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Seton Hall Law School
Life Sciences Compliance Program

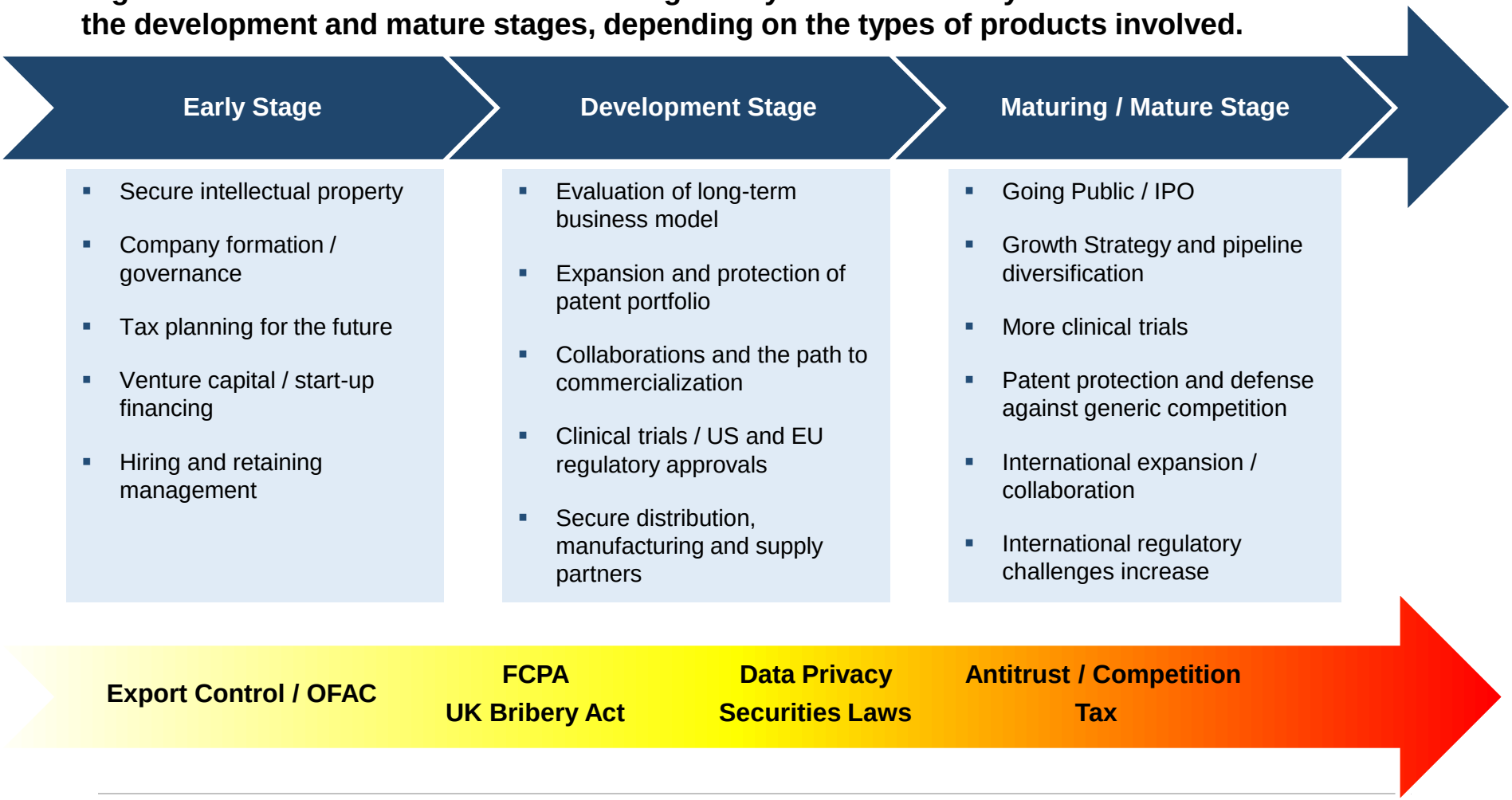
Cross-Border and International Regulatory Issues

Managing Evolving Compliance Priorities During the Lifecycle of Your Company

San Francisco, CA
March 23, 2016

Lifecycle of Life Sciences Companies – Compliance and Regulatory Issues

During the lifecycle of a life sciences company, the compliance and regulatory focus of the organization will evolve. Cross-border regulatory issues will likely become "front-burner" in the development and mature stages, depending on the types of products involved.



Compliance Program Overview: Early Stage Company

Early Stage | Development Stage | Maturing / Mature Stage

- **Secure intellectual property**
- **Company formation / governance**
- **Tax planning for the future**
- **Venture capital / start-up financing**
- **Hiring and retaining management**
  - Need to properly vet your new management team, particularly if hiring non-US citizens - **Sanctions**

Sanctions / Export Control / OFAC

SANCTIONS / EXPORT CONTROL / OFAC

- **Trading With the Enemy Act (TWEA)**
  - U.S. Companies, Branches and Subsidiaries
  - U.S. Citizens / Permanent Resident Aliens
  - All Employees / Agents of U.S. Companies (regardless of nationality or location)
- **Intl. Emergency Economic Powers Act (IEEPA)**
  - Same, except *bona fide* subsidiaries generally are not covered
- **Office of Foreign Assets Control (OFAC)**
- **Sanctioned Countries / Regions**
  - Balkans
  - Belarus
  - Burma
  - Cote d'Ivoire
  - Crimea
  - Cuba (TWEA)
  - Dem. Rep. Congo
  - Liberia
  - Iran
  - Iraq
  - Lebanon
  - Libya
  - N. Korea
  - Russia
  - Somalia
  - Sudan
  - Syria
  - Ukraine
  - Yemen
  - Zimbabwe

SANCTIONS / EXPORT CONTROL / OFAC

- **Asset Freezes**
  - Prohibition on transferring or otherwise dealing in any property (e.g., assets, liabilities, services, securities, or contracts) or interest in property of a named individual or entity.
  - Targets may include: Sanctioned governments and their Agents; Individuals; Companies; Cargo ships and other Vessels
- **Specially Designated Nationals and Blocked Persons (SDN List)**
  - SDN List includes thousands of names of companies and individuals who are connected with the sanctions targets.
  - A number of the named individuals and entities are known to move from country to country and may end up in locations where they would be least expected.
  - U.S. persons are prohibited from dealing with SDNs wherever they are located and all SDN assets are blocked.
  - Entities that a person on the SDN List owns (defined as a direct or indirect ownership interest of 50% or more) are also blocked, regardless of whether that entity is separately named on the SDN List.
- **"a U.S. person may not procure goods, services or technology from, of engage in transactions with, a blocked person directly or indirectly…"**

SANCTIONS / EXPORT CONTROL / OFAC

- **Other Types of Sanctions**
  - Trade Embargoes. General prohibition on importing or exporting any goods, services, or technology from or to particular targets
  - New Investment Restrictions. Prohibition on contributing or committing funds, loans, or credits to, or developing economic resources for, a target
  - Sectoral Sanctions. Prohibition on specific kinds of dealings (e.g., dealings in certain kinds of debt or equity) with targets in a particular economic sector
  - Other Prohibitions. Additional prohibitions may include, for example, travel bans or restrictions on the facilitation or brokering of commercial or financial transactions
- **Iran Update**
  - Under the Joint Comprehensive Plan of Action (Iran nuclear deal), the U.S. has removed many sanctions applicable to non-U.S. individuals and entities.
  - With limited exceptions, a comprehensive trade embargo remains in place with respect to U.S. persons.
  - Some relief for foreign subsidiaries owned or controlled by U.S. persons

SANCTIONS / EXPORT CONTROL / OFAC

- **Sanctions Compliance Program**
  - **Due Diligence is the Key to Sanctions Compliance!**
  - Policy – Code of Conduct
  - Procedures
    - Company Risk Assessment (know your risks)
    - Due Diligence Procedures (know your partners)
    - Screening (OFAC lists constantly changing)
    - Training (support your employees)
    - Auditing (always checking)
    - Reporting (if something goes wrong)
- **Consider Sanctions Risk in a Variety of International Business Settings**
  - Employment
  - Trade – goods, technology, licenses
  - Activities of your subsidiaries and branches
  - Business development efforts / trade shows
  - M&A / Joint Ventures
  - Trade finance / Syndicated finance

Compliance Program Overview: Development Stage Company

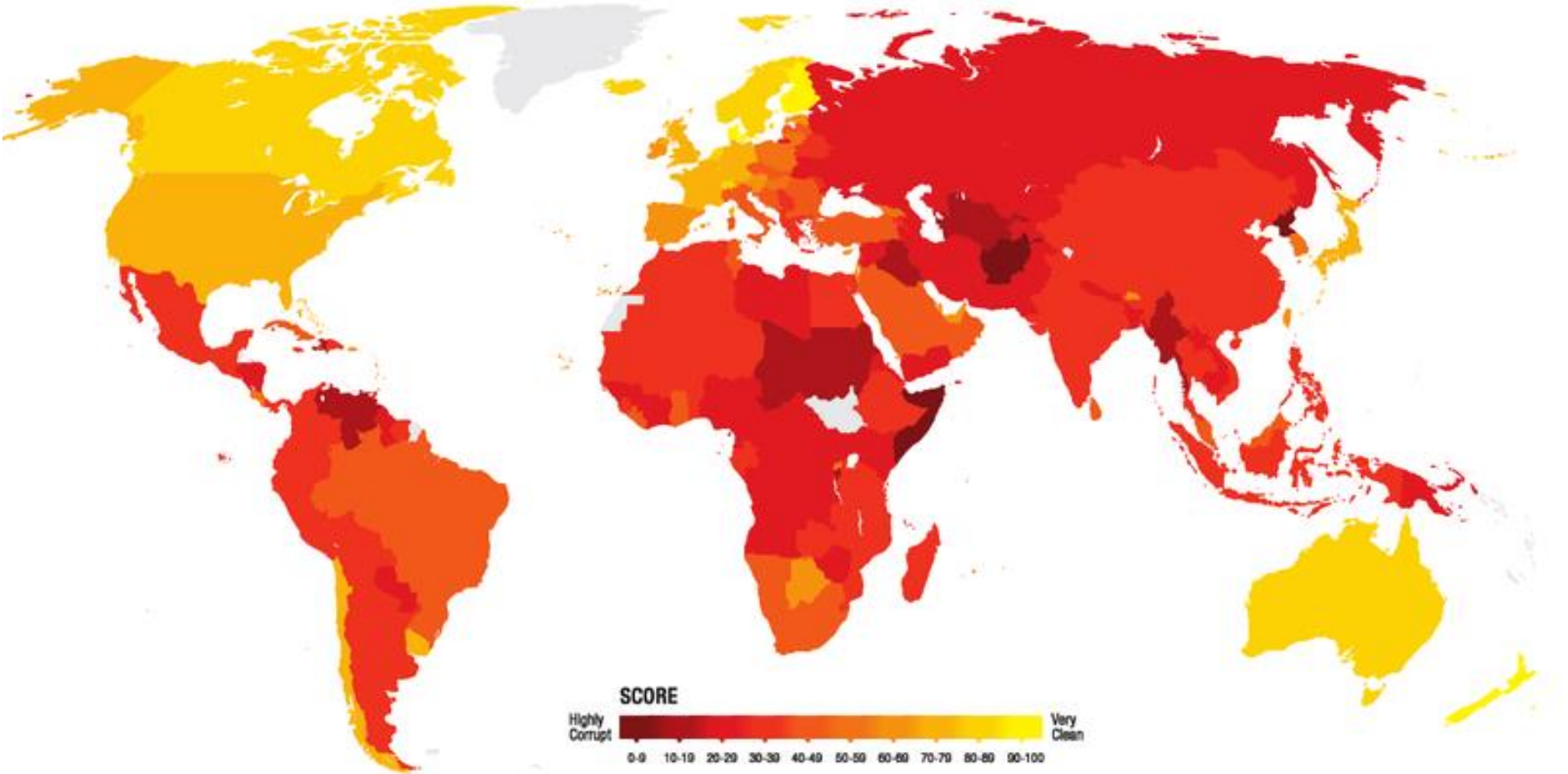
Early Stage | **Development Stage** | Maturing / Mature Stage

- **Evaluation of long-term business model**
- **Expansion and protection of patent portfolio**
- **Collaborations and the path to commercialization**
  - Need to know your potential commercialization partners – **Sanctions and FCPA / UK Bribery**
- **Clinical trials / US and EU regulatory approvals**
  - Need to know who is conducting your trials and interacting with regulators, must protect patient / subject data – **Sanctions, FCPA / UK Bribery**
- **Secure distribution, manufacturing and supply partners**
  - Vetting your new suppliers and business partners to understand who you are working with - **Sanctions and FCPA / UK Bribery**

Sanctions / Export Control / OFAC

FCPA
UK Bribery Act

Anti-Corruption Risks



Life Sciences Industry – FCPA Risk & Enforcement

➢ FCPA Resolutions - Life Sciences Companies

- AGA Medical Corporation (2008)
- Akzo Nobel (N.V. Organon) (2007)
- Baxter International Inc. (2013)
- Biomet Inc. (2012)
- Bio-Rad Laboratories (2014)
- Bristol-Myers Squibb (2015)
- DPC (Tianjin) Ltd. (2005)
- Eli Lilly and Company (2012)
- Immucor, Inc. (2007)
- Johnson & Johnson (2011)
- Medtronic Inc. (2013)
- Merck & Co (2013)
- Micrus Corporation (2005)
- Nordion Inc. (2016)
- Novo Nordisk A/S (2009)
- Olympus Corporation (2016)
- Orthofix (2012)
- Pfizer (2012)
- Philips Electronics N.V. (2013)
- Smith & Nephew (2012)
- Sciclone Pharmaceuticals (2016)
- Syncor Taiwan (2002)
- Schering-Plough Corporation (2004)
- Stryker Corporation (2013)
- Wyeth (2012)

➢ Disclosed FCPA Investigations - Life Sciences Companies

- Alexion Pharmaceuticals (2015)
- AstraZeneca (2011)
- Cubist (acquired by Merk & Co) (2014)
- Fresenius Medical (2012)
- GlaxoSmithKline (2010)
- Novartis AG (2013)
- Sanofi (2014)
- Teva Pharmaceutical (2012)

Life Sciences Industry – FCPA Risk & Enforcement

- **November 2009 – Lanny Breuer (DOJ Assistant Attorney General)**
  - "[I]t is entirely possible, under certain circumstances and in certain countries, that 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."
- **March 2015 – Andrew Ceresney (Director of the SEC's Enforcement Division):**
  - "There have been three types of misconduct that we have seen arise most often in our pharma FCPA cases. One is "Pay-to-Prescribe"; another is bribes to get drugs on the approved list or formulary; and the third is bribes disguised as charitable contributions."
- **February 2016 – Kara Brockmeyer (Director of the SEC's FCPA Unit):**
  - The SEC is "going back to the pharma industry after a break for a period of years" because the pharmaceutical industry in particular was "having a difficult time addressing the risks."

Foreign Corrupt Practices Act (FCPA)

- **Prohibits Bribery of Foreign Officials (all U.S. companies / citizens)**
- **Requires Accurate Books & Records / Internal Controls (public companies only)**
- **Third Parties are Your Biggest FCPA Risk Area!**
  - Commercialization and Distribution
    - Distributors / Wholesalers
    - Sales Agents
    - Contract Field Force
  - Clinical Trials
    - CROs
    - Investigators / Sites
- **Other Anti-Corruption Laws**
  - UK Bribery Act (2010)
  - Brazil – Anti-Corruption Legislation / Petrobras Investigations
  - Canada – Corruption of Foreign Public Officials Act (1999)
  - China – Various Anti-Corruption Laws (2013 Enforcement Push)
  - OECD Convention on Combating Bribery of Foreign Public Officials

FCPA Risk – Distributors – Development Stages

Early Stage | **Development Stage** | Maturing / Mature Stage

- 1995 – AGA Medical Founded (Univ. Minn. scientist)
- 1998 – Hired Chinese distributor
  - July 1998 email from AGA executive to distributor:
    - **"I understand that the fee you must pay each physician was to be included in the selling price. It should therefore not be an issue."**
  - March 2000 email from distributor to AGA executive:
    - **This week I have [made] an appointment with one key person in China knowledge and Patent Protection Bureau. Any action in China I must pay money to do."**
  - December 2003 email from distributor to AGA executive:
    - **"My company also need to provide 20% kickback for physician and sometimes 10% discount to hospitals."**
  - Distributor paid $460,000 to physicians and patent officials
- June 2008 – DOJ Settlement
  - $2 million criminal penalty
  - Deferred Prosecution Agreement

FCPA Risk – Distributors – Life Sciences Cases

- Biomet (2012)
  - Paid government doctors in Argentina, Brazil, and China more than $1.5 million between 2000 and 2008
  - Disguised the payments as commissions, royalties, consulting fees, and scientific incentives
  - Provided improper travel support
    - "[Doctor] is the department head of [public hospital]. [Doctor] uses about 10 hips and knees a month and it's on an uptrend, as he told us over dinner a week ago. …Many key surgeons in Shanghai are buddies of his. A kind word on Biomet from him goes a long way for us. Dinner has been set for the evening of the 24th. It will be nice. **But dinner aside, I've got to send him to Switzerland to visit his daughter." [*Distributor email to Biomet*]**
- Smith & Nephew (2012)
  - $9.4 million paid to three shell companies controlled by a distributor, which was used to bribe Greek doctors
  - Management failed to act on numerous red flags
  - **"… In case it is not clear to you, please understand that I am paying cash incentives right after each surgery…"** [Distributor email during discussions regarding reduced commissions]

Compliance Program Overview: Maturing / Mature Stage Company

Early Stage | Development Stage | **Maturing / Mature Stage**

- **Going Public / IPO**
  - Compliance with US laws - **Securities Laws, Dodd-Frank, FCPA, Accounting Rules, etc.**
- **Growth Strategy and pipeline diversification**
- **More clinical trials**
  - Need to know who is conducting your trials and interacting with regulators, must protect patient / subject data – **Sanctions, FCPA / UK Bribery, Data Privacy**
- **Patent protection and defense against generic competition**
  - Defending against infringement, but complying with Competition Laws – **Antitrust / Competition Laws**
- **International expansion / collaboration**
  - Need to know your potential international partners – **Sanctions and FCPA / UK Bribery**
  - Complying with and managing international tax exposure – **Tax**
- **International regulatory challenges increase**
  - Local anti-corruption and compliance challenges – **GSK China case, EU regulatory requirements, etc.**

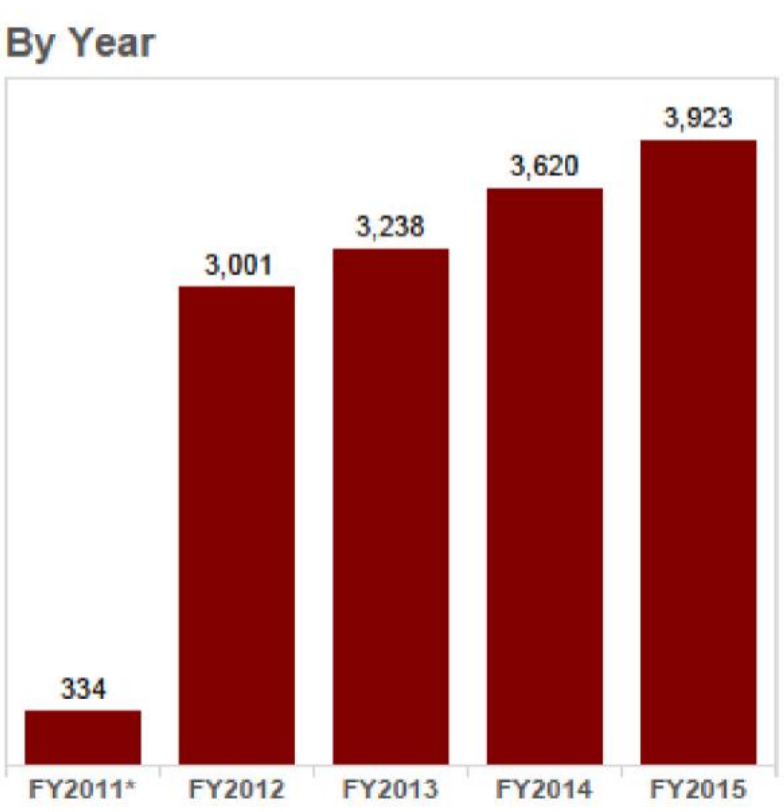
Sanctions / Export Control / OFAC | **FCPA** **UK Bribery Act** | **Data Privacy** | **Securities Laws** | **Antitrust / Competition** **Tax**

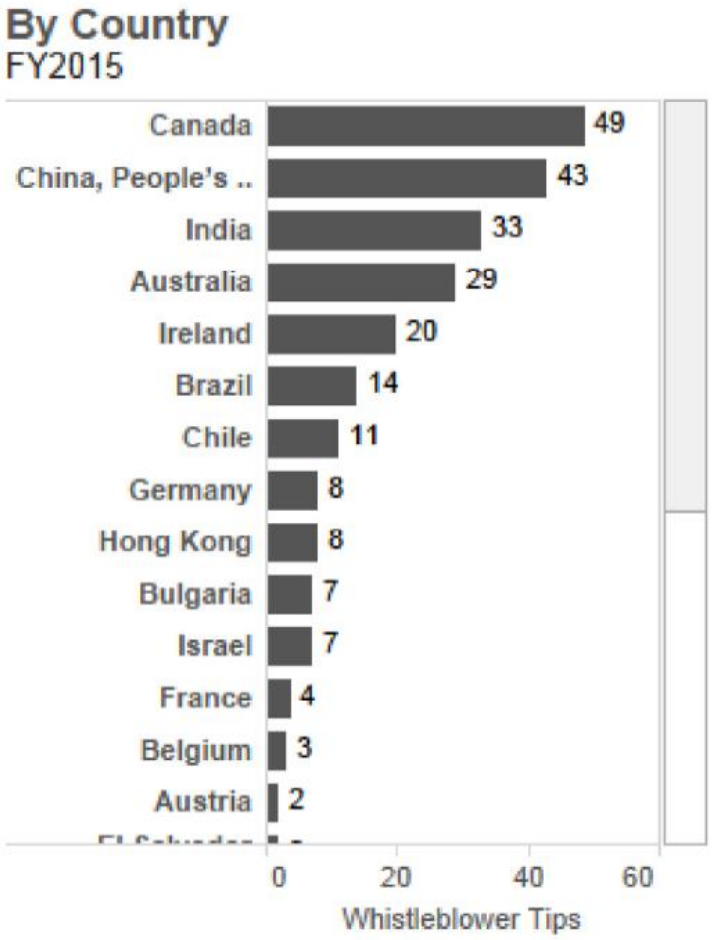
Public Company Issues

- **Books & Records / System of Internal Controls**
- **Dodd-Frank Wall Street Reform and Consumer Protection Act**
- **Compliance Program– International Issues**
  - Whistleblower Protections
    - Anti-Retaliation Policies
    - Investigative Functions
    - SEC Office of the Whistleblower
  - Compliance Reporting Mechanisms
    - Web-Based
    - Compliance Hotlines
    - Do you allow anonymous reporting?

SEC Whistleblower Tips – Trends and Ex-US Sources

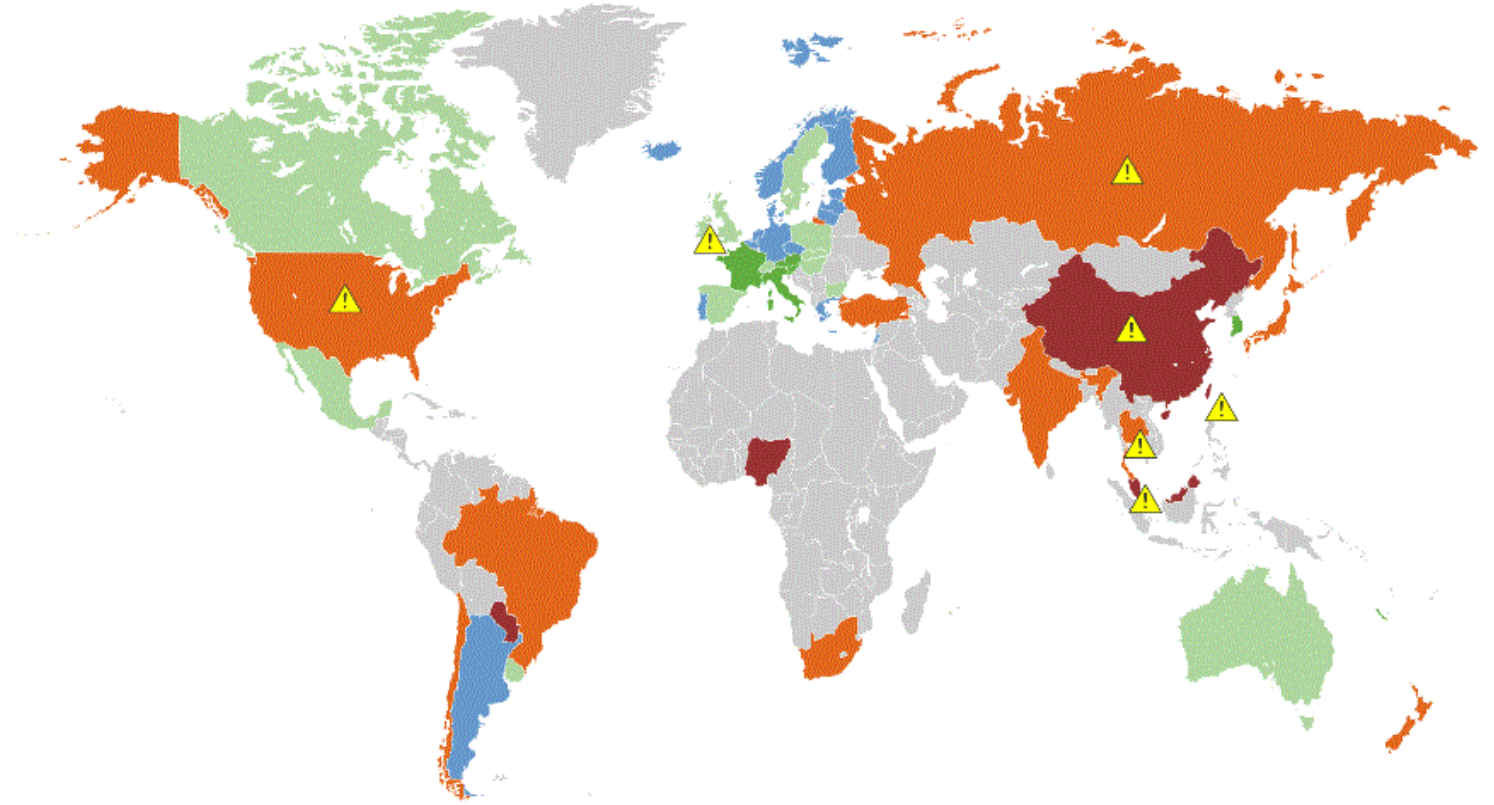
- **The number of tips filed has been growing, and the diversity of the countries from which whistleblower tips are filed has been expanding**





Data Privacy

- **Variety of systems and levels of restrictions exist – very country specific**



Data Privacy

- **Commercial Data Privacy Laws**
  - Dozens of countries around the world grant broad privacy protection to data processed for commercial purposes (the US is one of the few that does not).
  - They generally do not allow data to be transferred to foreign authorities without the approval of local regulators.
- **European Privacy Compliance**
  - EU's Data Protection Directive 95/46 / Member State implementing laws
    - Expected to be replaced by the EU General Data Protection Regulation in 2018
  - ePrivacy Directive 02/58 / Member State implementing laws
  - Council of Europe Convention 108 / European Convention on Human Rights
- **International Data Transfers**
  - Pending EU-US Privacy Shield framework for data transferred from the EU to the US
  - Global codes of conduct and intra-company agreements
- **Biotech and Medical Industry Privacy**
  - Local rules governing health privacy (HIPPA analogs)

Antitrust / Competition Laws

- **US Antitrust / Competition Structure**
  - Prohibited Joint Activity
    - Price-fixing between competitors
    - Dividing territory /customers / products or services
    - Boycotting
  - Questionable Joint Activity
    - Reciprocal Dealing / Exclusive Dealing
    - Tying / Choosing Customers
    - Territorial and Customer Restrictions
  - Monopolization / Unfair Practices And Business Torts / Price Discrimination
- **International Competition Rules**
  - European Union
  - China
  - Conflicts / Interplay With Other US Requirements / Restrictions
    - Russia – Novo Nordisk case
    - Korea – KFTC investigation of pharma companies

QUESTIONS?