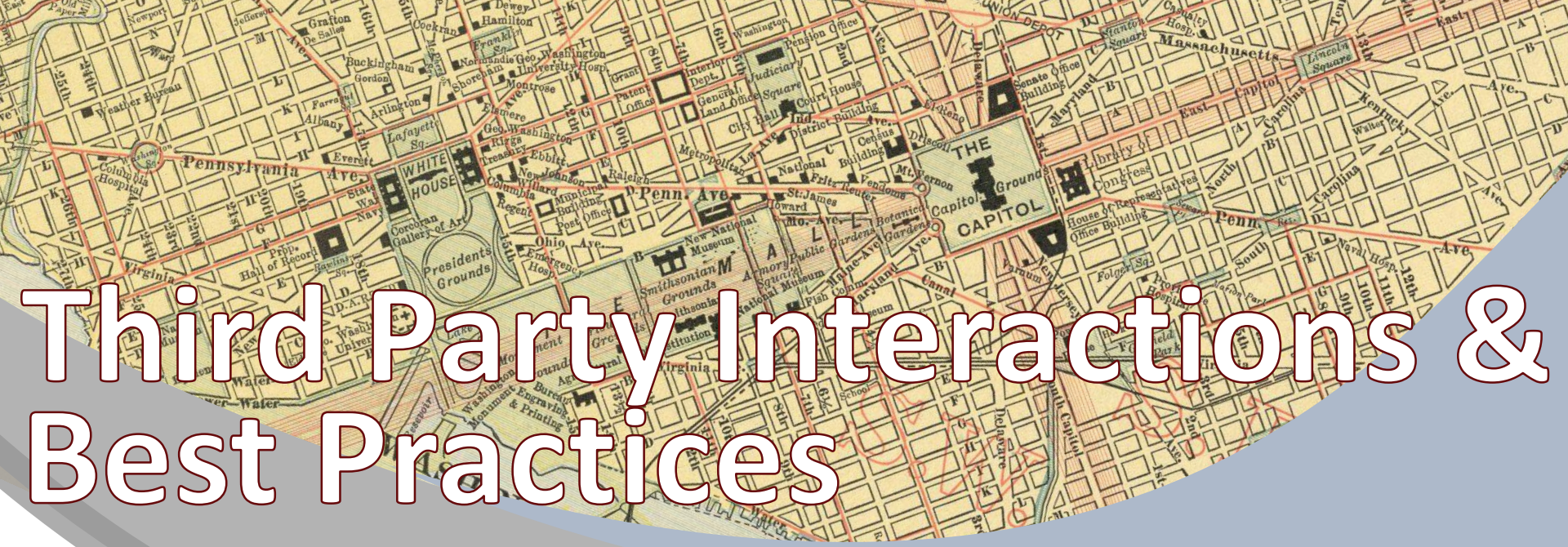

Third Party Interactions & Best Practices

20th Annual PHARMA Congress

Washington, DC
November 6, 2019

- **Angela Rodin,** Principal, KPMG – Session Moderator
- **Paul Melling,** Partner, Baker McKenzie - Moscow
- **Gregory Paw**, Partner, Freeh Sporkin & Sullivan
- **Nancy S. Travis,** VP, International Compliance & Governance, AdvaMed

Agenda

- Overview of Issues and Challenges
- Relationships of Concern
- Lessons from Recent Enforcement Actions
- A Focus on MedTech
- Leveraging Technology to Support Risk Management

Third Party Risk Management

Overview of Issues and Challenges

90%

Rough Share of FCPA Cases Involving Liability from **Third-Party Relationships**

Why do you think you experienced compliance issues with a third party after due diligence had been conducted?

45% *Issue did not exist at onboarding*

29% *Issue concealed*

Main Compliance Concerns

40% Third Party Misconduct

Regulatory Complexity

Employee Misconduct

Resources

JVs

Other

Management of Third Party Relationships

- Frequent area of liability and reputational risk
  - Principal/agent liability
  - “Willful blindness”
  - “Guilt by association”
- Board and Leadership Responsibility to control
  - A road map for a board to exercise its compliance oversight obligations
  - U.S. Sentencing Guidelines & DOJ: “As appropriate, a large organization should encourage small organizations (especially those that have, or seek to have, a business relationship with the large organization) to implement effective compliance and ethics programs.”

Particular Challenges of Emerging Markets

- Perception of high levels of corruption (whether justified or not) means a bright light is shone upon your business in such markets
- US or European enforcement agencies unlikely to be overly interested in your business in Denmark or New Zealand
- There is a reason why three of the top ten FCPA settlements involve Uzbekistan
- Use of third parties/intermediaries is an essential part of the business model in most all of these markets
- Other challenges include (a) culture of non-compliance, (b) little senior management accountability, (c) silos of responsibility and (d) lack of a whistleblower culture

Third Party Risk Management

Key Third Party Risks

Key Relationships Of Concern

1. HCPs
2. Customs/customs brokers
3. Tender facilitators
4. Distributors and their third parties
5. Product regulation specialists

Third Party Risk Management

Lessons from Enforcement Actions

Managing Third Parties

- **Risk-Based and Integrated Processes** – How has the company's third-party management process corresponded to the nature and level of the enterprise risk identified by the company? How has this process been integrated into the relevant procurement and vendor management processes?

- **Appropriate Controls** – What was the business rationale for the use of the third parties in question? What mechanisms have existed to ensure that the contract terms specifically described the services to be performed, that the payment terms are appropriate, that the described contractual work is performed, and that compensation is commensurate with the services rendered?

- **Management of Relationships** – How has the company considered and analyzed the third party's incentive model against compliance risks? How has the company monitored the third parties in question? How has the company trained the relationship managers about what the compliance risks are and how to manage them? How has the company incentivized compliance and ethical behavior by third parties?

Distributor Controls

Teva (Mexico)

Teva Mexico conducted no due diligence on Company, did not have a written distribution agreement, did not require Company to certify compliance with Teva's anti-corruption policies, and knew there was no legitimate purpose for an increased margin received on sales to Mexican government customers.

Distributor Management

Teva (Mexico)

Teva Mexico conducted no due diligence on
Company,
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Third Party Management

Appropriate Controls – What was the business rationale for the use of the third parties in question? What mechanisms have existed to ensure that the contract terms specifically described the services to be performed, that the payment terms are appropriate, and that the described contractual work is performed?

Distributor Controls

Teva (Russia)

Teva Russia conducted inadequate due diligence on third party distributor and agreed a distributor margin well in excess of market rate for which there was no legitimate purpose.

High Discount to Cover Improper Payments

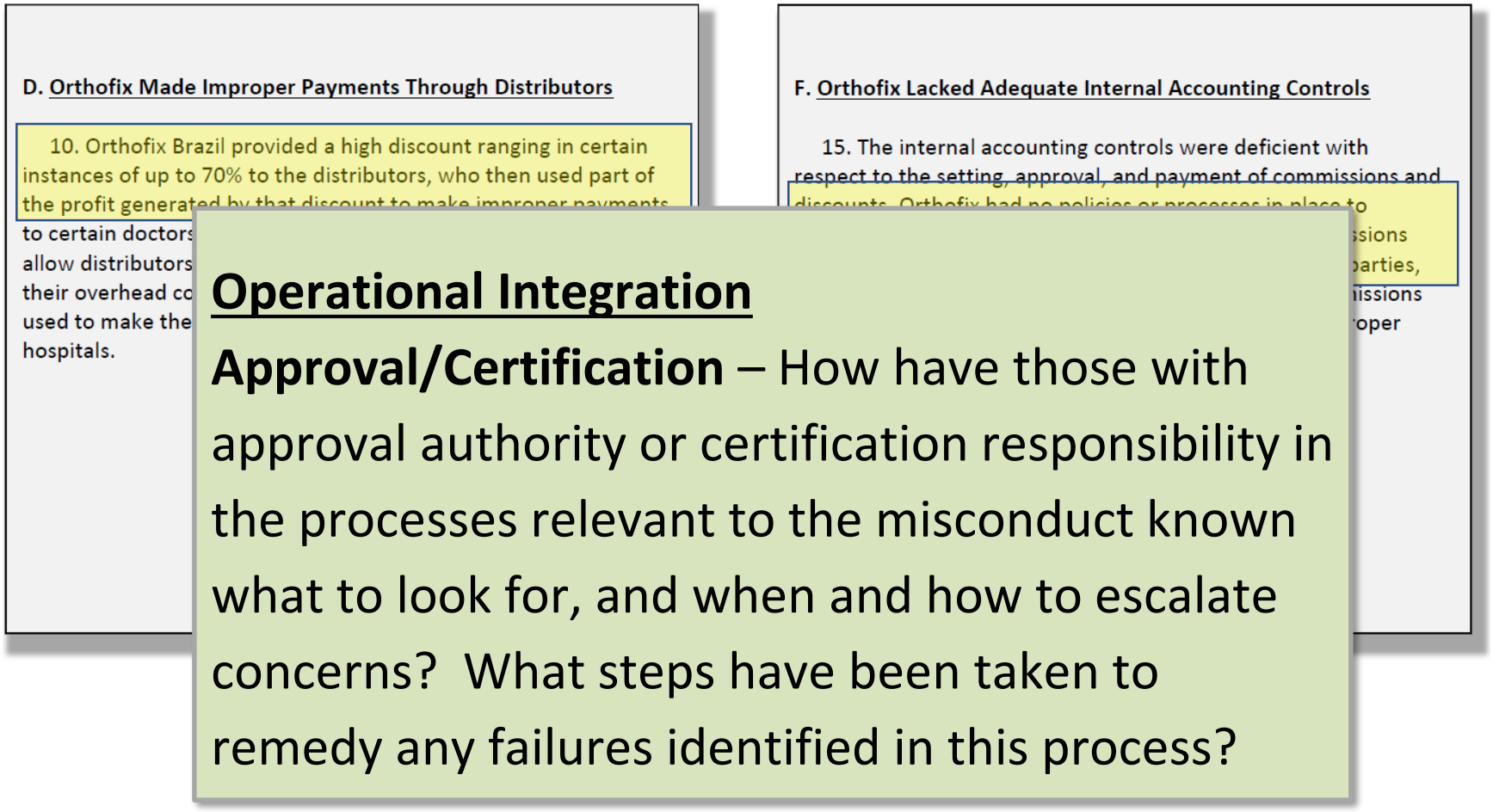
D. Orthofix Made Improper Payments Through Distributors

10. Orthofix Brazil provided a high discount ranging in certain instances of up to 70% to the distributors, who then used part of the profit generated by that discount to make improper payments to certain doctors. The high discounts were purportedly meant to allow distributors to make a sufficient profit while also covering their overhead costs. In reality, part of the discount was often used to make the improper payments to certain doctors at public hospitals.

F. Orthofix Lacked Adequate Internal Accounting Controls

15. The internal accounting controls were deficient with ~~respect to the setting, approval, and payment of commissions and~~ discounts. Orthofix had no policies or processes in place to standardize or centrally approve and monitor the commissions and discounts that Orthofix Brazil was providing to third parties, which allowed Orthofix Brazil to push through high commissions and discounts that ultimately were used to facilitate improper payments.

High Discount to Cover Improper Payments



Operational Integration

Approval/Certification – How have those with approval authority or certification responsibility in the processes relevant to the misconduct known what to look for, and when and how to escalate concerns? What steps have been taken to remedy any failures identified in this process?

Check Cashing Scheme to Funnel Cash

Fresenius (Saudi Arabia)

Saudi Distributor GM employed a check cashing scheme in order to funnel cash to publicly-employed doctors. Specifically, Saudi Distributor GM instructed employees to cash checks that had been made payable in their names and return the cash to him. Saudi Distributor GM then arranged to have the cash delivered to Saudi government doctors and others. Saudi Distributor GM concealed the true purpose of these transactions by falsely recording them as "Project Marketing Expenses" or "Collection Commissions" in Saudi Distributor's financial records.

Check Cashing Scheme to Funnel Cash

Fresenius

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Distributor's

Third Party Management

Management of Relationship – How does the company monitor its third parties? Does the company have audit rights to analyze the books and accounts of third parties, and has the company exercised those rights in the past? How has the company trained the relationship managers about the compliance risks and how to manage them?

Traditional Risks Revisited

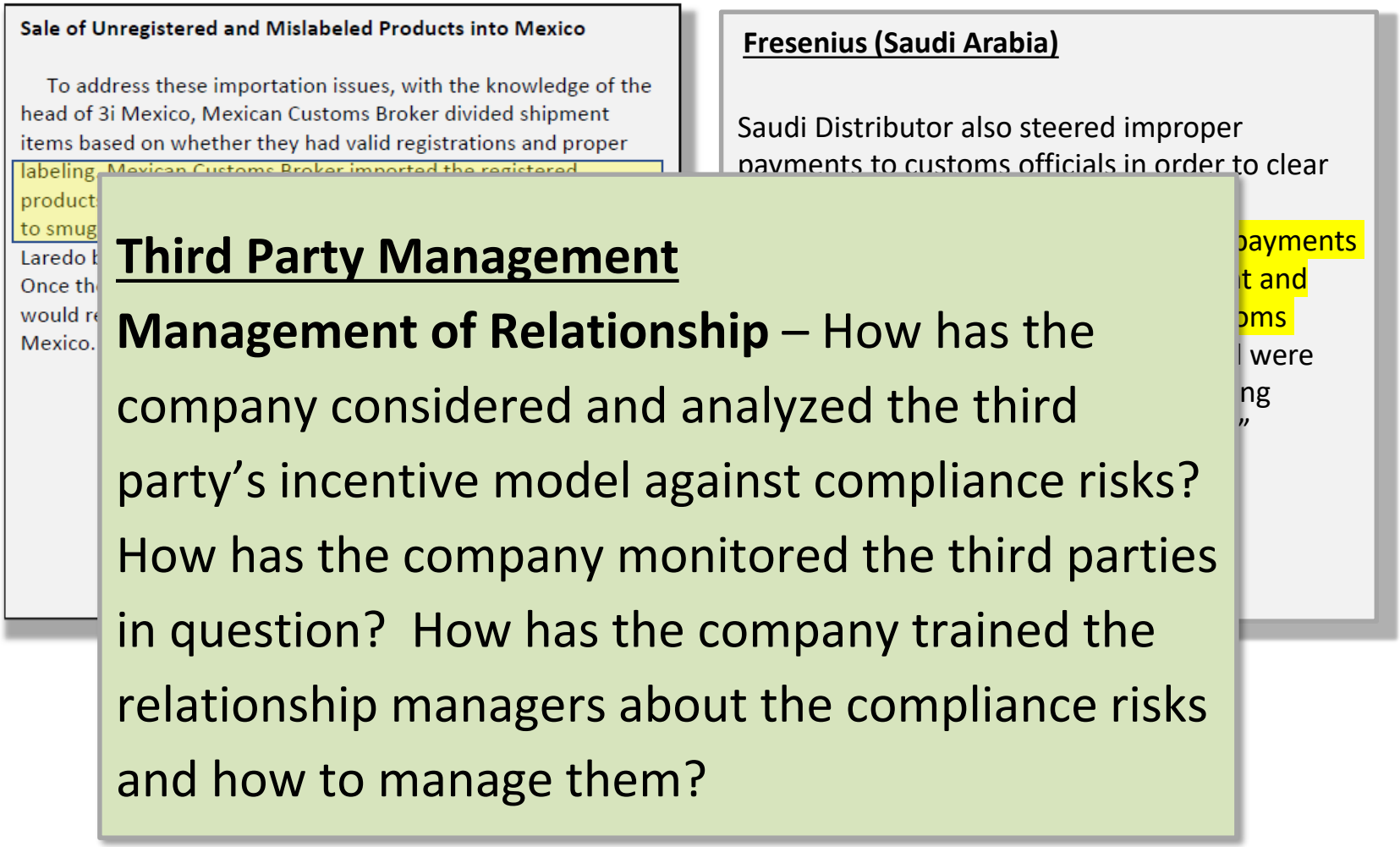
Sale of Unregistered and Mislabeled Products into Mexico

To address these importation issues, with the knowledge of the head of 3i Mexico, Mexican Customs Broker divided shipment items based on whether they had valid registrations and proper labeling. Mexican Customs Broker imported the registered products through the Mexico City airport, while hiring sub-agents to smuggle the unregistered and mislabeled product through Laredo by paying bribes to Mexican customs officials at the border. Once the divided items entered Mexico, Mexican Customs Broker would recombine them and deliver the complete shipment to 3i Mexico.

Fresenius (Saudi Arabia)

Saudi Distributor also steered improper payments to customs officials in order to clear shipments more quickly and avoid or reduce associated fees. The improper payments were made through a third-party freight and logistics company that served as a customs clearance agent ("Customs Agent") and were mischaracterized on invoices as "handling charges" and "miscellaneous expenses."

Traditional Risks Revisited



Managing Third Party Risk in Emerging Markets

- Qualifications and procedures for third party selection – freely available and consistently applied (functioning compliance program can be one such qualification)
- Zero tolerance policy for offshore distributors
- Satisfactory “use of corporate IT” policy should be another qualification
- Use of global and local corporate intelligence providers
- Regular third party training – face to face, in local language

Compliance in Emerging Markets is a Moving Target

- Third party compliance audit program recommended under which major distributors and high risk third parties are audited on a regular basis every two years
- Continue to revisit relationships and structures that may have passed inspection years ago but now may not
- Be alert to new legal developments (e.g. Teva, the emergence of tax evasion as a major compliance risk and exposure to Anti-money laundering liability

Third Party Risk Management

A focus on Med

OVERVIEW OF PRESENTATION

- About AdvaMed
- MedTech Challenges & Opportunities
- AdvaMed Distributor Capacity Building Program
  - Building a Culture of Compliance
  - Creating Implementation Tools

ADVAMED FACTS

- World's largest medical technology association
- More than 70 percent of member companies have less than $100 million annual U.S. revenue
- Global CEO Level Board of Directors representing the diverse nature of our industry
- Recognized by foreign governments and international organizations, Congress and the Administration, CMS, FDA, DoJ and Commerce/USTR as the organization speaking for the medical technology industry

Challenges Faced by Ethics and Compliance by Distribution Companies (Third-Party Sales & Marketing Intermediaries) in Today's Medical Technology Sector

1. Confusion between medical device and pharmaceutical industries
2. Differing laws, codes of ethics and business culture
3. Limited resources to develop & implement compliance programs
4. Different expectations between medtech companies & third parties

Opportunities Offered by Embracing Ethics and Compliance

1. Enhanced reputations and good will;
2. Reduced risks and costs;
3. Stronger competitive positions;
4. Expanded access to capital, credit, and foreign investment;
5. Increased profits;
6. Sustained long-term growth;
7. International respect for enterprises and emerging markets;
8. A common understating within the Sector;
9. Business relationships with certainty and clarity;
10. Benefit to patients.

Differences Between MedTech & Pharmaceutical Codes of Ethics

Codes of Ethics are different in each sector due to:

- ✓ Differences in the **innovation pathway**
- ✓ Differences in **use**
- ✓ Different needs for **training and education**

- Medical Technology **innovations** often come from companies working directly with health care professionals to invent or improve a medical device
- Drugs and biologics act on the human body by chemical means and can often be **used** by the patient independently
- Medical Technology often consists of complex tools, devices, and technology requiring highly dependent “hands on” interactions with health care professionals from beginning to end
- Health care professionals **require training** on and an understanding of how to use these products in a safe and effective way.

Interactions Between Health Care Professionals & MedTech Companies

	*Companies and Health Care Professionals advance medical care and clinical science through **research, product development, and product testing** that results in new or improved, innovative Medical Technology*
	*Companies **instruct, educate, and train** Health Care Professionals on the safe and effective use of complex Medical Technology*
	*Companies provide **product service and technical support** for Health Care Professionals to help ensure the safe and effective use of Medical Technology*
	*Companies support Health Care Professionals' **scientific and medical research, as well as the enhancement of clinical skills and educational opportunities** to improve patient care*
	*Companies promote **charitable giving and public awareness** of medical and health conditions through grants and donations in support of indigent care and patient education*

Source: AdvaMed Code of Ethics eff. January 1, 2020

Addressing Differing Laws, Codes of Ethics & Business Culture

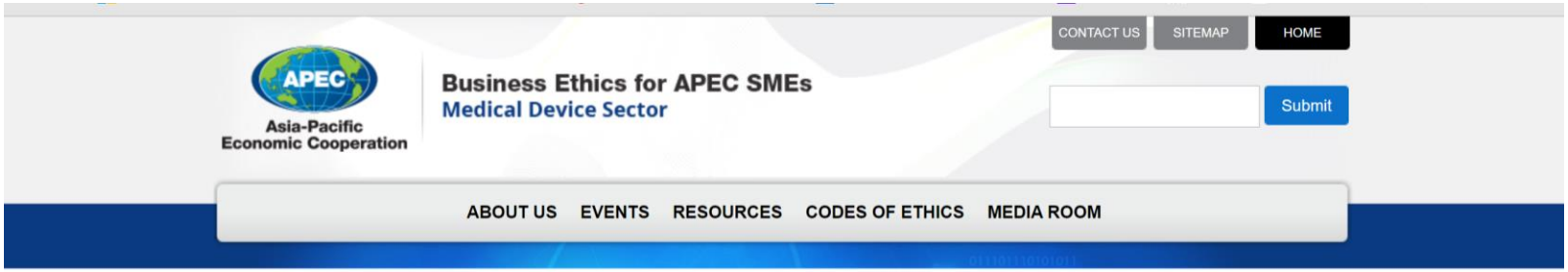
GMTA
Global Medical Technology Alliance
Innovating for a Healthier World

Global Medical Technology Alliance
Innovating for a Healthier World

Fundamental Principles

- **Integrity** – dealing honestly, truthfully and fairly with all parties.
- **Independence** – medical decisions should be in the best interest of the patient, and MedTech companies should not influence these decisions through undue or improper advantages.
- **Appropriateness** – arrangements conform to proper commercial standards and are free from corrupt practices.
- **Transparency & Documentation** – Companies shall document and be open and transparent regarding relationships between the parties.
- **Advancement** – ensuring that relationships are intended to advance medical technology, innovation and patient care

JOINT STATEMENT ON GLOBAL HARMONIZATION OF ETHICAL BUSINESS PRINCIPLES IN MEDICAL TECHNOLOGY, 3 May 2018



Home > Kuala Lumpur Principles

Kuala Lumpur Principles

Medical Device Sector Codes of Ethics

Medical technology sector Codes of Business Ethics promote ethical interactions between medical device and diagnostics companies ("Companies") and Healthcare Professionals ("HCPs"). Ethical interactions enhance patient access to the safe and effective use of medical technologies by ensuring appropriate training of HCPs by Companies. Ethical interactions also promote innovation and the ongoing development of advanced medical technologies through legitimate and transparent collaboration between HCPs and Companies to identify, and bring to market new products. Further, ethical interactions facilitate open and transparent business environments free from the high costs of corruption, enhancing the ability of Companies, especially small and medium size Companies, to participate in global markets.

Ethical interactions ensure that medical decision-making is made in the best interest of the patient. To ensure that relationships meet this standard, interactions between Companies and HCPs should be conducted in accordance with the following principles: Integrity, Independence, Appropriateness, Transparency and Advancement:

- **Integrity** means dealing honestly, truthfully, and fairly with all parties.
- **Independence** means that HCP interactions with Companies should not skew the HCP's medical decision making from the best interests of the patient.
- **Appropriateness** means that arrangements conform to proper commercial standards, and are accurate and free from corrupt purposes.
- **Transparency** means that Companies and HCPs are open regarding significant financial relationships between the parties.
- **Advancement** means that relationships are intended to advance medical technology, innovation and patient care.

Accordingly, medical technology industry codes of ethics ("Industry Codes") should incorporate, but not necessarily be confined to, the following:

1. Collaborative interactions between Companies and HCPs should preserve independent decision-making by HCPs and public confidence in the integrity of patient care, treatment and product selection.
2. Consultancy agreements between Companies and HCPs should support research and development to advance medical science, develop new technologies, improve existing products and services, and enhance the quality and efficacy of care for patients. Consultancy agreements should not be used as a means of

Source: Kuala Lumpur Principles, issued 2011

The Bogota Principles

Medical technology sector codes of business ethics promote ethical interactions between medical device and diagnostics developers / manufacturers ("Companies") and Healthcare Professionals[1] ("HCPs"). Ethical interactions enhance patient access to the safe and effective use of medical technologies by ensuring appropriate training of HCPs by Companies. Ethical interactions also promote innovation and the ongoing development of advanced medical technologies through legitimate and transparent collaboration between HCPs and Companies to identify, and bring to market new products. Further, ethical interactions facilitate open and transparent business environments free from the high costs of corruption, enhancing the ability of all Companies to participate in global markets.

Ethical interactions ensure that medical decision-making is made in the best interest of the patient. To ensure that relationships meet this standard, interactions between Companies and HCPs should be conducted in accordance with the following principles: **Integrity, Independence, Appropriateness, Transparency and Advancement**:

Integrity means dealing honestly, truthfully, and fairly with all parties.

Independence means that HCP interactions with Companies should not skew the HCP's medical decision making from the best interests of the patient.

Appropriateness means that arrangements conform to proper commercial standards, and are accurate and free from corrupt purposes.

Transparency means that Companies and HCPs are open regarding significant financial relationships between the parties.

Advancement means that relationships are intended to advance medical technology, innovation and patient care.

Source: Bogotá Principles, issued 2017

Addressing Limited Resources, Misunderstandings

AdvaMed Distributor Capacity Building Program

- ✓ **Training**
- ✓ **Resources**
- ✓ **Tool Kits**

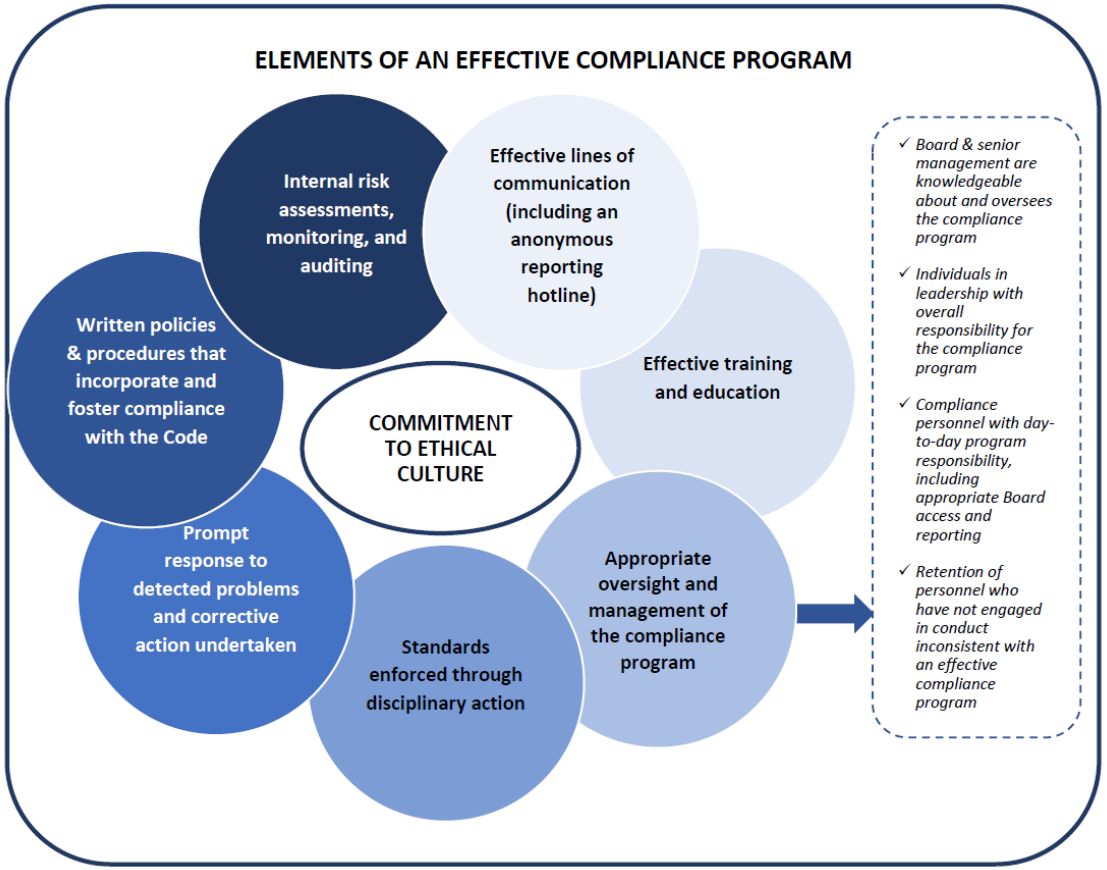
DISTRIBUTOR COMPLIANCE CAPACITY BUILDING PORTAL

Virtual resources to support implementation of the APEC Guidance for Ethical Third Party Intermediary Relationships in the Medical Device Sector

Learn More >>

5. Policies and Supporting Documents

- Policy Template - PDF
- Written Contract Guidance - PDF
- Form Request Consultant Services - PDF
- Consultant Contract - PDF
- HCP Invitation - PDF
- Speaker Agreement - PDF
- Notification to Employer Training - PDF
- Notification to Employer Consulting - PDF
- Sign in sheet HCPs Training - PDF
- Grants and Donations Form - PDF
- Payment Booth Fees Form - PDF
- Due Diligence Guide Sub Distributor 21 - PDF
- Template Agreement Sub Distributors - PDF
- Expenses Form - PDF

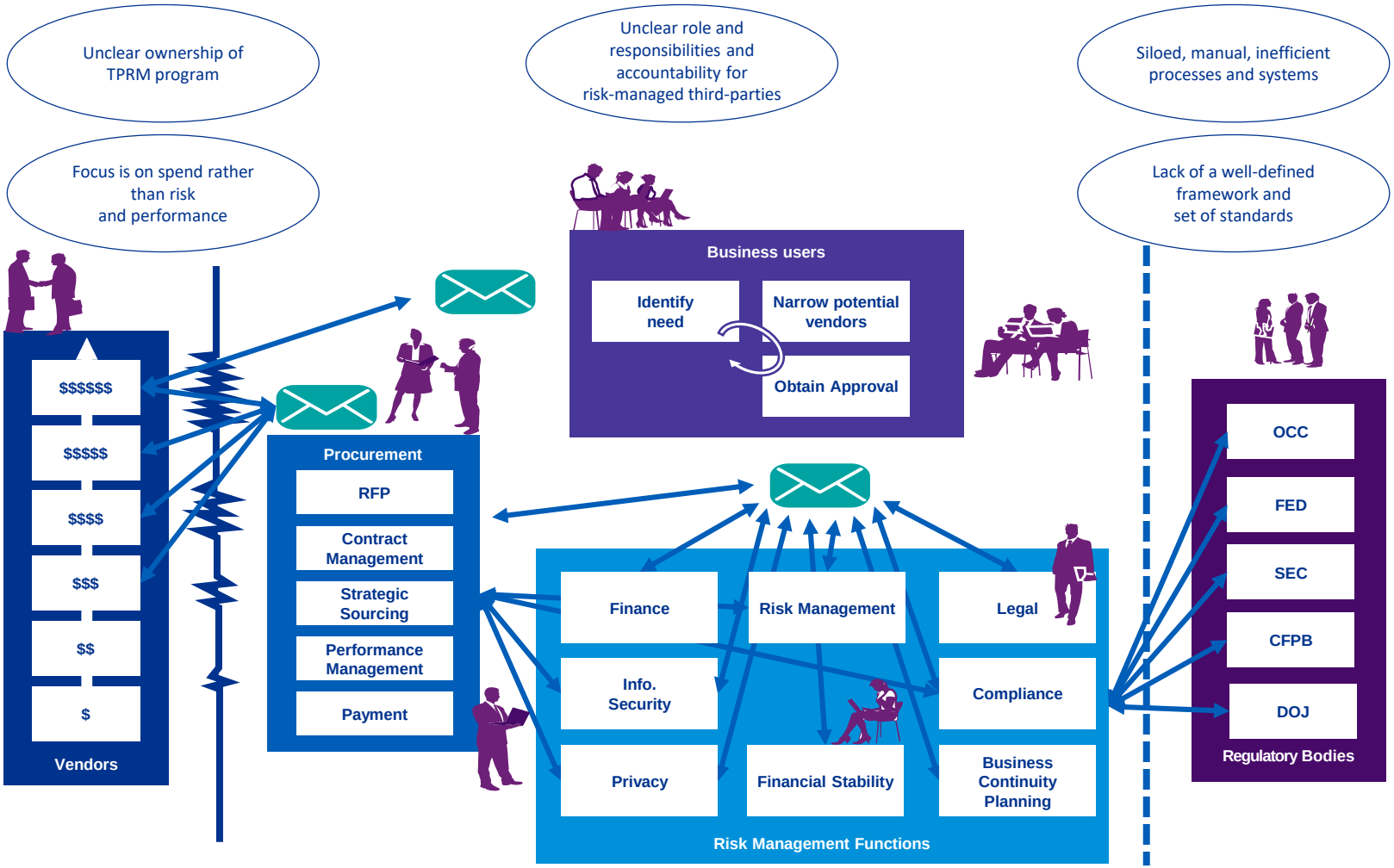


Source: AdvaMed Code of Ethics eff. January 1, 2020

Third Party Risk Management

Framework Options

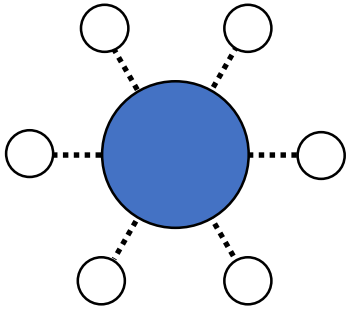
Third Party Risk Management Challenges



Global TPRM program organizational support model

In choosing an organizational approach, it is important to balance key goals of the program, with an understanding of what works in the organization, so a pragmatic plan can be designed and implemented.

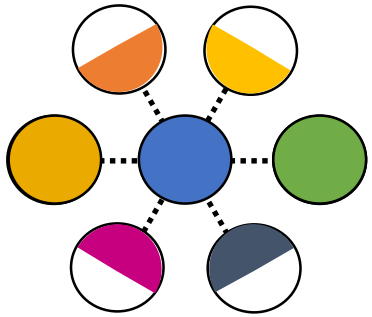
Centralized



PROS:.
- TPRM functions are centralized and serve the business unit according to risk priorities.
- Easier to obtain an enterprise level view and roll-out strategic priorities and program enhancements.

CONS:
- Requires strong enterprise level controls.
- Risk of “shadow” processes.
- Not as responsive to individual business unit requirements.
- Data quality centrally managed.

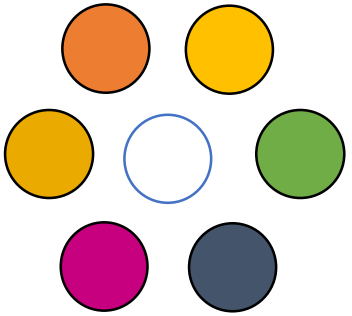
Hybrid (Hub and Spoke)



PROS:
- Significant centralized direction and a TPRM center of excellence. Programs and enhancements are prioritized according to strategy.
- Some key activities are decentralized to the business units

CONS:
- Formal collaboration and training processes in place.
- Data quality centrally managed.
- Requires strong governance and takes time to implement.

Decentralized



PROS:
- Each risk group or BU maintains its own TPRM organization, which is very responsive to its own business unit’s requirements.

CONS:
- No enterprise vies and minimal sharing of data and analytics.
- Difficult to share leading practices.
- Data integrity issues.
- Duplication of effort

TPRM Good Practices Framework

Strategy
- Mission and objectives
- Align third party use to risk appetite
- Management of operating expenditures
- Where in life cycle is first contact

Information Reporting and Technology
- Dashboards/reports
- Key risk indicators (KRIs)
- Key performance indicators (KPIs)
- Process automation

People
- Roles and responsibilities
- Skills and training
- Performance management and Compensation

Governance
- Oversight committees (i.e., Board, Enterprise Risk Management, Operations Risk)
- Tone and culture
- Group involvement (Procurement, Business Compliance, Legal, Finance)

Policies and Procedures
- Standard setting
- Policy management

Process
- Planning and strategic sourcing
- Risk assessment, initial due diligence and selection
- Contracting
- On-going diligence & monitoring
- Auditing
- Renewals
- Off-boarding

TPRM integrated approach

On-boarding

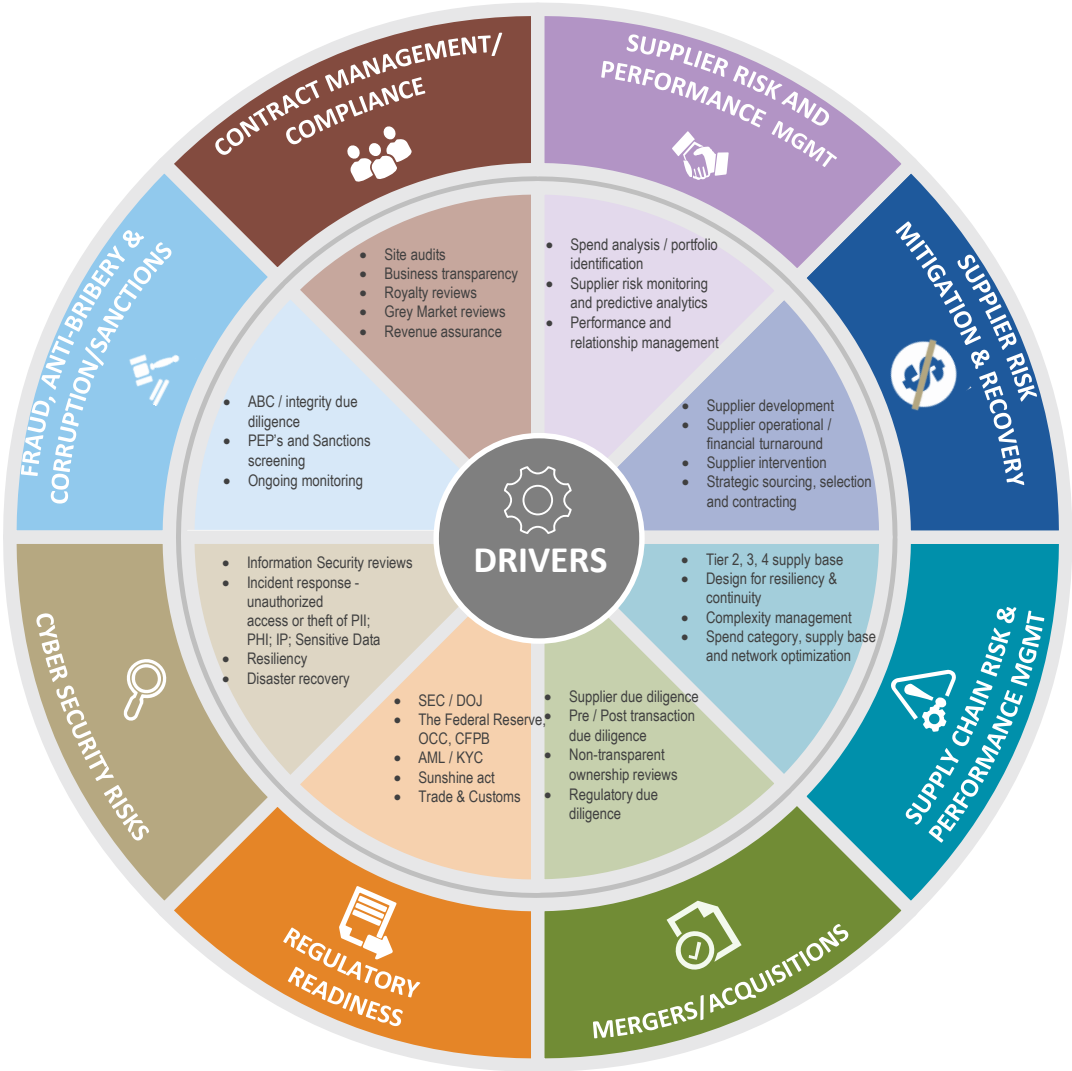
- Should we start doing business with these Suppliers?
- How do we ensure red flags are addressed?

Supplier performance, visibility and risk mitigation

- Do we know all our 3rd parties and what they do for us?
- Are we getting what we signed up for and/ or contracted?
- Do we know when a 3rd party's risk profile changes so we can take action?
- Are we tracking critical corrective actions?
- Are we managing the end to end process and sharing risk info?
- Should we keep doing business with these Suppliers?
- Do business relationship owners & employees understand specific supplier risk and mitigation expectations?

Off-boarding

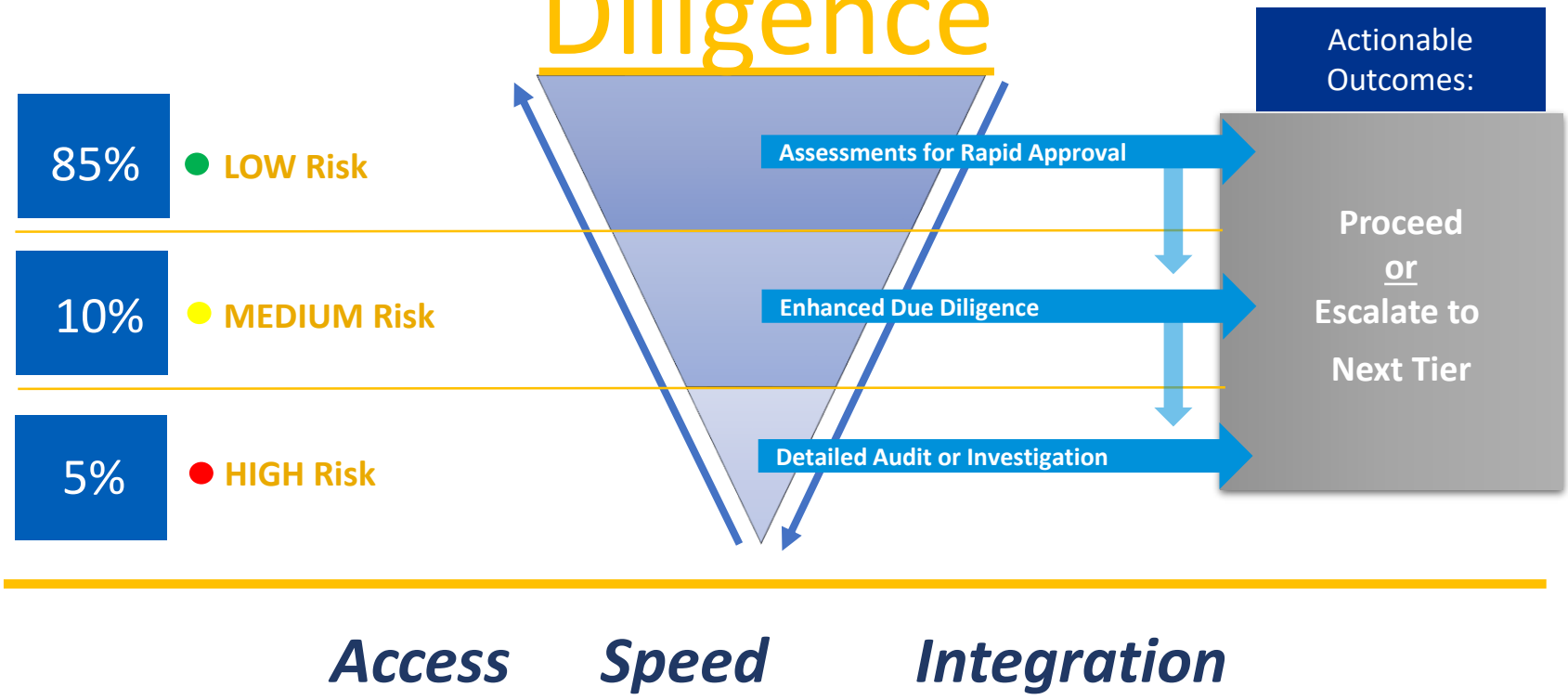
- How do we end a relationship once determined appropriate?



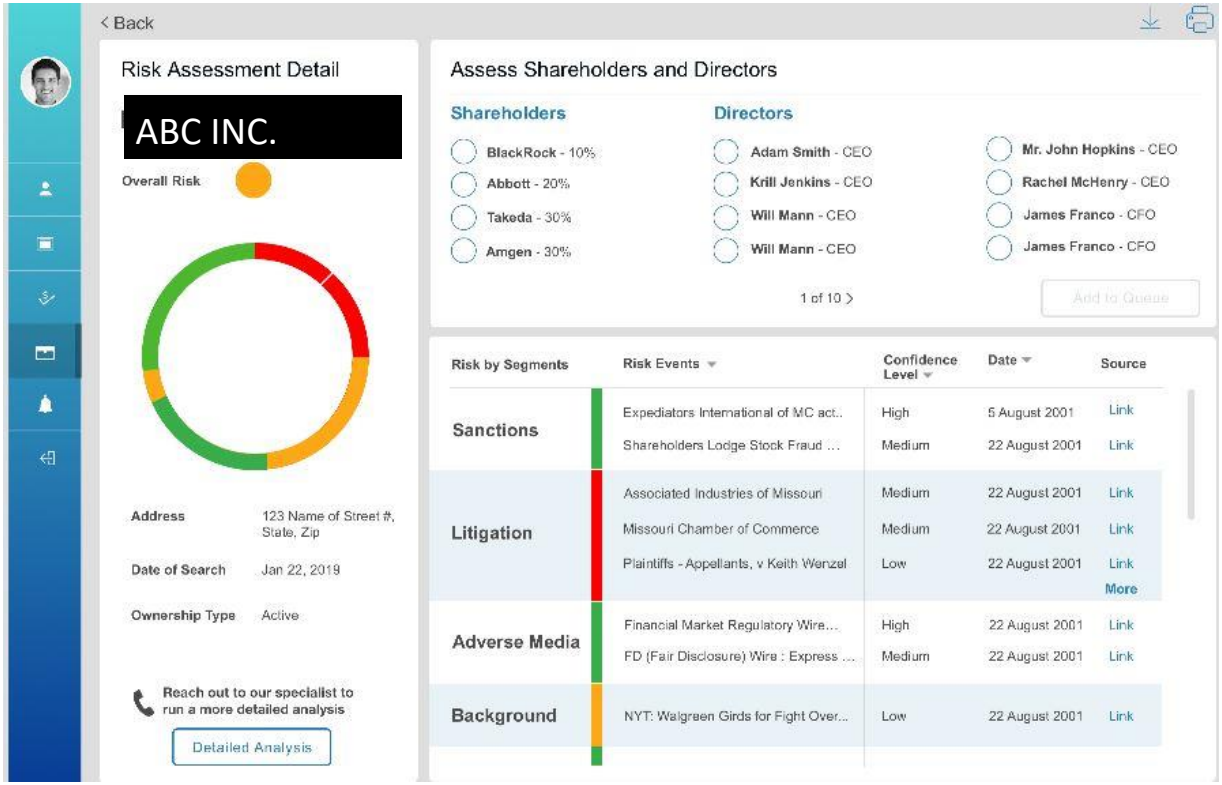
Third Party Risk Management

Technology Enablement

A Unified Approach to 3rd Party Due Diligence



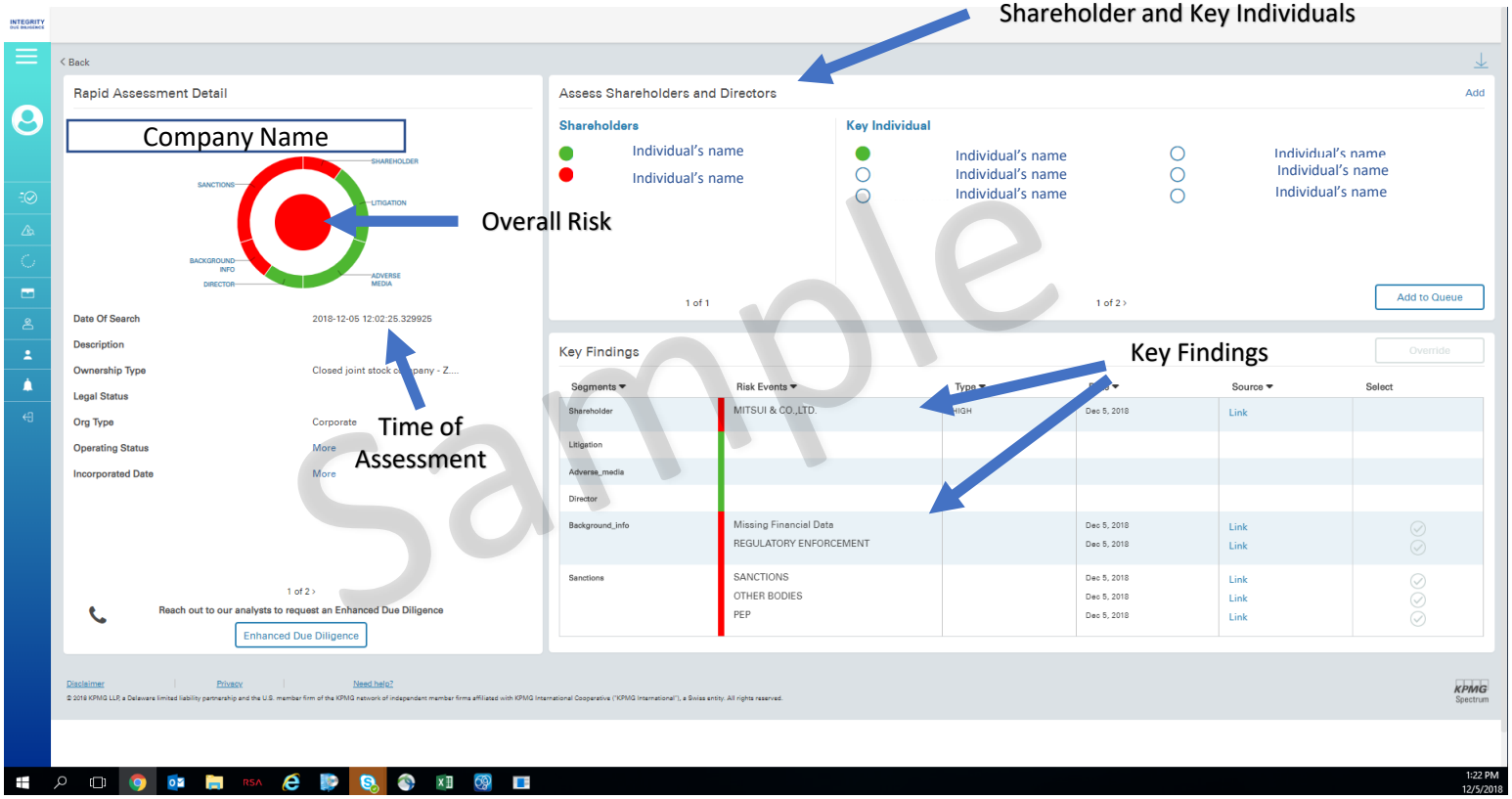
Integrity due diligence – Rapid assessment



Easy to interpret findings

Third Party Risk Dashboards

For Demonstration Purposes Only



KPMG

Enhanced due diligence

Ownership Conflicts

- **Foundations, Partnerships**
  e.g., Is there a conflict of interest?
- **Shareholding**
  e.g., Major competitor is large shareholder of key supplier
- **Deceptive Ownership**
  e.g., False business history, PO Box
- **Hidden Ownership**
  e.g., Organized crime group has a stake

Ethics Violations

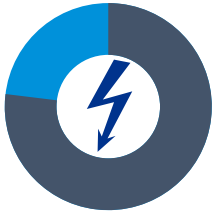
- **Regulatory Violations**
  e.g., Sanctions and fines
- **Scandal**
  e.g., Adverse media
- **Business Practices**
  e.g., Child labor, Kickbacks
- **Litigation**
  e.g., Multiple lawsuits with questionable outcomes

Leadership Conduct

- **Politically Exposed People**
  e.g., government touchpoints
- **Beneficial Ownership**
  e.g., Connection to money laundering
- **Directorships**
  e.g., Board member of conflicting organization
- **Track record/Experience**
  e.g., Falsified CV, financial statement misconduct

Did you know?

77%



Of global organizations have **experienced significant disruptions** in their supply chain in a two year period.

Yet only

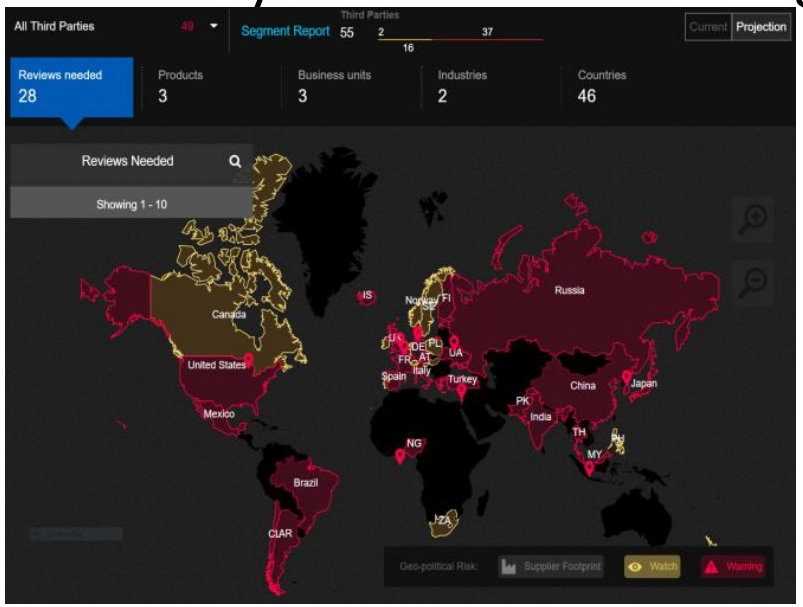
40% conduct risk assessment sporadically or only **after occurrence** of a big risk event.

65% have **poor visibility** into risk factors among Tier 2 to Tier n suppliers.

30% consider their cross-functional collaboration as **inadequately effective.**

Source: APQC Supply Chain Disruption: What Your Organization Should Know About Managing Risk in the Supply Chain

Viability risk monitoring



- See urgent threats, receive warnings of suppliers at greatest risk
- Shows which active threats impact the current and future vulnerability of the supplier;
- ‘Rewind’ feature to check past activity.

Contract performance management

Manage Performance

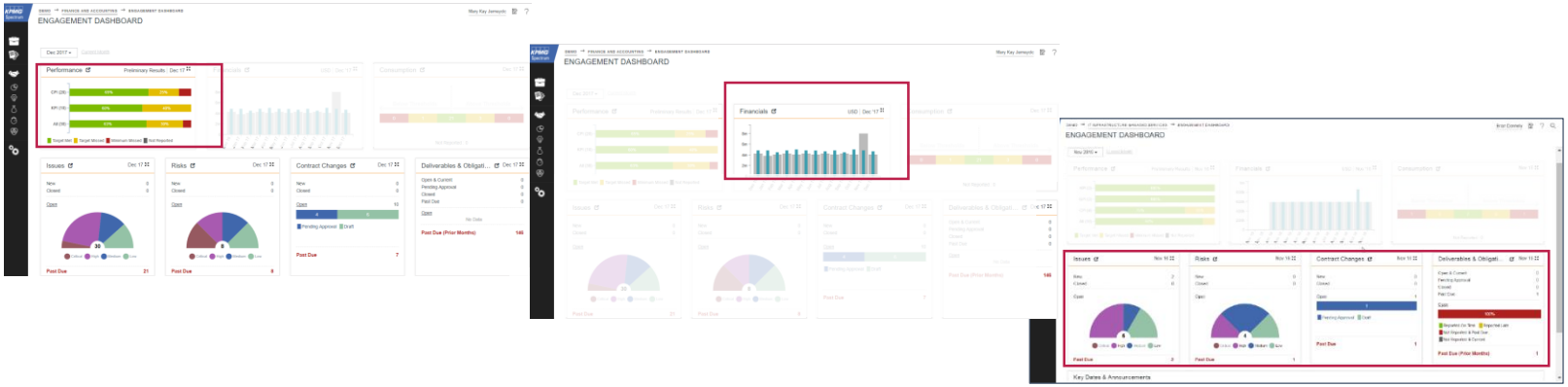
- Track performance trends & align to business requirements
- Manage service and service level changes
- Analyzes data and provides alerts to potential problems
- Define custom workflow to escalate by issuer type

Manage Financials

- Manage service credits and earn backs
- Facilitate financial reporting and supplier spend
- Verify services consumption & invoice details

Manage the Agreement

- Track and Escalate compliance with contract deliverables and obligations
- Clarify contract language for service users
- Manage work orders and contract changes



Key Takeaways

- Understand the role played by the third party
- Understand and monitor compensation
- Review and revise engagement terms
- Understand risks in the relationship
- Build controls to contain the risk
- Cultivate culture where concerns are elevated
- Update agreements to reflect expectations
- Resolve “red flags” in responsible ways
- Impose appropriate sanctions where warranted
- Leverage technology for better insights and planning
- Continuous improvements!