

Preparing for Liquidity

Compliance Issues to Consider

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Why does Compliance Matter?

Legal Mandates

Risk Mitigation

Sentencing Guidelines

Liquidity Event Preparedness

Anatomy of a Transaction

- Unsolicited Inquiry *or* “Process”
- NDA & Preliminary Diligence
- Letter of Intent
- Due Diligence
- Negotiation of Transaction Documents
 - Representations and warranties
 - Holdback
 - Schedule of Exceptions
 - Announcement
- Closing

Legal Risks

- AKS
- FCA
- FDCA violations
- FCPA
- HIPAA and EU Data privacy
- State Gift Bans
- Transparency Laws

Acquiring a Compliance Violation

- Kyphon (\$75M settlement by Medtronic under AKS, FCA)
- Orphan Medical (\$20M settlement by Jazz Pharmaceuticals)
- Acclarent (2012 subpoena after acquisition by J&J)
- Eisai (\$11M settlement re Zonegran; Elan paid \$203M).
- Depuy (\$70M settlement by J&J)
- Orthopaedics GmbH (\$22M FCPA settlement by Smith & Nephew)
- Wyeth (\$784 M settlement by Pfizer for pre-acquisition Medicaid rebates)

Smaller Companies in the Crosshairs

DOJ Settlement	Allegations
Endogastric Solutions 2014 - \$5.25M	Caused submission of claims under improper reimbursement codes Improperly paid physicians for participating in patient seminars and co-marketing arrangements to induce product use
Baxano Surgical (Trans1) 2013 - \$6M	Caused submission of claims with incorrect diagnosis and reimbursement codes Used speaker programs and consultant meetings to pay kickbacks
DFINE 2011 - \$2.3M	Paid physicians for UPEs (User Preference Evaluations) and provided lavish travel, meals, entertainment as inducements
Micrus Endovascular 2005 - \$450,000	Violated FCPA by granting stock options and paying sham consulting fees to European physicians to induce them to use products

Risks to Seller

- Delay of Transaction
- Reduction in Valuation
- Increased Escrow Holdback to cover potential exposure
- Increased Legal and Audit Fees
- Cancellation of Transaction

Interactions with HCPs

- Payments
- Physician Consulting Arrangements
- Grants
- Stock and Stock Options
- Transparency Reports
- Promotional Materials

Overseas Interactions

- Payments to Government Officials
- Subsidiary Books and Records
- Use of third Party Intermediaries
 - Screening
 - Training
 - Financial transactions
 - Monitoring & Auditing

Promotional Materials

- Promotional Materials
- FDA correspondence
- Website, Advertisements, Social Media
- Sales training materials and tools
- Quotas and sales incentives

Physician Ownership

- Media scrutiny (Atricare, FoxHollow)
- PODS – 2013 OIG Special Fraud Alert
- Sunshine Act Disclosure (private companies)
- Hospital Policies
 - In 2014, HCA implemented a policy barring purchase of drugs, biologics or implants from privately-held companies with any physician ownership
 - Policy softened somewhat after company and physician outcry, remains stringent
 - Other hospitals have implemented similar policies

Micrus Endovascular

- Private, San-Jose based device company with approximately \$25 million in revenue
- In diligence for IPO, underwriters' counsel identified questionable payments to French physician
- Investigation revealed additional questionable payments
- IPO delayed 9 months pending investigation and settlement with DOJ
- Settlement imposed 3-year monitor, \$450,000 fine; millions in legal and audit fees.

How does one consulting payment derail a transaction?

- Information raises serious legal question
- Investigation reveals that incident may not be isolated
- Potential materiality mandates disclosure
- Risk of exposure requires holdback/reserve OR delay pending resolution
- If exposure is too large, deal may be cancelled
- Delay may cause value to change, or window to be missed

DOJ Guidance

FCPA Pre-Acquisition Diligence

- Allows issuer to properly value target company
- Allows issuer to shift liability to target company
- Allows issuer to integrate target company rapidly into its compliance program

--Resource Guide to the Foreign Corrupt Practices Act, p. 62

Getting Ready for Liquidity

Implement Compliance Program

- Code of Conduct
- Global policy on interactions with HCPs
- Anticorruption policy and procedures
- Process for selection of consultants, approval of grants, review of promotional materials
- Screening, training and certifications matrix
- Tracking and reporting of payments to HCPs
- Privacy policies and procedures
- Compliance and Grant Committee Charters

Document Program Activities

- Approval of Program
- Committee Charters and Minutes
- Training, Monitoring, Auditing
- Employee Screening; Third Party Diligence
- Prompt Investigation of Complaints and Suspected Violations
- Resolution and Discipline
- Whistleblower Hotline awareness and followup
- Consultant approvals, FMV assessment, Grant approvals, Payment approvals
- Contracts and Letter Agreements

Know where your documents are!

- Policies and Procedures
- Contracts with HCPs and Distributors
- Payment information
- Meeting minutes and approvals
- Training and screening records
- Audit records
- Disciplinary action and investigations

Q&A

