



---

# The Impact of the Opioid Crisis on the Pharmaceutical Industry

Breakfast Roundtable  
November 8, 2018

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

**Rachael Honig**  
First Assistant United States Attorney,  
United States District of New Jersey



# Agenda

---



- I. Opioid Crisis Overview
- II. Public Response to Crisis
- III. Investigation and Litigation Trends
- IV. Investigative Focuses and Enforcement Theories
- V. Compliance Lessons for Pharmaceutical Companies



# Opioid Crisis Overview

---

- During 1990s, the introduction of new opioid products and increased advocacy for pain treatment led to a change in prescription trends
- From 2000s to present, there has been a significant proliferation of the use, misuse, and abuse of opioids in United States
- More than 350,000 people died from an opioid-related overdose between 1999 and 2016
- According to CDC, increase in opioid fatalities driven by three phenomena:
  - Increase in opioid prescriptions;
  - Increase in heroin overdose deaths; and
  - Increase in overdose deaths involving synthetic opioids, particularly illicitly-manufactured fentanyl



# Public Response to Crisis

---

- Heightened media focus on opioid overdoses and drug safety
- Rapid changes in industry attitudes and practices
  - Rapid shift in norms and attitudes towards pain treatment
  - Significant decrease in opioid prescriptions
  - Heightened payer and provider scrutiny
- Increased executive and legislative focus on crisis and reform efforts
  - Congressional investigations
  - President's Commission on Combating Drug Addiction and the Opioid Crisis
  - SUPPORT for Patients and Communities Act of 2018



# Investigative Focuses and Enforcement Theories

---

- U.S. Department of Justice
  - Multiple wide-ranging investigations of stakeholders' practices
  - Commitment of increased resources
  - Appointment of Director of Opioid Enforcement and Prevention Efforts
  - Prescription Interdiction and Litigation Task Force
- State Attorneys General (AGs)
  - Nearly every state AG is investigating the industry
  - Bipartisan coalition of state AGs investigating pharmaceutical companies
- Multidistrict Litigation



# Investigation and Enforcement Theories

---

- Multipronged focus on health-care providers, manufacturers, and distributors
  - Focus on pharmaceutical companies' marketing/promotional practices; and
  - High volume opioid prescribers
- Variety of legal theories
  - Anti-Kickback Statute
  - Racketeering Influenced and Corrupt Organizations (RICO) Act
  - Controlled Substances Act
  - Health Care Fraud Statute
  - Food, Drug, & Cosmetic Act- criminal misbranding
- Increasing focus on individuals
  - Yates Memo on “Individual Accountability for Corporate Wrongdoing”
  - *Park* Responsible Corporate Officer Doctrine

# Compliance Lessons for Pharmaceutical Companies



- Widely accepted norms and industry-wide practices can shift rapidly and drastically in response to public scrutiny
- Continued government scrutiny will likely spread beyond opioid space and lead to changes in pharmaceutical companies' broader marketing and promotional practices
- All pharmaceutical companies should respond to heightened scrutiny by demonstrating a robust internal commitment to compliance and proactively engaging with regulators and enforcement agencies