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DPAs, NPAs, CIAs
The Device Experience

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DPAs and NPAs: The Basics

- Essentially contractual agreements to resolve criminal investigations
  - Developed to avoid drastic and disproportionate impact of criminal prosecution/conviction, e.g. Arthur Andersen
  - Used initially in connection with financial crimes, but since extended to other areas such as FCPA
  - Limited use in traditional health care prosecutions other than in the District of New Jersey
    - Orthopedic implant cases involved extensive reliance on NPA/DPA model
    - Orthopedic cases provide best insight into how DPAs might work in a health care context

DPAs and NPAs: The Basics

- Form and content highly variable
- Morford Memorandum (March 2008) identifies nine principles to guide the use of DPAs
  - Issued in response to criticism about the selection process for monitors
  - Addresses selection, scope, oversight, communications, reporting of misconduct, duration
- 2009 GAO report questioned whether the 2008 guidelines were being consistently applied
- Grindler Memorandum (May 2010) articulates additional principle relating to the role of DOJ in resolving disputes with monitors

The New Jersey Experience
Orthopedic Implants

- 5 Companies Account for Nearly 95% of Market
  - Zimmer, Inc.
  - DePuy Orthopaedics, Inc.
  - Biomet Inc.
  - Smith & Nephew, Inc.
  - Stryker Orthopedics, Inc.
- 2 other companies – Wright Medical and Exactech – have a small but growing share

The New Jersey Experience
Orthopedic Implants

- More than 700,000 total hip and knee replacement surgeries performed in U.S. each year (HHS)
- Approximately 2/3 of implant patients are Medicare beneficiaries
- Physicians control selection of devices but typically do not bear the cost

The New Jersey Experience
Orthopedic Implants

- Role of Surgeon Consultants
  - Product Design
  - Product Evaluation
  - Surgeon Education and Training
  - Sales Force Education
  - Research

Resolution of New Jersey Investigations

- Game Theory exercise
- Companies wanted consistency, yet limited sharing
- Intensive focus on collateral consequences
  - No agreed upon statement of facts
  - No admissions
- Intensive, but separate, negotiation of DPA terms
- Monitor selection process prompted the Morford memorandum

The New Jersey Experience

- Five DPAs/NPAs announced in September 2007, all involving independent monitors and a term of 18 months
- Criminal informations filed
- Successful completion and dismissals in March 2009
- Two additional DPAs announced in 2010, one of which has been extended for a year
- Identical terms for all seven companies, driven by focus on physician relationships

Resolution of Criminal Investigations

Settlement Agreements:

- Settlement payments totaling $311 million:
  - Zimmer: $169.5 million
  - DePuy Orthopaedics: $ 84.8 million
  - Smith & Nephew: $ 28.9 million
  - Biomet Orthopedics: $ 26.9 million
  - Wright Medical $ 7.9 million
  - Exactech $ 2.9 million
- Release of civil and administrative claims, including
  - FCA
  - CMP statute
  - Permissive exclusion provisions of 42 U.S.C. § 1320a-7(b)(7)

Resolution of Criminal Investigations

Corporate Integrity Agreements:

- Five-year terms
- Compliance program requirements
  - Including unified Arrangements Database
- Reporting requirements
- Engagement of independent review organization, after expiration of DPAs

DPA content
Monitor Duties & Authority

- Access to all non-privileged documents deemed reasonably necessary
- Authority to meet with any employee or agent
- Review and evaluate all policies, practices and procedures relating to retention and payment of consultants
- Approve annual needs assessment
- Veto power over any consulting arrangements or payments
- Quarterly reports to USAO, to include recommendations to enhance future compliance

DPA Requirements Driven by Physician Consultant Focus

- Consultant and payment disclosures
- Imposition of needs assessment process
- Consulting agreements terms and limitations
- Consulting payment caps and process requirements
- Limitations on royalty arrangements
- Limitations on data collection arrangements, fellowship programs, and charitable contributions to organizations linked to HCPs.

Prescribed Duties for Compliance Officers

- Oversight, evaluation and approval of needs assessment
- Approval of consulting services budget and all payments
- Evaluation of each new proposed consultant
- Execution of all consulting agreements
- Approval of fellowships and charitable contributions, in consultation with the Monitor

Assessment of the Orthopedics Experience

- Behavior changed across the market
- Needs assessment process worked because it aligned with business needs
- Spending on consultants declined, but not to a material degree
  - Elimination of questionable practices like retainers worked to benefit of companies
- Royalties continued to be paid, although increased focus on transfer of intellectual property may have ongoing impact
  - No royalties for merely being a “product champion”
- Monitor costs were significant
- Some of the DPA mandated processes viewed as burdensome and incidental to effective compliance
  - Institutionalization of those processes hard to reverse
- Absent an industry wide approach, DPAs could place a company at an extreme competitive disadvantage
- Little evidence that DPA model will be embraced generally by DOJ in health care cases

Living With a DPA/Monitor: Lessons Learned

- This is not a CIA
- Crucial to establish credibility, both with the Monitor and within the organization
  - The first 3 months set the tone
- Need to pressure test the compliance program in advance and provide enhanced resources
- The level of scrutiny and access is extraordinary
  - Get used to it
- There is a role for outside counsel, but a much more limited scope for advocacy
- Revisit best practices after DPA end

Device CIAs

- Device CIAs have followed the pharma model
  - Focus on physician relationships has resulted in a number of arrangements reviews
  - Indirect reimbursement has meant that AKA cases still predominate, but off-label cases are percolating
- Reportable events provisions in most device CIAs focus on federal health care programs, as opposed to broader FDCA language
  - How might GMP theories of liability to devices?
  - Impact of recalls

Outlook

- Is the New Jersey approach an outlier or a harbinger?
- DPAs not considered necessary to resolve standard health care fraud cases, even those with criminal elements
  - Alternative plea structures (e.g., subsidiary or charge selection) combined with CIA continues to be the prevalent model
  - Industry wide approach continues to be rare
  - Strong resistance given some recent experiences with DPAs
- FCPA resolutions have taken a different path, with DPAs being a standard feature
  - So far, DPA agreements in FCPA cases describe a more limited role for monitors compared with the orthopedic agreements
  - Will the FCPA experience result in broader use of DPAs across the sector?

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