

# The Opioid Crisis: Compliance and Enforcement Trends



---

**John C. Richter**  
Partner  
King & Spalding LLP

**Danielle Davis**  
Director, Compliance Counsel  
Heron Therapeutics, Inc

**Michael G. Hercz**  
Senior Vice President, General  
Counsel Sentyln Therapeutics, Inc.

**Seth B. Whitelaw**  
President, Chief Executive Officer  
Whitelaw Compliance Group, LLC

# Background – Opioid Epidemic

---

- From 2000s to the present, significant proliferation of the use, misuse and abuse of opioids in the United States
- Drug overdose deaths continue to rise from 1995 to the present
- Centers for Disease Control and Prevention estimates more than 64,000 Americans died from drug overdose in 2016
- Factors led to extensive scrutiny of industry by the press and advocates

# Social and Political Response to Crisis

---

- Political pressure from rising overdose rates resulted in a multi-pronged enforcement approach
  - Industry-wide DOJ investigations
  - Congressional investigations
  - Presidential Commission on Combating Drug Addiction and the Opioid Crisis
  - State attorneys general investigations
  - Other private litigation
- Comprehensive model of industry scrutiny
  - CDC guidelines, payer reaction, provider scrutiny

# Department of Justice Enforcement

---

- DOJ engaged in multiple wide-ranging investigations of stakeholders' practices, including manufacturers and distributors
- Increasing individual prosecutions, driven in part by the Yates Memo
- In August 2017, Attorney General Jeff Sessions announced new Opioid Fraud and Abuse Detection Unit
  - Data-driven investigations
  - Increased resources provided to U.S. Attorney's Offices
- Broad interpretations of the law – Mallinckrodt

# Mallinckrodt Settlement

---



“In addition to the significant monetary penalty, this settlement includes a groundbreaking parallel agreement with the DEA, as a result of which the company will analyze data it collects on orders from customers down the supply chain to identify suspicious sales. The resolution advances the DEA’s position that controlled substance manufacturers need to go beyond ‘know your customer’ to use otherwise available company data to ‘know your customer’s customer’ to protect these potentially dangerous pharmaceuticals from getting into the wrong hands.”

# Avoiding the Pitfalls

---

- Be proactive
- The law is a “floor” not a “ceiling”
- Assess what “should be done” vs. what “can be done”
  - Particularly when you serve vulnerable patient populations
- Engage with government enforcement agencies and regulators pre-investigation
- Don’t lose sight of the “big picture”

# Avoiding the Pitfalls

---

- Maintain an engaged board
- Set the proper tone at the top
  - Lead by example
  - Managers and supervisors should be empowered to promote compliance
- Focus on “compliant sales”
- Ask “why” and push for answers

# Avoiding the Pitfalls

---

- Pay attention to the data
- Do not ignore red flags
- Develop system to identify outliers
  - Use it earnestly and in good faith
- Data can be used against you



# Avoiding the Pitfalls

---

- Auditing and monitoring
  - Detect issues before they become a problem
- Take swift corrective action when necessary
- Design and implement crisis management plan
- Compliance programs must evolve to remain effective
  - Evaluate whether processes are achieving intended goals