

HCCA's 23rd Annual Compliance Institute

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

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PRESENTED BY:

Abraham R. George
Assistant U.S. Attorney
U.S. Attorney's Office
District of MA

David S. Schumacher
Partner
Hooper, Lundy & Bookman, P.C.
Boston, MA

Hooper, Lundy & Bookman, P.C.



Los Angeles | San Francisco | San Diego | Washington D.C. | Boston

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HEALTH CARE LAWYERS & ADVISORS

Agenda

01 | DOJ Update

02 | Opioid Enforcement Initiatives

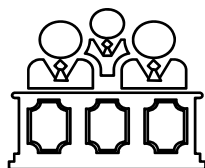
03 | Recent Kickback Cases

04 | Compliance Takeaways

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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**

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Opioid Enforcement Initiatives





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


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Opioid Enforcement Initiatives	
	<ul style="list-style-type: none">▪ Criminal cases<ul style="list-style-type: none">• “Pill mill” doctors• Diversion• Pharmaceutical companies• Pharmacies• Laboratories• Rehab Industry
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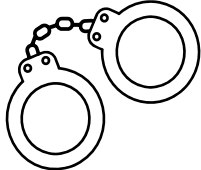
Opioid Enforcement Initiatives	
	<ul style="list-style-type: none">▪ Case Study: Insys Therapeutics<ul style="list-style-type: none">• Background• Indictments/pleas• Current Status• Takeaways
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Opioid Enforcement Initiatives	
	<ul style="list-style-type: none">▪ Case Study: Mashali/Aboshady<ul style="list-style-type: none">• Background• Indictments• Mashali Plea• Aboshady Trial• Takeaways
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Opioid Enforcement Initiatives	
	<ul style="list-style-type: none">▪ Civil Cases<ul style="list-style-type: none">• Controlled Substances Act• Recent TN pharmacy TRO• Local Cases• False Claims Act cases
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Opioid Enforcement Initiatives	
	<ul style="list-style-type: none">▪ Case Study: Millenium Laboratories<ul style="list-style-type: none">• Case Background• Result• Takeaway
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Opioid Enforcement Initiatives	
	<ul style="list-style-type: none">▪ Recent. D. Mass. Actions<ul style="list-style-type: none">• U.S. Attorney's Office Letter• Safe Injection Sites ▪ Recent Mass. AGO Actions
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Kickbacks	
	<ul style="list-style-type: none">▪ Background on Anti-Kickback Law▪ Arrangements that are red flags▪ Safe harbors
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Kickbacks	
	<ul style="list-style-type: none">▪ Case Study: Patient Assistance Programs<ul style="list-style-type: none">• Background• OIG Guidance• Recent cases• Common fact patterns• Takeaways
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Kickbacks

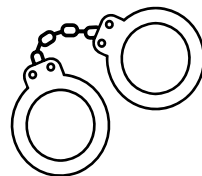


- **Case Study: Warner Chilcott**
 - Background
 - Company plea
 - Kickback prosecutions
 - Prior authorization fraud
 - HIPAA prosecution
 - Reichel trial
 - Takeaways

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Kickbacks



- **Recent DOJ Kickback Cases**
 - Unlawful physician arrangements

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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

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Conclusion/Questions?

Hooper, Lundy & Bookman, P.C.
 470 Atlantic Ave.
 Suite 1201
 Boston, MA 02210
 (617) 532-2704
dschumacher@health-law.com

David S. Schumacher

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.



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