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Advanced issues in third party relationships: cross-border engagements, fair market value, monitoring and auditing of on-going relationships

May 11, 2016

Disclaimer

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Introducing the panel (I)

- Ela Bochenek, Esq.
  Vice President, Global Compliance, Insmed Incorporated, Bridgewater, NJ, USA
  - Pre commercial biotech company – Chief Compliance Officer
  - Before this she was at Shire, CR Bard, BMS, and Schering
  - In her job she has managed international relationships, conducted vendor due diligence, screened HCPs / consultants, managed anti corruptions process for 20 years.
  - Currently interviewing vendors for due diligence
- Maria Teresa Rico Perez, MD**.** Europe and Canada Regional Compliance Officer, Biogen, Zug, Switzerland
  - Biogen compliance EU and Canada
  - Merck EMEA compliance
  - Managing director for Schering in Greece
  - Medical Doctor as a background
  - Experience in FMV, Sales and Marketing ABAC, broad scope. TP into identifying risk levels for TP depending on type of work, and FMV for third parties. Develop a TP intermediary approach, using risk profiles.

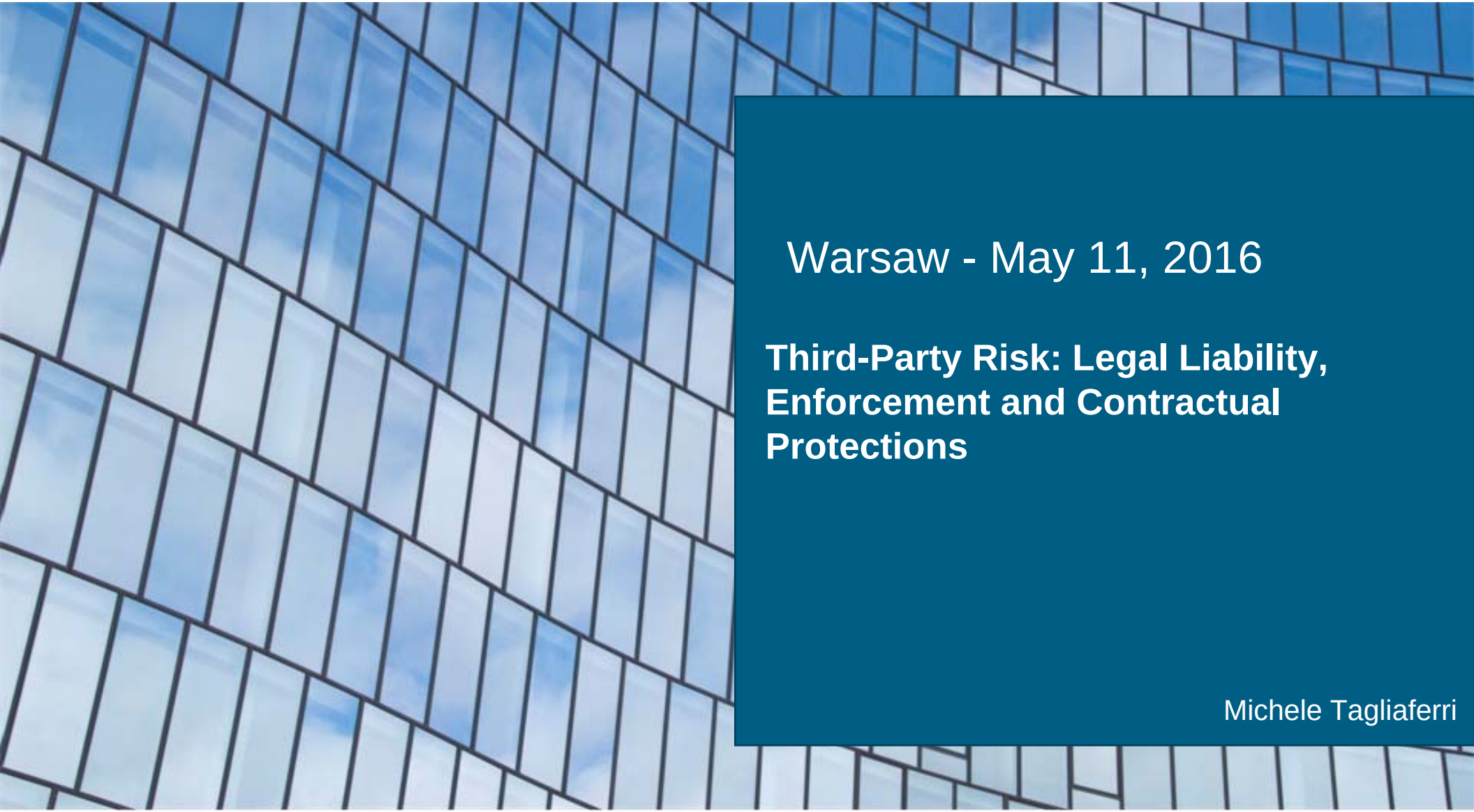
Introducing the panel (II)

- Michele Tagliaferri, Esq. Partner, Sidley Austin LLP, Brussels, Belgium
  - Michele Tagliaferri leads the investigations and compliance team. He represents corporate and individual clients in white collar matters, government enforcement actions and internal investigations involving a wide range of issues, including matters arising under the FCPA and other anti-bribery laws, data privacy legislation, and life sciences regulations.
- Mirjam Weiss, Esq. Senior Director, Head of Compliance EMEA, Merz Pharma GmbH & Co. KGaA, Frankfurt, Germany
  - Head of compliance EMEA region at Mertz, little over a year
  - Before this at Siemens in Munich, developing business partner process
  - Currently to translate business partner program and standards into Merz, needs to be workable from an internal perspective for a smaller company (for my colleagues)
- Andy Bender, MS, MBA**.** President and Founder, Polaris, New York, NY, USA (Moderator)
  - Run a global compliance consulting and technology firm
  - Covering topics from FMV, to Third Party Assessments, to aggregate spend collection and reporting

Topics to cover

Issues in third party relationships: cross-border engagements, fair market value, monitoring and auditing of on-going

- *Covering the legal framework around managing risks, and contractual implications - Michele*
- *Due diligence process, covering the methodology and process - Ela*
- *Cross Border engagements - Ela*
- *Monitoring and auditing; Validation of risk and monitoring risks - Miriam*
- *Fair Market Value of payments – Maria Teresa*
- *Internal process, who owns this? – Andy ask the Panel*



Warsaw - May 11, 2016

Third-Party Risk: Legal Liability, Enforcement and Contractual Protections

Michele Tagliaferri

SIDLEY AUSTIN LLP
SIDLEY

Third-Party Liability: Legal Bases

- Under most anti-bribery laws, corrupt payments made by third parties can be imputed to the company under various legal theories:
  - FCPA Third-Party Liability Provision
  - Section 7 of the UK Bribery Act
  - OECD Anti-Bribery Convention and Other National Implementing Laws

Third-Party Liability: Enforcement

- Increased Enforcement Focus on Third Parties

  – "About 60% to 70% of the SEC's FCPA actions involve third-party intermediaries - payments to agents who then pass money to government officials." (*Kara N. Brockmeyer, Chief of the FCPA Unit at the SEC, December 2013*)

  – Intermediaries were involved in 3 out of 4 foreign bribery enforcement actions conducted by OECD countries from 1999 to 2014 (*OECD Foreign Bribery Report*).

  – "The biggest issues in FCPA enforcement right now are third-party intermediaries […] I am amazed to see companies enter into arrangements with third parties to get business without knowing anything else about that third party." (*Kara N. Brockmeyer, Chief of the FCPA Unit at the SEC, February 2014*)

Third-Party Compliance

To avoid third-party liability, companies are expected to have effective controls for all phases of their relationships with intermediaries and business partners:

– Pre-Engagement: Due Diligence

– Engagement: FMV and Contractual Representations and Warranties

– Post-Engagement: Training, Monitoring and Auditing

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Questions

- **Third-Party Risk: Legal Liability, Enforcement and Contractual Protections**
  - Enforcement Risk
    - Third-Party liability is a well known risk under the FCPA. Are there cases based on the conduct of third parties also under the UK Bribery Act?
      - Under other laws?
    - What type of third parties are particularly high-risk for pharma and medical device companies?
  - Managing Third-party Liability Risk Through Contractual Clauses
    - What kind of clauses should be included in contracts with third parties?
      - Best practice? Expectations of authorities?
    - How important is it to have audit clauses?
      - Can self certifications replace audit clauses?
      - What is the push back you have been getting?
    - Are there legal differences to consider in different parts of the world?

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Ela Bochenek
Importance of Third Party Due Diligence – SEC has stated its focus

- "A healthy compliance program should also include third-party agent due diligence. In addition to using third-party agents, many pharmaceutical companies use distributors. This creates the risk that the distributor will use their margin or spread to create a slush fund of cash that will be used to pay bribes to foreign officials. Because of this added layer of cash flow, companies frequently improperly account for bribes as legitimate expenses.

- To properly combat against these abuses, a compliance program must thoroughly vet its third-party agents to include an understanding of the business rationale for contracting with the agent. Appropriate expense controls must also be in place to ensure that payments to third-parties are legitimate business expenses and not being used to funnel bribes to foreign officials."

Andrew Ceresney, Director, SEC Division of Enforcement, 2015 (emphasis added)

Hypothetical 1: Due Diligence - How Not to Get Overwhelmed

- I am updating our compliance program to require that specified due diligence be conducted on company distributors. Our Company has 500 existing distributors. Do I need to go back and conduct due diligence on all 500?
- In some markets, the business clients have worked for years with large publicly-traded companies as their only distributors. Do they need to conduct full-blown due diligence on their distributors?
- May I rely on outside resources to conduct due diligence on my distributors, or must I conduct all due diligence internally?

How do you streamline and prioritize your due diligence process?

How do you have a robust yet realistic due diligence process?

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Hypothetical 2: Experienced Regulatory Consultant Dilemma

- You are interested in expanding your Company's operations into Russia. You contact a friend at another reputable pharmaceutical company who does business there and ask her if she knows of any consultants who can help lay the ground work for gaining regulatory approval with the Ministry of Health. Your contact provides you with a name of a consultant who has worked in Russia for over 25 years and has great contacts within the government.
- You meet with the consultant. She says that she can guarantee you regulatory approval within two years, which is one year quicker than you anticipated. When you discuss fees, the consultant requests a substantial up-front payment (an advance). However, the consultant insists that the remaining part of her fee only needs to be paid if and when the drug gets regulatory approval.

Does this situation raise any FCPA concerns?

What due diligence questions do you need to ask before you can approve this engagement?

Hypothetical 3: The Creative Distributor

- Company engages a distributor in Greece. The distributor works with many other reputable pharmaceutical companies from around the world.
- As part of Company's global pricing strategy, it seeks to keep the listed price of its drug at a certain amount. The distributor understands, and insists that it will pay list price for the drug. In return, distributor asks that Company deposit in the distributor's foreign bank account a certain amount of money for each unit of the drug sold. The distributor does not have any other business in the country in which it maintains this bank account.
- Company's payment, the distributor insists, will act as a discount while enabling the company to keep a high list price for its drug.

Does this type of arrangement raise any FCPA concerns?

What due diligence is needed to address the red flags in this scenario?

Business Partner Compliance

Monitoring and auditing - Validation of risk and monitoring risks

Dr. Mirjam Weisse, Head of Compliance EMEA
Merz Pharma GmbH & Co. KGaA

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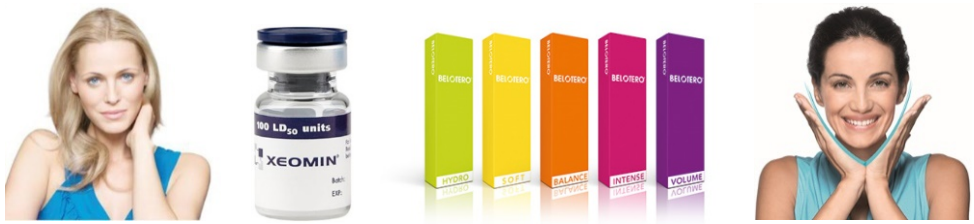

Objectives of Business Partner Monitoring and auditing: Validation of risk and monitoring risks

- Minimize business risks
- Continuously evaluate risks
- Project upcoming risks for the future
- Prevent third party misconduct
- React to misconduct and mitigate negative effects
- Prevent penalties and fines
- Protect company reputation
- Optimization and harmonization of internal processes
- Appropriate documentation

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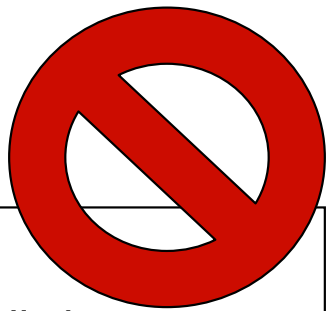
Center Pieces of BP - *Monitoring and Auditing*

Do you STILL know your business partner?

Continuous Monitoring	***/ Regular Audit***	***/ Audit with cause***
Performance	***Contract***	***Areas of Concern***
Deviations	***Documentation***	***Allegations***
Sanity Checks	***Spot tests***	***Investigation***

Red Flags that may indicate a requirement for an extraordinary audit:



- Conceptual Changes in the Cooperation (e.g. Consultant to Distributor)
- Abrupt changes in contract execution (e.g. sudden demand for confidentiality)
- Continuos problems in the cooperation / findings in regular audits
- Allegations of misconduct.

Questions for discussion

- **Responsibilities for Audit?**
- **Who exercises Audits?**
- **Responsibilities for follow up?**
- **Findings: Remediation or Termination?**
- **Integration of Compliance improvement – adaption of due diligence process?**
- **Continuous Risk Assessment – how to?**
- **Performance Assessment as part of the Audit?**
- **Business Partner Database adjustments?**

The opinions and analysis expressed in this presentation are solely those of the presenter and not necessarily those of Merz Company Group.

Hypothetical 4: The Well Connected Distributor

- Company just started doing business in Italy. It is trying to find a reputable distributor that will reliably distribute the drug throughout the country.
- Company interviews one distributor that has a great reputation but is demanding a steep discount of 30% off the price of the drug. All other pharmaceutical distributors in Italy would be satisfied with little to no discount. After conducting a little due diligence, there is no indication that the distributor has been involved in any FCPA investigations, but you learn that the company has no experience distributing pharmaceuticals. That said, the new president of the distribution company used to work at the Italian Ministry of Health.

What compliance risks does this information present?

What sort of additional diligence would need to be done for you to feel comfortable using this distributor?

Ela Bochenek

Risks in Cross Border Transactions – View from the SEC

- "A few factors combine to make [pharma] a high-risk industry for FCPA violations. Pharmaceutical representatives have regular contact with doctors, pharmacists, and administrators from public hospitals in foreign countries. Those people often are classified as foreign officials for purposes of the FCPA, and they often decide what products public hospitals or pharmacies will purchase. This influence over the awarding of contracts is true for virtually every country around the globe."

- "The best way for a company to avoid some of the violations that I have just described is a robust FCPA compliance program."

- "The best companies have adopted strong FCPA compliance programs that include compliance personnel, extensive policies and procedures, training, vendor reviews, due diligence on third-party agents, expense controls, escalation of red flags, and internal audits to review compliance."

Andrew Ceresney, Director, SEC Division of Enforcement, 2015

Hypothetical 5: The Expert on the Other Side of the World

- Company is sponsoring a local medical conference in Croatia that focuses on serious lung infections. The organizers of the conference are looking to find a KOL to give a short talk about your new pulmonology product which has been effective in treating a rare form of lung infections.
- Company is considering paying for an international KOL to fly from Australia to Croatia to give remarks on the subject. There are some regional KOLs in Croatia who may be able to speak about your pulmonology product, but none of them are as knowledgeable or as connected to serious lung infections research as the KOL from Australia.

Should the company pay for the Australian KOL to speak at the conference?

Does this situation present any compliance risks?

Hypothetical 6: The Well Travelled HCPs in Need of Learning

- Your Company would like to sponsor three HCPs in Romania, with whom the company has developed good relationships, to attend a large pulmonology congress in the United States. These three HCPs also happen to have the greatest number of Cystic Fibrosis patients in the country.
- You have heard rumblings that if your company does not sponsor the three HCPs to attend the congress, the HCPs will be less inclined to prescribe your product in the future because, without potentially gaining more insight about the drug at the congress, they don't feel sufficiently educated about the product to prescribe it. The congress will be in Europe next year.

Does the potential sponsorship of the three HCPs raise any compliance concerns?

What additional information would you like to gather prior to making a decision on whether to approve the sponsorships?

Fair Market Value

Maria Teresa Rico
EU/Canada Regional Compliance Officer
Biogen

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THE RISK

- Compensation relationships between pharmaceutical manufacturers and physicians may implicate the federal Anti-Kickback Statute (AKS) (1) if compensation is more than nominal in value and exceeds the fair market value.

- ...notwithstanding that there may be other ostensibly legitimate purposes for which arrangement have been entered, a compensation arrangement may violate the AKS if just one purpose of the arrangement is to induce or reward referrals.

(1) OIG Special Fraud Alert: Prescription Drug Marketing Schemes (issued Aug. 1994), republished at 59 Fed. Reg. 65372, 65376 (Dec. 19, 1994).

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Approaches to FMV determination

- 1. The Market Approach
- 2. The Cost Approach
- 3. The Income Approach
  - THE MODIFIED MARKET APPROACH

1. The specific requirements & nature of the duties associated with the consultants expected services.
2. The specific skills and unique qualifications that a specific physician may bring to a consulting position.
3. The extent of the time requirements that are associated with the contemplated position (4).

(4) Andrea M. Ferrari. *Determining " Fair Market Value" for Physician Consulting Services: The New "Big Question" for Life Sciences Companies.* Life Sciences. A publication of the American Health Lawyers Association Life Practice Group- Vol. 3- Issue 1- April 2009

Factors to Consider When Employing The Market Approach Methodology

- A. <u>Factors Specific To The Consulting Services</u>
  - Specific duties and responsibilities
  - Specific objectives and deliverables
  - The expected or required allocation of time (hours) for each duty
- B. <u>Factors specific to the physician who will provide the consulting services.</u>
  - Educational credentials and specialized training
  - Professional certifications
  - Leadership experience
  - Academic appointments
  - Research experience
  - Invited presentations
  - Publication history
  - Reputation in the community

Making FMV a defensible framework. Key elements (5)

Legitimacy of business relationships and framework of engagement

Bonafide business need

Identify activities required to perform the service

Selection criteria for consultant engagements

Components of FMV fee ranges

Confirming service is performed

How all this elements are put together is what may vary in the different companies
that are building their FMV processes.

(5) S. Rothenberg. *Defending Fair Market Value Assessments.* *http://*pharmaceuticalcommerce.com

Questions to the Audience

1. Does your company have a FMV process standard across the organization?
    1. Yes
    2. No
2. What elements do you use to calculate FMV? : (see elements in the right hand side)

    1. Both from A and B elements
    2. Only elements from A
    3. Only elements from B
    4. None of the ones highlighted on A and B

y

3. Who in your company calculates FMV
    1. Activity Owner
    2. Events / Meetings Department
    3. Compliance Department
    4. Other

ELEMENTS FOR FMV CALCULATION

A. Factors Specific To The Consulting Services

- Specific duties and responsibilities
- Specific objectives and deliverables
- The expected or required allocation of time (hours) for each duty

B. Factors specific to the physician who will provide the consulting services.

- Educational credentials and specialized training
- Professional certifications
- Leadership experience
- Academic appointments
- Research experience
- Invited presentations
- Publication history
- Reputation in the community

Questions (I)

- **Due diligence process; covering the methodology and process**
  - Process for determining risk levels
  - Information you review, analyze
  - Different levels of risk
  - Process for review and follow up

- **Monitoring and auditing; Validation of risk and monitoring risks**
  - How do you decide which third parties to select for monitoring?
  - What are the keys to planning a third party audit?
  - Third party resources used vs in-house
  - How to set up an audit?
    - What is push back? Who pays for this?
    - What things do you check for?
  - Self certification vs audits or boots on the ground?

Questions (II)

- **Covering the legal framework around managing risks, and contractual implications**
  - Managing risk through a legal framework – what to include in contracts – trends?
    - Audit clauses?
    - Verification of audit clauses? Self certifications?
    - What is the push back you have been getting?
    - Who pays?
  - Legal and contract differences in different parts of the world?

- **Fair market value payments**
  - HCPs:
    - Describe FMV process and methodology?
    - FMV for HCPs
  - HCOs:
    - What are challenges for FMV for HCOs? How do you address these challenges
    - Do you have different risk levels? Which and how do these impact the process?

Questions (III)

- **Cross border engagements**
  - HCPs:
    - How do you manage cross border engagements? Can you please describe the process?
    - Who is responsible for cross border engagements?
    - What are risks? And what are recommendations?
  - HCOs
    - How do you conduct due diligence?
    - What services do you use, to conduct background checks?
- **(Optional) Management processes and buy in Internal processes, and internal allocation of resources?**
  - Who owns this process – compliance or sourcing or the business?
    - Have companies been investing in resources?
    - How has the process been evolving- what are the major changes?
  - Priority of compliance risk vs long term relationships the business has
    - How so you handle a process where business wants and compliance risk ir too high?

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