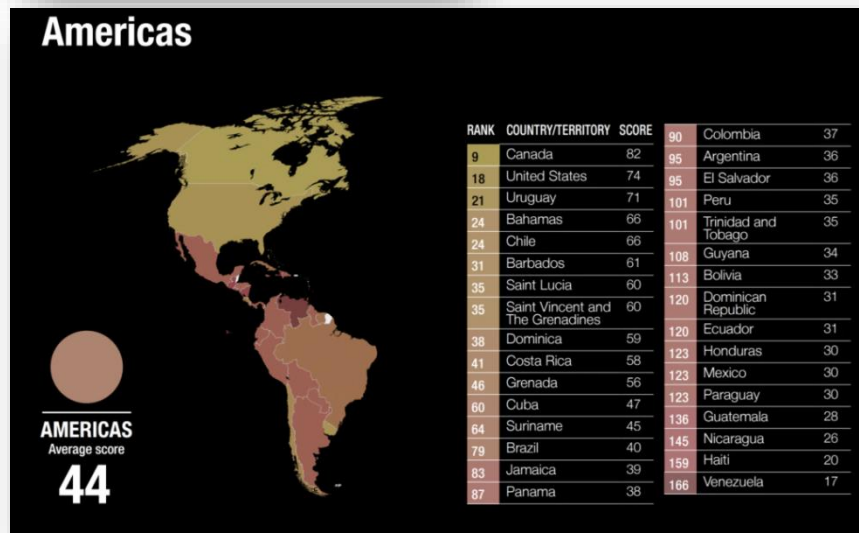
- No less than **21 current and former Latin American heads of state** have been indicted, charged, or under investigation for a broad range of criminal/corrupt acts, underscoring the political and social challenges the region faces

Growing Intolerance and Increased Accountability

- The region's low corruption perception index ("CPI") scores do not necessarily mean an increase in corruption
- An emboldened and mobilized **civil society, timely legislation and judicial reforms**, and an **active media** have all contributed to a new era of accountability and increased focus

Focus on Failing Public Services and Institutions

- There is an intense focus on the link between corruption and **low quality/limited access to public services**, particularly in infrastructure and **healthcare**, not just with blatant acts such as paying and receiving bribes



To an audience in life sciences: “**nearly every aspect of the approval, manufacture, import, export, pricing, sale, and marketing of a drug product in a foreign country will involve a ‘foreign official’** within the meaning of the FCPA . . . Our focus and resolve in the FCPA area will not abate, and **we will be intensely focused on rooting out foreign bribery in your industry.**”

November 2009, then-Assistant Attorney General,
Department of Justice (DOJ)

“[O]ur FCPA focus obviously covers many industries . . . But **the pharma industry is one on which we have been particularly focused in recent years.**”

March 2015, then-Director of the Division of
Enforcement, Securities and Exchange Commission (SEC)

The SEC is “**going back to the pharma industry after a break for a period of years,**” because the industry had historically been problematic and was “**having a difficult time addressing [FCPA] risks.**”

February 2016, then-Chief of the FCPA Unit, SEC

A new partnership between the DOJ’s **Healthcare Fraud Unit’s Corporate Strike Force and FCPA prosecutors** was created with the mission to “**investigate and prosecute** matters relating to **health care bribery schemes, both domestic and abroad.**”

July 2017, Acting Chief of the DOJ’s Criminal Fraud
Section

PARTICULAR FOCUS ON LATIN AMERICA

Meaningful Enforcement Activity in Latin America

- Approximately **one-third of the 53** FCPA enforcement actions of 2016, one of the most active years on record, arose out of alleged misconduct in Latin America
- Late last year the then-Chief of the SEC's FCPA Unit forecasted the Commission's ongoing interest in Latin America, including **“several cases in the pipeline,”** while recapping a **record fiscal year for FCPA enforcement**

Ongoing Investigations

- True to this warning, of the **131** companies that publically disclosed ongoing FCPA investigations, **48** involved conduct in one or more Latin American markets



ONGOING INVESTIGATIONS IN THE REGION

List of Companies with Publically Disclosed Investigations that Are Ongoing in Latin America

Aberdeen Emerging Markets Fund, Inc.	Peru	Grupo Aval Acciones y Valores S.A.	Colombia	Shikun & Binui Ltd	Guatemala
Alexion Pharmaceuticals, Inc.	Brazil; Colombia	Harding, Loevner Funds, Inc.	Panama	Seadrill Limited	Brazil
AMBEV S.A.	Brazil	Herc Holdings Inc.	Brazil	Sevan Marine ASA	Brazil
Corporación América Airports S.A.	Brazil	Hertz Global Holdings, Inc.	Brazil	Stericycle	Region
Bilfinger SE	Brazil	IBM , Inc.	Argentina	Technip FMC plc	Brazil
Estre Ambiental S.A.	Brazil	Itaú Unibanco Holding S.A.	Brazil	Teekay Corporation	Brazil
Brazilian Electric Power Company	Brazil	Keppel Corporation Limited	Brazil	Telefônica Brasil S.A.	Brazil
BRF S.A.	Brazil	McDermott International, Inc.	Brazil	Tenaris, S.A.	Brazil
Brookfield Asset Management Inc.	Brazil	Millicom International Cellular S.A.	Guatemala	Interpublic Group of Companies, Inc.	Brazil
CEMEX, S.A.B de C.V.	Colombia	Noble Corporation	Brazil	Transocean Ltd.	Brazil
Companhia Siderúrgica Nacional	Brazil	Norte Energia S.A.	Brazil	Vantage Drilling International	Brazil
Construções e Comercio Camargo Correa S.A.	Brazil; Argentina; Peru; Venezuela	Novelion Therapeutics Inc. (Aegerion Pharmaceuticals, Inc.)	Brazil	Wal-Mart Stores, Inc.	Brazil; Mexico
Cosan Ltd.	Brazil	Paragon Offshore plc	Brazil	World Acceptance Corporation	Mexico
Enscopl	Brazil	PEMEX	Mexico	Quad/Graphics, Inc.	Peru
Gerdau S.A.	Brazil	Petróleo Brasileiro S.A	Brazil	Graña y Montero S.A.A.	Peru
Gol Intelligent Airlines, Inc.	Brazil	Pilgrim's Pride Corporation	Brazil	Glencore plc	Venezuela

ACTIVE LIFE SCIENCES INVESTIGATIONS: AEGERION

Focus on Orphan Drug Practices

- In January 2015, Aegerion Pharmaceuticals (now Novelson Therapeutics) disclosed that it had received a 2014 subpoena from the SEC requesting certain information related to its **sales activities and disclosures** related to its flagship drug
- The SEC also has requested documents and information on a number of other topics, including **documents related to the investigations by government authorities in Brazil** into whether the company's activities in Brazil **violated Brazilian anti-corruption laws**, and whether the company's activities in Brazil violated the FCPA
- Despite pleading guilty to two FDCA/REMS misdemeanors, and entering into a \$40 million settlement and deferred prosecution agreement with the DOJ for HIPAA and False Claims Act violations, the agreement in principle **does not cover the DOJ and SEC's inquiries concerning the company's operations in Brazil**



ACTIVE LIFE SCIENCES INVESTIGATIONS: ALEXION

Focus on Orphan Drug Practices

- **In May 2015**, Alexion Pharmaceuticals disclosed that it received a subpoena regarding an investigation by the SEC asking for information related to **grant-making activities** and compliance with the FCPA in several countries, including Brazil
- **In May 2017**, Brazil's federal police executed a search warrant on Alexion and the patient association Associação dos Familiares, Amigos e Portadores de Doenças Graves ("AFAG"), based on allegations that the company **subsidized lawsuits, through grants and donations**, for patients to gain access to its drug through legal injunctions
- The search warrant was premised on indications of fraud under Articles 299 (false statements & declaration in public or private documents) and 304 (use of falsified or altered document), **not bribery and corruption statutes**

- Example of DOJ sharing information where there was no "foreign official" or jurisdictional hook?

- Example of enhanced media focus and attention to potential corruption in public services



Better policies in Brazil on orphan drugs and treatments for rare diseases would improve access to these medicines and help stem the growing number of law suits brought by patients against the authorities in pursuit of the treatments they need, says Alexion Pharmaceuticals Inc.

PAUL
HASTINGS

- **Olympus of Latin America (Mar. 2016)**



- Headquartered in Japan; manufactures and distributes specialized medical imaging and surgical equipment
- Allegedly 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** (Argentina, Brazil, Bolivia, Chile, Colombia, Costa Rica, and Mexico)
- No voluntary disclosure; but DOJ noted cooperation and awarded cooperation credit
- The company agreed to pay **\$612M** plus interest to resolve **parallel investigations under the Anti-Kickback Statute and the False Claims Act**
- DPA with the DOJ: \$22.8M penalty; 3-year compliance monitor

- **Teva Pharmaceuticals/Teva LLC (Dec. 2016)**



- Israel-based company, largest generic drug manufacturer in the world
- Size of resolution/penalty reflects systemic bribery (Russia, Ukraine, and Mexico) + knowledge and/or willful ignorance by management
- DOJ (3-yr. DPA) – \$283M criminal fine + 3-yr. compliance monitor; guilty plea of Russian subsidiary
- SEC C&D – \$236M disgorgement (2nd largest disgorgement to date)
- No voluntary disclosure; seriousness of allegations cited by DOJ in its decision to offer only partial cooperation credit to Teva (20% reduction)

INCREASE IN MULTI-JURISDICTIONAL ENFORCEMENT

Combined Resources and Enhanced Enforcement Cooperation

- In the last five years:
 - **28% increase** in the number of **requests to DOJ** for legal assistance from foreign enforcement agencies
 - **147% increase** in the number of **requests from foreign counterparts** seeking U.S.-based evidence to support foreign bribery and corruption investigations
 - **75% increase** in the number of **requests from the U.S. to foreign agencies** for evidence to support U.S. prosecutors conducting FCPA and corruption investigations

“I want to start with stating what is probably abundantly clear to all of you: over the last few years, Brazil has become one of the DOJ’s closest allies in the fight against corruption. Thus far, the DOJ and Brazilian authorities have entered into **four global resolutions** and **assisted one another in dozens of other cases**. This requires high levels of coordination, trust and resolve between our prosecutors and law enforcement agents. On a **nearly daily basis**, our prosecutors and agents are in touch, **exchanging information** and **assisting** one another as appropriate.”



Acting Principal Deputy Assistant Attorney General Trevor N. McFadden at the American Conference Institute’s 7th Brazil Summit on Anti-Corruption

May 2017, São Paulo, Brazil

RISE OF THE GLOBAL RESOLUTIONS

- Emergence of **coordinated resolutions and penalties** among multi-jurisdictional government agencies apportioning penalties/disgorgement for overlapping conduct
- **5 of 9 global resolutions** to date involve conduct in Latin America
 - **Odebrecht (Dec. 2016)** \$2.6B - \$4.5B (depending on ability to pay) among Brazil (\$2.08B); U.S. (\$260M); and Switzerland (\$260M) relating to conduct throughout Latin America
 - **Braskem (Dec. 2016)** \$957M among Brazil (\$702M); U.S. (\$160M); and Switzerland (\$95M)
 - **Rolls-Royce (Jan. 2017)** \$800M among U.S. (\$170M); UK (\$599M); and Brazil (\$25.5M) relating to conduct in Asia, Africa, the Middle East, and Brazil
 - **SBM Offshore N.V. (Nov. 2017)** \$238M among U.S., Dutch, and Brazilian authorities related to conduct in Brazil
 - **Keppel Offshore & Marine Ltd. (Dec. 2017)** \$422 among U.S. (\$105.5M); Singapore (\$105.5M); and Brazilian (\$211.1M) authorities for conduct in Brazil


 ODEBRECHT

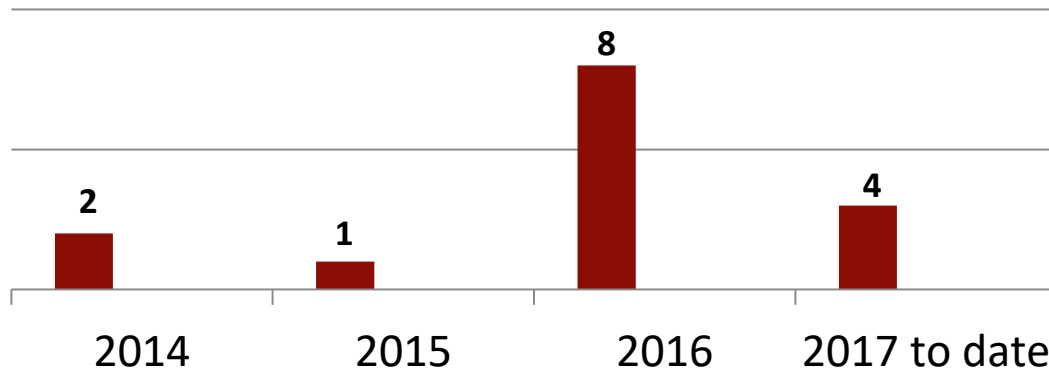

 Braskem


 SBM
OFFSHORE


 Keppel


 PAUL
HASTINGS

RESURGENCE OF CORPORATE MONITORSHIPS



5 of the 9 most recent FCPA resolutions, including independent monitorship obligations, have involved conduct in Latin America

- **Embraer (Oct. 2016)** Three-year retention of independent compliance monitor
- **Odebrecht (Dec. 2016)** Three-year retention of independent compliance monitor
- **Braskem (Dec. 2016)** Three-year retention of independent compliance monitor
- **Zimmer Biomet (Jan. 2017)** Two-year retention of independent corporate compliance monitor
- **SQM (Jan. 2017)** Two-year retention of independent corporate compliance monitor, with additional year of self-reporting
- **Halliburton (July 2017)** 18-month engagement of “independent compliance consultant,” with focus on Africa

“ROUND TWO” ENFORCEMENT ACTIONS

- Three life sciences companies have recently faced repeat enforcement actions – all involving conduct in Latin America



GRIFOLS

- **Grifols S.A. – “Double declination”** Dec. 2012 declination relating to Talecris (purchased in 2009) activity in Europe and China; Oct. 2016 declination relating to alleged corruption in Europe, Latin America, and Asia



ORTHOFIX®

- **Orthofix – July 2012 \$7.5M resolution w/ SEC/DOJ** relating to subsidiary conduct in Mexico; 12-month DPA extension; Jan. 2017 \$6M SEC resolution (DOJ declination) related to payments to doctors at government hospitals in Brazil made through sales reps and distributors



ZIMMER BIOMET

- **Zimmer Biomet – March 2012 \$23M resolution** between Biomet and SEC/DOJ for misconduct in Argentina, Brazil, and China; Jan. 2017 \$30M DOJ/SEC resolution for Biomet (acquired in 2015) misconduct in Mexico and Brazil—including use of the same Brazilian distributor implicated in 2012 enforcement action

“OTHER ISSUES” AS A HOOK

▪ Alere, Inc. (Sep. 2017)

- Investigation arose in the context of purported **revenue recognition and financial reporting concerns** out of Korea; later involved wholly-owned Colombian subsidiary that was a **former independent distributor**
- The former distributor’s customers included an Entidad Promotora de Salud (“EPS”), which were responsible for organizing and guaranteeing the provision of health services on behalf of their participants through a mixed **network of public, private, and their own health service providers**—EPSs were both private and government-controlled and some were later taken over by the government
- The former distributor made \$275,000 in sham **consultant payments to husband, sister-in-law, and friend** of EPS manager in position to recommend Alere products
- The owner of the former distributor, and then GM of Alere Colombia, hired the EPS Manager to work at the company as a **full-time employee**
- Under the terms of the proceeding, the SEC ordered Alere to **cease and desist** violations of the FCPA and other securities provisions and further ordered the company to pay \$3.3 million plus interest of about \$495,00 and a penalty of \$9.2 million
- **FCPA concerns threatened to cancel buyout** by Abbott Laboratories and Abbott sued in Delaware Chancery Court, seeking to terminate the deal – in part because of the FCPA investigation
- Companies agreed in April 2017 to merge for reduced price



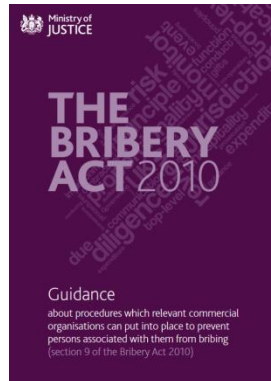
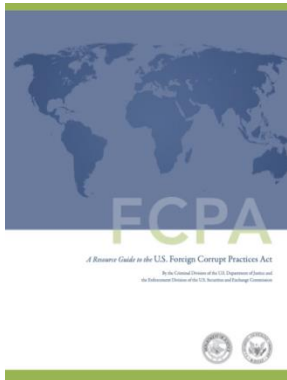
ACTIVE WHISTLEBLOWING: SEC STATISTICS ON EXTERNAL TIPS

33

Country	2015	2016	2017
Argentina	1	1	5
Bahamas	1	1	0
Belize	1	0	0
Brazil	14	7	6
Chile	11	0	21
Colombia	0	2	3
Costa Rica	0	1	1
Dominican Republic	0	1	0
Ecuador	1	0	0
El Salvador	2	0	0
Guatemala	0	0	1
Honduras	1	1	0
Jamaica	1	1	0
Mexico	13	29	26
Panama	1	0	1
St. Lucia	0	0	1
Uruguay	0	1	0
Venezuela	1	1	1

PART IV: FCPA AND UK BRIBERY ACT COMPLIANCE CONSIDERATIONS

CORE GUIDANCE FROM U.S. AND U.K. REGULATORS



SFO

- SEC and DOJ's FCPA Resource Guide ("FCPA Guide")
- DOJ Evaluation of Corporate Compliance Programs
- Prior Enforcement Actions
- DOJ Opinion Procedure
- SEC's Enforcement Manual
- U.S. Federal Sentencing Guidelines Manual ("FSG Manual")
- Resolution Requirements
- U.K. Bribery Act 2010 SFO Guidance
- Joint Prosecution Guidance of the Director of the SFO and the Director of Public Prosecutions on the Bribery Act 2010

FCPA Guide

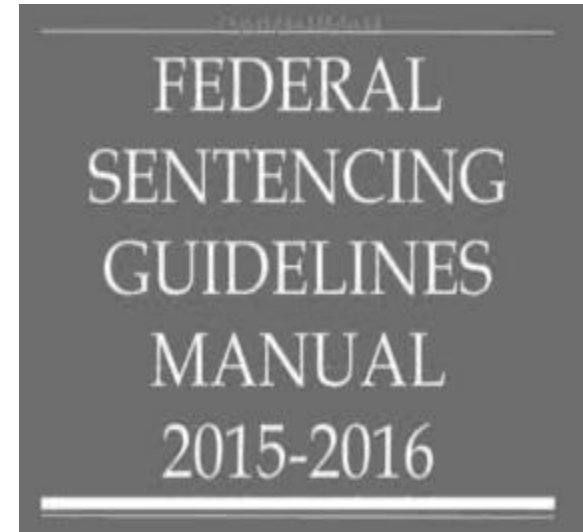
has taken steps to make certain that the code of conduct remains current and effective and whether a company has periodically reviewed and updated its code.

Whether a company has policies and procedures that outline responsibilities for compliance within the company,

chapter 5
Guiding Principles
of Enforcement

Risk Assessment

Assessment of risk is fundamental to developing a strong compliance program, and is another factor DOJ and SEC evaluate when assessing a company's compliance program.³¹⁷ One-size-fits-all compliance programs are generally ill-conceived and ineffective because resources inevitably are spread too thin, with too much focus on low-risk markets and transactions to the detriment of high-risk areas. Devoting a disproportionate amount of time and resources to low-risk areas can result in high-risk areas being overlooked. DOJ and SEC will give meaningful credit to a company that implements in good faith a comprehensive, risk-based compliance program, even if that program does not prevent an infraction in a low risk area because greater attention and resources had been devoted to a higher risk area.



The requirements set forth in this guideline are intended to achieve reasonable prevention and detection of criminal conduct for which the organization would be vicariously liable. The prior diligence of an organization in seeking to prevent and detect criminal conduct has a direct bearing on the appropriate penalties and probation terms for the organization if it is convicted and sentenced for a criminal offense.

Direct Healthcare Regulators

- Product approval and registration
- Product pricing
- Product reimbursement
- Placement on hospital formularies



Government-Employed Doctors

- Gifts and hospitality
- Congresses and meetings
- Consultant arrangements
- Education and research grants

Other Public Officials

- Government procurement
- Customs and importation officials
- Charitable and political contributions
- Third-party agreements (ex. wholesalers, distributors and other service providers)
- Environmental, employment, etc.

PREVALENT FCPA RISK POINTS: BRAZIL

Third Party Invoicing Schemes

- Third party service providers (e.g., consultants, agents, etc.) continue to pose significant kickback risks and the creation of slush funds through the submission of invoices for goods and services that are either **inflated, overpriced, or fictitious**
- There has been a noticeable transition from **on-the-book kickbacks** (e.g., commissions, travel, direct consultancies) during the previous decade to **off-the-book slush funds** and the use of **excess distributor margins** to generate those funds



Price Collusion, Bid-Rigging and Other Anti-Competitive Conduct

- Operation Car Wash, and ancillary investigations like Operation Exposed Invoice, have established that price collusion and bid-rigging not only permeated public works and infrastructure contracting, but virtually every other public sector; Brazil's anti-trust enforcement agency ("CADE") is very actively pursuing cartel investigations and using **leniency and cease-and-desist settlement agreements** as investigative resources (e.g., Braskem, Petrobras, and numerous local enforcement actions)

PREVELANT FCPA RISK POINTS: BRAZIL

Operations Car Wash & Exposed Invoice

- As Operation Car Wash progressed, there was a sense that prosecutors would turn to some of the **medical device and pharmaceutical distributors identified** in the probe and focus on graft and kickbacks in the **public health sector**
- In April 2017, the **Operation Car Wash Task Force in Rio de Janeiro** brought criminal charges against a number of individuals involved in a massive organized crime ring that centered around the former Governor of the State of Rio de Janeiro
- The Operation Car Wash Task Force, which is overseeing **Operation Exposed Invoice**, used information gathered in previous investigations Operation Calcutta and Operation Efficiency which looked into corruption in the past terms
- The corrupt scheme centered around executives from a well-known **medical device distributor, a public trauma and orthopedic institute in Rio de Janeiro, and a cartel** of companies that colluded to inflate prices and bribe public officials
- The unsealed indictment listed **20 distributors and manufacturers** who allegedly participated in the cartel, representatives of which have been imprisoned, including those affiliated with, or employed by, U.S. entities or their subsidiaries, including Philips, Johnson & Johnson, and Stryker



PREVALENT FCPA RISK POINTS: COLOMBIA

Bypassing Bureaucratic Barriers with Third Parties & Economic Extortion

- Use of “gestores” or fixers, often characterized as consultants, advisors, or legal service providers, to navigate red tape and regulatory approvals (e.g., Walmart, Stryker, Key Energy, Biomet)
- Grease payments to customs and/or other regulatory agents who threatened to delay, deny, or otherwise economically extort multi-national companies



Use of Politically Connected Distributors for Public, Especially State-Level, Tenders

- Inconsistent and unstructured pricing practices, that either purposefully or unintentionally, create excess margin for distributor’s misuse in public bidding
- Often have longstanding kickback arrangements with public customers/agencies (e.g., Orthofix, HP, etc.)

Personal Gifts or Other Items of Value to Tender Committee Members or Technical Advisors

- Asset Misappropriation/employee expense reimbursement fraud used to purchase gifts or other items to value to influence tender committee officials or those responsible for drafting technical requirements for public tenders



PREVALENT FCPA RISK POINTS: MEXICO

Bypassing Bureaucratic Barriers with Third Parties & Economic Extortion

- Use of “gestores” or fixers, often characterized as consultants, advisors, or legal service providers, to navigate red tape and regulatory approvals (e.g., Walmart, Stryker, Key Energy, Biomet)
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PREVALENT ANTI-CORRUPTION RISK POINTS

Layered Distribution Chain and Connected Intermediaries

- Third party intermediaries (e.g., distributors, wholesaler, agents, etc.) have commonly used their **own undisclosed third parties** (e.g., sub-distributors, local sales agents, etc.) with key “relationships” or ties for local (i.e., state and municipal) tenders/sales (e.g., Alere)
- Payments to these undisclosed sub-distributors/local agents may be to **entities owned by close family members** of the public official and are often executed through sham consultancies/invoices paid to **offshore entities**, primarily in Panama



Tenders at Military Hospitals/Institutions

- Following years of systemic bribes/kickbacks associated with narco-terrorism and paramilitary conflict, **military institutions** are particularly susceptible to bribe/kickback requests

Foreign Travel and Entertainment

- It is not uncommon for Colombian HCPs to request sponsorships for educational and training opportunities at **international events and congresses** when adequate or comparable training or education is available locally (e.g., Olympus)
- Exchange business class fare to pay for spouse/guest

QUESTIONS?

THE AMERICAS

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Houston
Los Angeles
New York
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Palo Alto
San Diego
San Francisco
São Paulo
Washington, D.C.

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AND EUROPE

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TO INTEGRATE WITH THE STRATEGIC
GOALS OF YOUR BUSINESS

PAUL
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