HCCA’s 23rd Annual Compliance Institute

A Compliance Case Study from the Trenches with Current and Former DOJ Prosecutors

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Agenda

01   DOJ Update

02   Opioid Enforcement Initiatives

03   Recent Kickback Cases

04   Compliance Takeaways
DOJ Update

- Current state of health care fraud enforcement at DOJ
- Recent statistics
- Signs of False Claims Act pullback?
  - New Attorney General
  - Granston Memo/dismissals

Opioid Enforcement Initiatives

- DOJ Opioid Task Force
- Focused effort on stemming opioid diversion and abuse
- Additional resources in targeted locations
- Criminal and civil cases
# Opioid Enforcement Initiatives

- **Criminal cases**
  - “Pill mill” doctors
  - Diversion
  - Pharmaceutical companies
  - Pharmacies
  - Laboratories
  - Rehab Industry

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# Opioid Enforcement Initiatives

- **Case Study: Insys Therapeutics**
  - Background
  - Indictments/pleas
  - Current Status
  - Takeaways
## Opioid Enforcement Initiatives

### Civil Cases
- Controlled Substances Act
- Recent TN pharmacy TRO
- Local Cases
- False Claims Act cases

### Case Study: Mashali/Aboshady
- Background
- Indictments
- Mashali Plea
- Aboshady Trial
- Takeaways
Opioid Enforcement Initiatives

- Case Study: Millenium Laboratories
  - Case Background
  - Result
  - Takeaway

Opioid Enforcement Initiatives

- Recent. D. Mass. Actions
  - U.S. Attorney’s Office Letter
  - Safe Injection Sites

- Recent Mass. AGO Actions
Kickbacks

- Background on Anti-Kickback Law
- Arrangements that are red flags
- Safe harbors

Kickbacks

- Case Study: Patient Assistance Programs
  - Background
  - OIG Guidance
  - Recent cases
  - Common fact patterns
  - Takeaways
Kickbacks

- Case Study: Warner Chilcott
  - Background
  - Company plea
  - Kickback prosecutions
  - Prior authorization fraud
  - HIPAA prosecution
  - Reichel trial
  - Takeaways

Kickbacks

- Recent DOJ Kickback Cases
  - Unlawful physician arrangements
Compliance from the DOJ Perspective

- How your compliance program can help—and hurt—in a government investigation
- Culture/tone at the top
- Real life examples
  - The good
  - The bad
- Best practices

Conclusion/Questions?

Mr. Schumacher is managing partner of HLB’s Boston office. Prior to joining HLB, Mr. Schumacher was deputy chief of the Health Care Fraud Unit in the U.S. Attorney’s Office for the District of Massachusetts. He focuses his practice on criminal defense, fraud & abuse, and health care enforcement actions.