TRACE Forum 2012

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“En guerra avisada no muere gente”

Old Spanish proverb

What are “Industry Sweeps”

- Both SEC and DOJ are conducting “industry sweeps”(generally SEC led)
- Trigger could be information about FCPA violations by a company (could be tied to specific regions) which could reflect patterns in the industry sector
- Companies in same industry segment may receive “inquiry letters” or subpoenas
- It may mean USG might have received information on you…or might be “fishing”

Known Industry Sweeps

- **Known or suspected industry sweeps**
  - **Medical Device Industry**
  - **Life Sciences**
  - **Financial Industry**
  - **“Hollywood”**
  - **Retail**
  - **Oil & Gas**
- **Possibly started circa 2005/6**

DOJ Countries of Interest

DOJ particularly interested in:

- **Italy**
- **Greece**
- **Vietnam**
- **“anywhere in Eastern Europe”**
- **Indonesia**
- **Pakistan**
- **Brazil/Mexico**
- **China**

What the “sweeps” focus on

- **Recent settlements indicate government focused on these areas**
  - **Use of third party agents**
  - **Successor Liability**
  - **Liability for acts of foreign subs**
  - **Expansive notions of “government official”**
  - **Extra-Territoriality**
  - **FCPA as predicate crime for AML**
  - **Systemic excessive gifts/entertainment**

Why be concerned?

- The sweep may involve a “cooperating” company who may provide information about competitors
- When caught in ‘the cross hairs’ your company will not know if the government has information about your company or if the government is looking to identify patterns of wrongdoing

Some things to consider if your industry sector is subject of a sweep

- **Even if you haven't received a letter of inquiry or subpoena**
  - **Involve your GC**
  - **Brief the Board/Senior Management**
  - **Appraise business unit/regional teams**
  - **Consider**
    - **Document preservation notices**
    - **Suspension of routine document/email destruction**
  - **<u>Prepare a detailed plan to assess the effectiveness of your compliance program</u>**

Where to look for guidance

"Although the increasing number of FCPA trials provides more opportunities for courts to define the contours of a statute often criticized as vague, companies are largely left to find their way through FCPA traps by studying the enforcement actions already brought by the SEC and the DOJ and the opinion of the Justice Department sought through the opinion release process."

Arnold & Porter LLC FCPA & Global Anti-Corruption Insights
Winter 2012

Start with the basics

- Essential Elements of a Compliance Program from the US Sentencing Guidelines
- OECD Good Practices
- UK Bribery Act Six Principles
- Study recent settlements in your industry sector
- Pay particular attention to “Attachment C” (including “enhanced compliance obligations)

Prepare the Work Plan

- **Key Components**
  - **Compliance Assessment**
    - **Is your program "proportionate to the bribery risks faced"?**
    - **How well do you understand your bribery risks?**
    - **What are some risk elements to consider?**
      - **Company's geographical organization/how is the business managed**
      - **How and by whom do you interact with governments and officials/Use of 3P's**
      - **Risks inherent to your industry sectors**
      - **Employee training levels, skills and knowledge**
      - **Compensation and rewards culture**
      - **Existing policies and financial/operational controls**
  - **Risk Based Assessment**
  - **Analyze Assessment Work**

    } Consider independent assessors
  - **Identify Program and Process Enhancements**

A good offense is the best defense

- **Don't wait for DOJ/SEC meeting to address your risks and enhance your program**
- **Govt. does <u>not</u> want to hear about what you plan to do**
  - **"Have you implemented, monitored and tested an effective compliance program appropriate to your business' risks"**
  - **If you discover an issue don't claim the rouge employee defense—unless you truly absolutely have a "Morgan Stanley" defense**
  - **Be honest about your business challenges. The Government has become incredibly well versed about what is going on around the world**

Benefits of a good “offense”

- **If you had a strong pre-existing program when violations are discovered, you greatly improve opportunity for a NPA (Morgan Stanley)**
- **If you are move promptly and display exemplary cooperation you may earn Significant Discounts of 20-30% from the bottom of the Guidelines range for “extraordinary” cooperation and remediation**

Life Sciences Case Study

Example: Pharma/Medical Equipment

- **Broad sweep has snared major players in global pharma/devices**
  - **Pfizer**
  - **Merck**
  - **Astra Zeneca**
  - **Teva Pharmaceuticals**
  - **Bristol Myers Squibb**
  - **Glaxo Smith Klein**
  - **Johnson & Johnson**

Life Sciences: What is the government looking for?

- Screening and monitoring foreign third parties
- Interactions with doctors ("pay to prescribe")
- Compliance procedures and internal controls
- Travel, gifts, entertainment and hospitality
- Clinical research
- Advisory Boards
- Grants and doctor sponsorships

Risk Areas Life Sciences "Sweep"

✓ Specific DOJ areas of concern

- Approval of Products
- Scientific Research (inc. Clinical Trials; Investigator Initiated Trials)
  - "sham" investigations
- Pay to Prescribe
- Tenders/Bid Rigging
- Charitable Contributions
- Lavish Gifts/Entertainment (if systemic)
- Discount programs
  - Using significant discounts to disguise corrupt payments
- Consulting Contracts (with "Key Opinion Leaders")
  - No legitimate deliverables or output
- Collusive Vendors (including Travel Agents)
  - Fake congresses and conferences; elaborate fake invoicing and documentation
- Educational/Conference Sponsorships (fake conferences; incentives)
- Third Party Due Diligence

Example of a Life Sciences program

- Anti-Corruption Policy addresses risk associated with marketing, approval, licensing, importation and reimbursement of drugs
- Enhanced procedures for 3P diligence and approval
- Detailed procedures with FCPA checklists for HCP courtesies, engagements and sponsorships
- Training for key stakeholders and functions (marketing, donations committee, clinical trials, etc.)
- Annual face to face meetings and training of 3P's
- FCPA testing plan for internal audit
- Creation of high level review board

How “sweeps” and enforcement impact compliance programs

- Helps get the message across: Jail sentences and multimillion dollar settlements are real, not hypothetical…from the BOD and senior management all the way to line employees
- Drives more focused risk assessment by understanding what the DOJ/SEC pressure points are
- Changes perception that only US companies are prosecuted
- Improves training: no more hypotheticals; lots of real and interesting cases get the audience engaged
- Better/ more robust business processes; e.g. every company should have/improve procedures for vetting third parties
- Supports the mission of the Compliance Department…helps preserve key resources during tough business cycles
- Validates what compliance has been “saying” all along

Summarizing the Developing Elements of a Compliance Program

Building upon Sentencing Guidelines principles, settlements have provided guidance on components of an effective compliance programs

Key aspects / <u>best practices</u> of an effective program include:

- ✓ Corporate risk based assessment and tailored programs
- ✓ Anti-corruption policies, standards, procedures
- ✓ Financial and accounting procedures and controls
- ✓ Tone from the top; oversight by senior executives with authority/independence
- ✓ Adequate anti-corruption compliance resources
- ✓ Training, certifications, and communication
- ✓ Third Party Management Program
- ✓ Contractual representations and warranties
- ✓ Whistleblower reporting and anti-corruption advice mechanisms
- ✓ Pro-active audits and program reviews
- ✓ Investigation and disciplinary procedures