

PRE-CONFERENCE IV: ADVANCED GLOBAL COMPLIANCES ISSUES

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- **Doing Business in China in 2016**
 - Scott Bass, Global Life Sciences Head, Sidley Austin LLP, Washington, DC
- **Is Brazil the Next Hot Spot?**
 - Henrique Frizzo, Partner, Life Sciences and Public Law, Trench, Rossi e Watanabe, A Baker McKenzie Affiliate, São Paulo, Brazil
- **Managing Compliance Risks Presented by Pharma Suppliers and Vendors: Beyond QRM and GMP**
 - Traci Coughlan, Esq., Principal, Advisory Services, The Red Flag Group, Berlin, MD
- **Applying Analytics to Compliance Programs Resulting in Informed Business Decisions**
 - Joseph Coniker, GMP, Principal, National Practice Leader, Business Analytics, Grant Thornton, Philadelphia, PA
- **Monitoring and Auditing of Third Parties**
 - Jeff Antoon, Director Internal Audit, Johnson & Johnson, New Brunswick, NJ
- **Application of Attorney-Client Privilege in the Context of Internal Cross-Border Bribery Investigations**
 - Vivian Robinson, Esq., Queen's Counsel, Partner, McGuireWoods; Former General Counsel of the UK Serious Fraud Office; Former Head QEB Hollis Whiteman Chambers, Recorder of the Crown Court and Former Treasurer of Inner Temple, London, UK

Introduction: Framework and Trends in Enforcement

- Over \$1 trillion in bribes paid every year = ~ 3% of the world economy per the World Bank.
 - Over \$2.5 billion in bribes every day (\$100 million in bribes an hour)
- Over one in four people (28%) have acknowledged paying a bribe in the last year, according to the Transparency International Global Corruption Barometer.
- Corruption issues arise in almost all aspects of international business: obtaining contracts, onboarding contractors, distributors or suppliers, tax disputes, licensing, zoning, permitting, real estate transactions, customs clearances, etc.
- Corruption risks exist in every industry and geography, but life sciences industry appears to be particularly prone to risks..

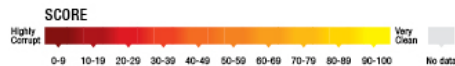
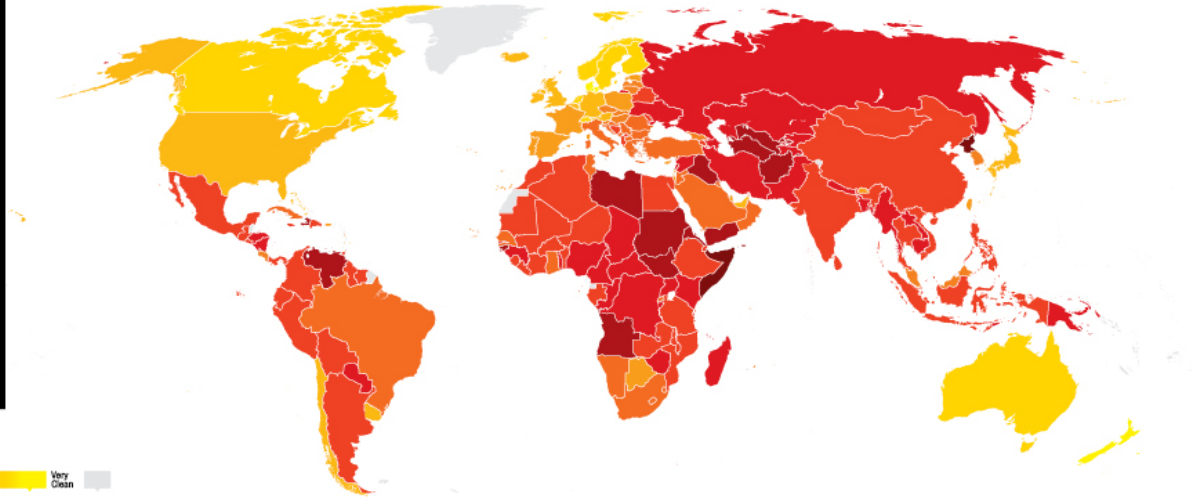
TRANSPARENCY INTERNATIONAL CORRUPTION PERCEPTIONS INDEX 2014

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CORRUPTION PERCEPTIONS INDEX 2014

The perceived levels of public sector corruption in 175 countries/territories around the world.



RANK	COUNTRY/TERRITORY	SCORE	RANK	COUNTRY/TERRITORY	SCORE	RANK	COUNTRY/TERRITORY	SCORE	RANK	COUNTRY/TERRITORY	SCORE	RANK	COUNTRY/TERRITORY	SCORE	RANK	COUNTRY/TERRITORY	SCORE
1	Denmark	92	21	Chile	73	81	Croatia	48	100	Algeria	36	136	Nigeria	27	156	Zimbabwe	21
2	New Zealand	91	22	Uruguay	73	82	Ghana	48	101	China	36	137	Russia	27	157	Burundi	20
3	Finland	89	23	Austria	72	83	Cuba	46	102	Suriname	36	138	Sierra Leone	31	158	Syria	20
4	Sweden	87	24	Bahamas	71	84	Oman	45	103	Bolivia	35	139	Tanzania	31	159	Uganda	20
5	Norway	86	25	United Arab Emirates	70	85	Latvia	55	104	Mongolia	39	140	Vietnam	31	160	Ukraine	26
6	Switzerland	86	26	Estonia	69	86	The FYR of Macedonia	45	105	Morocco	39	141	Ouyana	30	161	Guinea-Bissau	19
7	Singapore	84	27	Guyana	69	87	Turkey	45	106	Moldova	35	142	Azerbaijan	29	162	Haiti	19
8	Netherlands	83	28	Costa Rica	67	88	Kuwait	44	107	Niger	35	143	Kenya	25	163	Venezuela	19
9	Luxembourg	82	29	Hungary	67	89	South Africa	44	108	Argentina	34	144	Laos	25	164	Yemen	19
10	Canada	81	30	Mauritius	67	90	Brazil	43	109	Djibouti	34	145	Timor-Leste	22	165	Eritrea	18
11	Australia	80	31	Georgia	65	91	Bulgaria	43	110	Indonesia	34	146	Madagascar	28	166	Libya	18
12	Germany	79	32	Malaysia	63	92	Greece	43	111	Albania	33	147	Nicaragua	28	167	Uzbekistan	18
13	Iceland	79	33	Cyprus	63	93	Italy	43	112	Ecuador	33	148	Timor-Leste	22	168	Turkmenistan	17
14	United Kingdom	78	34	Portugal	63	94	Romania	43	113	Ethiopia	33	149	Congo Republic	23	169	Iraq	16
15	Japan	76	35	Puerto Rico	63	95	Senegal	43	114	Kosovo	33	150	Tajikistan	23	170	South Sudan	15
16	Belgium	76	36	Slovakia	61	96	Switzerland	43	115	Malawi	33	151	Chad	22	171	Afghanistan	12
17	Barbados	74	37	Bahrain	58	97	Montenegro	42	116	Cote d'Ivoire	32	152	Democratic Republic of the Congo	21	172	Sudan	11
18	Hong Kong	74	38	Jordan	55	98	Sao Tome and Principe	42	117	Dominican Republic	32	153	Myanmar	21	173	Korea (North)	8
19	Ireland	74	39	Israel	60	99	Lebanon	40	118	Guatemala	32	154	Lebanon	27	174	Gambia	8
20	United States	74	40	Spain	60	100	Benin	39	119	Belarus	31	155					

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U.S. FOREIGN CORRUPT PRACTICES ACT (FCPA)

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U.S. Foreign Corrupt Practices Act of 1977



Anti-Bribery Provisions



Books & Records Provisions

- Prohibits making, promising, or authorizing corrupt payments to non-U.S. government officials (“GOs”), directly or indirectly
- Requires issuers to maintain accurate financial records and implement effective financial controls

FCPA “FOREIGN OFFICIALS” IN THE LIFE SCIENCES CONTEXT

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- The FCPA defines “foreign official” very broadly to include every type of government official or employee of a state-owned entity
- For a life sciences company, almost all of your employees’ interactions outside the U.S. will be with individuals considered “foreign officials” for purposes of the FCPA
 - **Government Officials:** Ministry of Health, FDA-analog, Members of Parliament, etc.
 - **Government Employees:** HCPs employed by or conducting research in government hospitals or research facilities (e.g., Brazil - Fiocruz, Bio-Manguinhos, etc.)
 - **Employees of State-Owned Entities:** HCPs employed by or conducting research in state-owned or controlled hospitals or universities
 - **Individuals or Entities Performing a Governmental Function:** Private individuals acting in an advisory role to the government (e.g., Czech MOH advisory committees); Private companies contracted to perform a government function (e.g., Russian customs certification services)
 - **Employees of Public International Organizations:** Red Cross, IMF, United Nations, etc.
 - **Individuals As Government Officials Under Local Law** (e.g., lawyers in Italy)
 - **Employees of Political Parties or Candidates for Office**

PHARMACEUTICAL INDUSTRY SWEEP

- Parallel FCPA investigations by the SEC and DOJ were initiated in 2010; SEC and DOJ made numerous requests of several pharma companies for information and documents
- Issues identified at certain pharma companies were investigated and continue to be investigated across the industry
- Geographic focus was initially Brazil, China, Russia, Germany, Saudi Arabia, Poland, and Italy, but expanded to other jurisdictions.
- DOJ/SEC publicly identified several key risk areas for improper payments:
 - Sales and marketing practices, particularly use of third parties such as distributors, agents, representatives, and consultants;
 - Payments to regulatory authorities for licenses, trials, or approval to market products or expand to new uses;
 - Payments to listing authorities in connection with tenders at the national, state or hospital level;
 - “Pay-to-prescribe”;
 - Customs payments and logistics;
 - Manufacturing issues, real estate, permits; and
 - Gifts, travel and entertainment.

- Deferred Prosecution Agreements of Life Science companies add enhanced obligations, including:
 - Commitment of resources to compliance functions
 - Risk assessments and proactive reviews
 - Policies, procedures, training and controls over gifts, speaker fees, travel, honoraria, donations, and other industry-specific areas
 - Risk-based due diligence requirements for acquisitions, including thorough pre-close diligence as possible, and post-close integration
 - Risk-based due diligence of sales intermediaries, including agents, consultants, representatives, distributors and JV partners
 - Standard anti-corruption contractual provisions that include anti-corruption representations, audit rights, and ability to terminate
 - Regular training for all appropriate employees on anti-corruption laws and regulations, as well as enhanced training for lawyers or auditors performing FCPA-related functions, and, where appropriate, FCPA training for agents and business partners

- The Guide provides insight into DOJ's and SEC's enforcement practices through hypotheticals, examples of enforcement actions and anonymized declinations, and summaries of applicable case law and DOJ opinion releases
- It does not create new law or a shift in policy or approach
- The Guide provides non-binding insights into best practices and how the government views certain activities from an enforcement perspective.
- Guiding principles in the Guide include a focus on risk assessment.
- The Guide also discusses resolutions and declinations, whistleblower provisions and protections, and the DOJ Opinion Procedure.

