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Beyond the AdvaMed Code:

Compliance Challenges After Implementing the Code

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The Fine Print

The views presented by the speakers are their own and do not represent those of the respective companies.

This presentation is not intended to give legal advice. Companies should consult their own legal counsel with regard to interpreting and implementing the Code.

Compliance Beyond the AdvaMed Code

- The Code is a consensus document and represents current thinking
- Not intended to be the “silver bullet” to address every situation
- The Code is the floor, not the ceiling for compliance
- Some regulators suggest the Code is a “good start”
- Intended to be dynamic, evolving with changes in the regulatory environment

A Peek Over the Horizon

- Inclusion of practices from DPAs
- Should training and education be expanded beyond product-specific training
  - Disease state training
  - General medical education
- Guidance regarding the provision of off-label information and off-label promotion
- Direct to consumer advertising

A Peek Over the Horizon (cont'd)

- Acceptability of venues for meetings or training programs having the word "resort" or "spa" in their name
- Compliance with institutions' policies restricting what their HCPs can accept from industry
- Is there latitude in differences in implementing the Code without being out of compliance?

Challenges of Code Certification

- Within the company itself
  - Educating employees and contractors
  - Personal liability of CEO and CCO
  - Auditing and monitoring
  - Implications under state laws
  - Company-specific issues
    - Product portfolio (drugs and devices)
    - What if company or division is not a Member?

Challenges of Code Certification

- In connection with 3rd parties
- Who? Distributors, contractors, providers
- How to ensure compliance
  - Enlist management to help
  - Build 3rd party awareness / commitment to compliance
  - Training on policies and procedures
  - Document it
  - Auditing and monitoring of third party compliance
  - Response to acts of non-compliance

Longer-Term Challenges

- Trusting but verifying
- Avoiding compliance complacency
- Documenting current state of compliance

Recent Device Settlements (Partial List)

Date	Company	Resolution	Alleged Conduct
5/22/08	Kyphon	$75 million civil settlement	False claims regarding kyphoplasty
6/3/08	AGA Medical	$2 million criminal fine 3 year DPA	Self-disclosed payments to Chinese Officials (FCPA)
7/14/08	Adv. Bionics	$1.1 million CMP	Failed to notify FDA of supplier change
11/25/08	Bayer Healthcare	$97.5 million civil fine	Payments to suppliers to convert patients to company products
2/9/09	Neurometrix, Inc.	$2.5 million civil/$1.2 million criminal 36 month DPA	Provided physicians free supplies to recommend purchase of its NC-stat System
2/18/09	Cardinal Health 303	Amended Consent Decree	QSR deviations relating to infusion pumps
3/30/09	Orthopaedic Settlements	DPAs expired on satisfactory completion of their terms.	Consulting agreements with orthopedic surgeons as inducements
4/15/09	NID (Quest sub)	$302 million civil/criminal	Shipping misbranded product
5/21/09	HealthEast Care System	$2.28 million	Inappropriately kyphoplasty procedures to increase reimbursements.
7/14/09	Endoscopic Tech.	$1.4 million civil penalty	Off-label promotion; kickbacks
9/29/09	IN and AL Hospitals	$8 million	Inappropriate kyphoplasty procedures to increase reimbursements.

Device Settlements (1993-Current)

Trends and Analysis

Scope & Methodology

- Skadden analyzed 42 settlements involving medical device companies from 1993 to the present
- Medical device companies:
  - Manufacturers of medical devices (including DME manufacturers)
  - Excluded medical device providers/suppliers
- The analysis is limited to criminal settlements for FDA violations and civil/criminal settlements for healthcare violations. Not included:
  - FDA Seizures and Injunctions
  - FDA Consent Decrees
  - FDA Civil Money Penalty Settlements

Scope/Methodology (cont'd)

- Analysis included detailed review of public documents (not all readily available)
- Government documents reviewed:
  - Complaints
  - Sentencing Memoranda
  - Agreed Statements of Fact
  - Civil Settlement Agreements
  - Corporate Integrity Agreements (CIAs)
  - DoJ Press Releases (some of which were not available on line)
  - SEC Filings
- Backstopped the analysis (and filled in some gaps) with reliable press sources

Summary of Findings

- Differences between drugs and devices lead to different risks, enforcement actions
- Advertising and promotion was not the most common type of misconduct
- Over the relevant time, most cases were resolved civilly
- While fines and penalties have been modest compared to drug cases, fine amounts are increasing
- Prosecution of individuals appears more likely in device cases

Findings: Risk Areas Flow from Unique Nature of Devices

Difference	Drug	Device
Product life cycle	Long development cycle, significant changes in product are infrequent	Short product life cycle, modifications (large and small) are common
Development and approval process	Phase I-III trials, rigorous scrutiny at FDA	510(k): Modest clinical investment; modest FDA review PMA: Clinical process often less rigorous than for drugs
Relationships with Physicians	Limited, brief oral discussions in office	Often extensive, particularly for devices require training, Short product life cycle requires frequent HCP interactions
Reimbursement and Payment Systems	Generally, cost of drug is borne by health plan (gov't, private) and patient	Numerous payment systems (DRGs, HOPS), cost often borne by provider (HCP, hospital) who is reimbursed a set amount Makes cost pressures more acute

Findings: Advertising and Promotion Not the Greatest Risk

- Advertising and Promotion was **not** the most prevalent category of misconduct in settlements that were resolved for at least $5 million
  - Different than pharma settlements
- Inducements/payments and pricing/reimbursement were the most common form of misconduct
  - Underscores the role of physician relationships for device companies
- Manufacturing and quality issues were the second most common form of misconduct
  - This does not include FDA consent decrees, which typically address these issues

Findings: Most Cases Resolve Civilly for Under $100 Million

- Most cases are resolved civilly
  - 26 of 42 settlements involved exclusively civil resolutions
  - 14 settlements included civil and criminal provisions
  - Only 2 cases involved exclusively criminal resolutions
- Fine amounts are mostly under $100 million
  - 38 of 42 settlements were under $100 million in total fines
  - Remaining 4 cases involved fines of:
    - $169.5 million
    - $622 million
    - $704 million
    - $302 million

Prosecution of Individuals

- Prosecutions of individuals -- particularly executives -- appears more common in device cases
- Companies are small, management involved in daily operations
- Examples:

•CEO/Founder (Augustine)
•Chairman/CEO (Bard)
•President/CEO (AbTox)
•Executive Vice President (Bard)
•VP, Regulatory Affairs (AbTox)
•General Counsel (Augustine)
•Medicare Reimbursement Consultant (Augustine)
•Director of Marketing and Clinical Services (AbTox)
•National Sales Manager (Augustine)
•Director of Regulatory Affairs and QC (Bard)
•Director of Reimbursement (Augustine)
•President and COO (Synthes/Norian)
•Director of Regulatory and Clinical Affairs (Synthes/Norian)
•Vice President of Operations (Synthes/Norian)
•Senior Vice President, Global Strategy (Synthes/Norian)

Government Theories of Liability

- Examined 24 device settlements involving criminal and/or civil fines of > $5 million
- 1993-present
- Frequency of Misconduct:
  - Pricing and Reimbursement: 11
  - Inducements and Payments: 10
  - Manufacturing and Quality: 8
  - False Statements and Obstruction 6
  - Advertising and Promotion: 2
  - Patient Safety and/or Research: 2
- Interestingly:
  - “advertising and promotion” had fewest cases

Risk Areas Covered by AdvaMed Code	Other Risk Areas
• Company-sponsored training • Funding for 3rd party educational programs • Sales, promo, business mtgs. • Consulting arrangements with HCPs • Entertainment and recreation • Meals provided during informational presentations • Gifts • Coverage and reimbursement info • Research and educational grants and charitable donations • Evaluation and demonstration products	• Off-label promotion • Manufacturing and product quality • Medical device reporting • Discounts and pricing terms • FDA inspection issues • Patient safety

Insights and Analysis

- Device manufacturers face unique issues. As a result, off-the-shelf compliance efforts from pharma may not target the highest risk activities
- AdvaMed Code addresses some – but not all – major risk areas for device manufacturers
- Prosecutors are making good on prior statements that they will investigate the activities of individuals, particularly executives and management personnel, and are willing to bring both strict liability misdemeanor charges under the FDCA and felony charges for fraud.

Insights and Analysis (cont'd)

- Several recent enforcement actions appear to be motivated, in part, by false statements to FDA.
  - Such "flouting" of regulators can be a critical factor in charging decisions by prosecutors.
- Prosecutors have signaled an increase in *qui tam* filings premised on product quality and manufacturing issues.
- Also seeing long-predicted rise in off-label enforcement actions
- As companies raise compliance-type defenses, prosecutors are focusing on how programs worked in practice – e.g., how companies received, investigated and remedied improper conduct.
  - Compliance efforts even more important today in light of prosecution of individuals under Park doctrine

Thank You!

Enjoy the rest of the congress.